

Medical Writing

Good Pharma

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Themes of upcoming issues of *Medical Writing*

March 2014: The theme will be ‘**Software for Medical Writers**’. This issue will be designed to help medical writers more efficiently use Microsoft Office, Adobe Acrobat and Reader, and EndNote, and to introduce other software packages. This issue is already closed to new articles, but if you missed out and still would like to contribute an article on this subject for another issue, please contact us.

June 2014: The theme will be ‘**Pre-approval Regulatory Writing**’. This issue will be designed to help new medical writers and writers from non-regulatory areas become familiar with various basic regulatory documents, such as clinical study reports, protocols, investigators’ brochures, and the common technical document. The deadline for feature articles is 10 February 2014.

September 2014: The title for this issue has not been decided, but it will include articles on regulatory documents that medical writers might not be familiar with but can easily work on, such as documents for veterinary medicine, food and nutritional supplements, cosmetics, and environmental toxicology. The deadline for feature articles is 9 May 2014.

December 2014: The theme will be ‘**Post-approval Regulatory Writing**’. This issue will include articles on post-approval documents and pharmacovigilance. The deadline for feature articles is 8 September 2014.

If you have ideas for themes or would like to discuss any other issues, please write to editor@emwa.org.

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Good pharma

Adam Jacobs

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Drugs companies publish only a fraction of their results and keep much of the information to themselves. Drug companies are 'debas-ing' drug trials whose publication in journals can apparently confer scientific approval. Merck had fought for years to cover up evidence linking its painkiller Vioxx to heart attacks and strokes. Some treatments on the market have been linked to fatal side effects. Companies run bad trials on their own drugs, which distort and exaggerate the benefits by design. When these trials produce unflattering results, the data is simply buried. Patient groups who are in the pay of the pharmaceutical industry will go into battle for them. There's a hidden agenda here.

Not my words, I hasten to add. All the sentences in the above paragraph are taken from articles in just one UK newspaper (the *Guardian*, in case you were wondering). These are just a few examples of how it's become quite fashionable to believe that Evil Big Pharma are one of the most dangerous bad guys in the modern world.

Medical Writing is grateful to Kim Goldin and the International Society for Medical Publication Professionals (ISMPP) for working with us to produce this issue. More about ISMPP can be found on page 272. We hope that this issue marks the beginning of a mutually beneficial collaboration between our two associations.

The reality, of course, is rather more complicated. Sure, there have been times when pharmaceutical companies have done bad things. I don't think any sensible person would attempt to defend, for example, Pfizer's behaviour in marketing Neurontin for off-label uses, which resulted in them being fined \$430 million. But in the same way that we don't conclude that all doctors are evil because of Harold Shipman, it would be very shoddy thinking to conclude that a few tales of bad practice show the pharma industry in general to be a force for evil.

Editorial

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The fact is that the pharmaceutical industry has been responsible for amazing advances in health-care for many decades. When I was at primary school, one of my classmates died of leukaemia. Today, a primary school child with leukaemia has an excellent chance of survival thanks to modern chemotherapy.¹ The 10-year survival rates for many adult cancers have doubled since I was at primary school;² again, thanks in no small part to advances made by the pharmaceutical industry.

And it's not just cancer treatment that has improved: many EMWA members are probably too young to remember just how serious gastric ulcers could be before the era of modern acid-suppressive drugs, but for people of my parents' generation, a gastric ulcer was a serious illness with dramatic effects on quality of life, for which the only effective treatment was often surgery. Nowadays, most gastric ulcers can be successfully treated just by taking a few pills for a few weeks.

Nonetheless, there is undoubtedly great sport to be had in criticising the pharma industry, or 'pharmaism', as Wendy Kingdom explains on page 262. Wendy suggests that one possible reason for this may be that pharma companies make money out of treating disease, which some people find distasteful. Nonetheless, any economist will tell you that desirable activities need to be profitable; otherwise, why would anyone bother to do them in the first place? An alternative, state-run model of drug development was of course tried in the Soviet Union, which resulted in a list of therapeutic advances that would fit 'on the back of a stamp'.³

Because it is so fashionable to bash the pharmaceutical industry, claims that have broad anti-industry conclusions are often accepted as fact by those who should know better, even if those claims are based on shaky evidence. There is a great irony in using dodgy data to criticise the pharmaceutical industry for putting out dodgy data, as I've written about myself more than once.^{4,5}

One recent high-profile criticism of the pharmaceutical industry is provided by Ben Goldacre in his book *Bad Pharma*, and on page 252 of this issue, Stephen Senn explains why one of

Goldacre's criticisms of the pharma industry is based on a misunderstanding of statistics: a strange mistake for Goldacre to make when he's usually good at spotting dodgy statistics. Perhaps dodgy statistics are always a little harder to spot when they support the argument you're trying to make.

Criticisms of the pharma industry may start with well-meaning articles in medical journals, but they don't stop there: they can develop into full-blown conspiracy theories. On page 259, Bob Blaskiewicz explains why the pharmaceutical industry is such a favourite target of conspiracy theorists. This is a serious worry: while the sort of conspiracy theorists who believe that NASA faked the moon landings can be laughed off as harmless cranks, anti-pharma conspiracy theorists can cause real harm, as they can lead people away from proven conventional medicine into the hands of unscrupulous practitioners of unproven alternative medicine.

While most EMWA members are no doubt highly competent at spotting the difference between claims for real medicine and claims for crank alternative medicine, it shouldn't be forgotten that it's not so easy for many members of the general public. On page 275, Hayley Johnson explains how difficult it can be at the sharp end of interacting with patients as a community pharmacist. An average customer may know nothing of the difference between an evidence-based medicine and an alternative medicine with zero evidence (and may not even care). There are real difficulties for pharmacists trying to reconcile good customer service with their professional responsibilities when someone is convinced that some ineffective remedy is just what they need.

What can medical writers do about all this? One hugely important thing that all medical writers must do, of course, is to ensure that they always work to the highest ethical standards. Some criticisms of unethical ghostwriting within the

pharmaceutical industry have been well founded, and the last thing we want to do is give more examples of bad practice for critics to point to.

But another thing we can do is be ready to challenge critics when they perpetuate non-evidence-based myths about things like ghostwriting. On page 256, Art Gertel describes the GAPP initiative, something I have been proud to be a part of, which has been helping to set the record straight when inaccurate articles about ghostwriting appear in the medical literature.

Yes, there have been problems in the pharmaceutical industry. As in any other industry, some people in some companies have done bad things. As medical writers, we should not only be quick to challenge unethical behaviour from our colleagues when we see it, but we should also be proud of working for the pharmaceutical industry: an industry which, despite a few problems, has still made enormous contributions to human health and well-being and will certainly continue to do so.

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Message from the President

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Dear colleagues



Time really does fly when you're having fun: I'm writing my third message since becoming EMWA President in May!

The 37th EMWA Conference in Barcelona was an exciting event in a great location. We welcomed 102 new members, and 240 delegates from 19 countries attended the most workshops ever included in an Autumn EMWA conference (28), most of which were overbooked. The meeting was yet another success thanks to the (mostly) obscure work of EMWA's Head Office, run by Kingston Smith Association Management, together with the voluntary contribution of workshop leaders and Executive Committee members. The opening session with Inga Abed and Nacho Mbaeliachi of the EMA was the first step in forming a collaboration that EMWA members have desired for a long time, something that we intend to build on. The networking reception meeting with representatives of the Spanish Medical Writers Association, Mediterranean Editors and Translators, and Tremédica, as well as articles on the web sites of these organisations, was our first attempt to bring EMWA into the local writing environment. The number of professional partners supporting EMWA at conferences is continuously increasing, too.

But EMWA is not only conferences. EMWA development is continuing according with priorities stated and updated through time by ECs. Our good economic performance will allow us to make some investments for an even brighter future:

- **EMWA's website is undergoing a complete overhaul.** The structure will be modernised to simplify navigation and avoid double id and password entering when accessing the member's section.
- **E-learning capabilities are being developed,** paralleling website restructuring, to complete the training we offer.

- **An increasing number of high-level workshops** are being developed by the Educational Committee.
- **Our journal, *Medical Writing*, continues to increase its global reputation.** The journal now has several non-EMWA subscribers and we're looking into making improvements needed to have the journal listed in citation databases.
- **EMWA's presence in social media continues to increase.** EMWA's Facebook profile has almost 500 'likes', and interviews on Twitter ('twitterviews') of recognised members EMWA have attracted questions and followers. Also, LinkedIn discussions continue to be popular, with many different people contributing.
- **Programs for honoring long-time members and to increase awareness by new medical writers continue to develop.**
- **EMWA has partnered with Adept Scientific to offer members a 50% discount on EndNote,** yet another good reason to be an EMWA member. Other similar collaborations are under evaluation as partnerships with other professional associations.

The next Spring EMWA congress will be in Budapest in May, with a full day symposium dedicated to the EMA Transparency Act, which will become effective at the beginning of 2014. The collaboration has already been fruitful, as top-level speakers are expected to discuss the impact of this new legislation on the disclosure of clinical trials results.

EMWA is an organisation of medical writers who volunteer their time to provide all members what they need to improve in their profession. Those who benefit most from EMWA are the motivated individuals who volunteer to serve on the Executive Committee or board, teach workshops, or provide other year-round activities, like helping with the journal, website, or social media. Volunteering brings you into contact with a large network of experts in the field of medical writing,

helps develop and demonstrate leadership skills, and provides the opportunity to share and exchange professional knowledge.

Our Executive Committee is working very well together. To keep growing our association and support different activities, we have been involving a growing number of volunteers. Being a member of the Executive Committee, in particular, gives you excellent opportunities for career advancement, but even other roles can help and can give back a substantial benefit. Voting for Executive Committee positions will take place before the May conference via an online voting system. If you would like to find out more about joining the Executive Committee, check out the job descriptions

at <http://www.emwa.org/EMWA-Officers.html>. For those of you who don't feel ready to be a member of the Executive Committee but are interested in volunteering in some way, send an email to info@emwa.org to let us know.

The contribution of all members is fundamental to reaching our objectives, so we look forward to hearing from many EMWA members interested in volunteering for the Executive Committee or other roles!

Last but not least, I'd like to take this opportunity to wish everyone a happy and healthy Christmas and the 2014 you're dreaming of.

Ciao
Andrea

Transparency and the healthcare industry: The Sun is shining

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Abstract

The demand for greater transparency in financial relationships between the healthcare industry and healthcare professionals is increasing globally, and has led to establishing government regulations and professional guidelines for detailed reporting and public disclosure of these relationships. In the US, under the Physician Payment Sunshine Act, the government requires an annual report on payments and transfers of value made by healthcare product manufacturers to physicians and teaching hospitals. The implementation rules for this act were announced in February 2013, with data collection beginning on 1 August 2013. The first reports are due to the US government by March 2014, and public disclosure of the data will begin in September 2014. Concerns are growing within the healthcare industry regarding these new transparency requirements, and the likely unintended consequences, such as reduced participation of physicians in industry-sponsored clinical trials and delays in publication of clinical trial data.

Keywords: Open Payments, Physician Payment Sunshine Act, Reporting Requirements, Transparency

For over a decade, we have seen a significant erosion of public trust in the healthcare industry. Nearly 10 years ago, in an editorial in *Circulation*, Alice Jacobs, MD, former president of the American Heart Association, noted the criticality of rebuilding public trust in medicine.¹ Her commentary raised issues related to financial conflicts of interest in medical research and medical publications, and raised the question 'whether individuals with relationships with industry, arguably often the most knowledgeable experts in a field, should be allowed to participate in the writing of scientific statements and guidelines'.¹ Today, nearly 10 years

later, some of the same concerns continue to be heard.²

On the positive side, steps have been taken towards restoration of public trust, especially with respect to the reporting of data from industry-sponsored clinical studies and the role of professional medical writers.³⁻⁶ The International Society for Medical Publication Professionals (ISMPP) introduced a certification program, based in large part on the ethics of developing medical publications and disseminating clinical trial data.⁷ Manufacturers of drugs and medical devices have taken important steps to broaden transparency around clinical trials information.⁸⁻¹⁰ Government-mandated transparency laws or self-policing guidelines or policies exist in several countries such as Australia, Denmark, France, Japan, Portugal, Slovakia, The Netherlands, and the United Kingdom. In the US, individual state legislation has been in effect since 1993, and US Federal legislation, known as the US Physician Payment Sunshine Act, was passed in 2010 (Figure 1).

The Sunshine Act: An overview

In March 2010, the Patient Protection and Affordable Care Act, popularly called Obamacare, was signed into US law. It includes the Physician Payment Sunshine Act (Sunshine Act), which is formally called the National Physician Payment Transparency Program: Open Payments.¹¹

The Sunshine Act arose out of activities related to enforcement of the US federal anti-kickback statute involving financial relationships between the healthcare industry and healthcare professionals (HCPs).¹² The act is based on the belief that if financial relationships between industry and HCPs were made public, it would help government enforcement and curb such activities. The law established

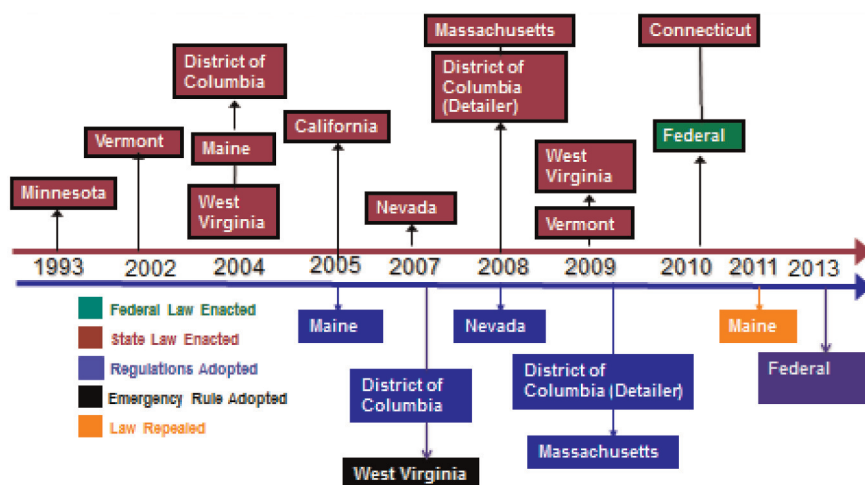


Figure 1: Laws enacted to increase transparency in industry-healthcare provider (HCP) relationships. Reproduced with permission, Porzio, Bromberg & Newman, P.C., Morristown, NJ, USA.

legal requirements for the reporting of certain financial transactions (payments or transfers of values [TOV] ≥ US\$10) between manufacturers of healthcare products that are covered by the US government Medicare, Medicaid, or Children’s Health Insurance Programs (applicable manufacturers [AMs]) and physicians who carry a US licence to practise medicine (covered recipients [CRs]). It also applies to teaching hospitals and group purchasing organisations (Table 1).¹³

The law required that AMs begin data collection on 1 August 2013, and report data for calendar year 2013 (1 August to 31 December) to the Centers for Medicare and Medicaid Services (CMS) on 31 March 2014. The physicians themselves do not have to report the data. CMS is required to publish aggregate data on a public website by September 2014, and each year thereafter (Figure 2).¹³ The reporting categories include, among others, consulting fees, honoraria, compensation for participation in research or

education, grants, charitable contributions, royalties, current or prospective ownership or investment interest, gifts, entertainment, travel and lodging, and food and beverages.¹³ A summary of the Sunshine Act directed towards healthcare practitioners was recently published in the *New England Journal of Medicine*.¹⁴

Failure to adhere to the reporting requirements of the Sunshine Act is associated with significant financial penalties. Unintentional failure to submit data has a penalty of at least \$1,000 but no more than \$10,000 for each payment or other TOV, or ownership or investment interest not reported as required, with an annual maximum of \$150,000. Penalties for intentional failure to submit are even higher.¹³

Exemptions and exclusions

The rules for implementation list a number of exemptions from and exclusions to the reporting

Table 1: Definitions of applicable manufacturers, covered products, and covered recipients under the Sunshine Act (CMS Rules 2013).¹³

| Applicable manufacturers | Covered products | Covered recipients |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Any manufacturer, foreign or not, which operates in the US (including by selling a product) must comply with the reporting requirements, regardless of where the product is physically manufactured | Any drug, device, biologic, or medical supply, that is reimbursable by Federal government (Medicare, Medicaid, or Children’s Health Insurance Program) | Physicians (MD, DO, DPM, OD, DCh) holding a US licence to practise medicine |
| Entities based outside of the US that have operations in the US are subject to these reporting requirements | Excludes OTC | Teaching hospitals (CMS to provide list annually) |
| Joint ventures/co-promotions requires reporting by the applicable manufacturer that actually made the payment or other transfer of value (unless decided by the parties to report differently) and that the payment or transfer of value be reported once | Devices and medical supplies limited to those that, by law, require premarket approval by or notification to the FDA | Group purchasing organization that purchases, arranges for or negotiates purchase of covered drug, device, biological, or medical supply, operating in the US, or in a territory, commonwealth or possession of the US |

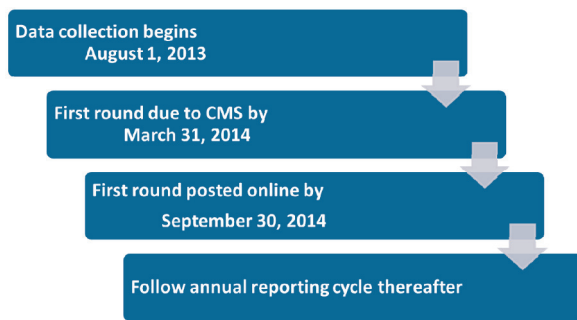


Figure 2: Timeline for Sunshine Act reporting. CMS, Centers for Medicare, and Medicaid Services.

requirements. For example, physicians who are employees of AMs are exempt. The exclusions include, but are not limited to, indirect payments or other TOV where the AM does not know the identity of the CR; payments or other TOV less than \$10 unless the aggregate amount exceeds \$100 in a single calendar year; product samples; and educational materials and items that directly benefit patients. The full listing of exclusions can be found on the CMS website.¹³

The Sunshine Act and medical publications

The Sunshine Act implementation rules mention but do not provide clarity on support provided to CRs for the development of industry-sponsored medical publications. To help address the questions surrounding this issue, ISMPP has recently released the 'ISMPP Suggested Approaches for Sunshine Act Interpretation and Implementation for Publication Support Requirements'.¹⁵ Based on research and meetings with various stakeholders from industry and CMS, the Task Force concluded that '...provision of publications support is a TOV to CRs who are authors on medical publications'.¹⁵ This is believed to be the case for publications that are included in research contracts and for those that are not (e.g. review articles). For the purpose of medical publications, ISMPP's suggested definition of the TOV is 'any support provided to CR authors for any publication that will be submitted, or is intended to be submitted, to a scientific or medical journal, or provided to authors/speakers for submission to or presentation at a professional congress'.¹⁵ As ISMPP understands, a TOV is not reportable if the authors of publications are employees of the AM that provided the support; by extension, this may also include authors who are employees of medical writing agencies or freelance medical writers that are paid by AMs.

ISMPP has suggested two alternatives for consideration in determining the value to be assigned to publication support for authors who are CRs.¹⁵

The first is on a project-by-project basis, where one would divide the total cost of the publication support by the number of authors associated with the publication. To do this, actual costs are assessed, divided by the total number of authors, and assigned to each external CR; internal/company, and ex-US authors are included in the calculation but have no reportable TOV. The second is to determine the fair market value (FMV) of publication support that CRs would receive across various publication types (e.g. abstract, manuscript, poster) using a sum of average costs associated with the type of publication divided by the average number of authors on that publication type. Each AM would determine a representative sample size upon which to base the FMV calculation.

Because of the complexity of the issue, and the various scenarios that could occur across different manuscripts, ISMPP did not issue a prescriptive algorithm for determining the value of the support provided to CRs.

Transparency, global legislation, and policies

As mentioned previously, transparency is an important issue that is impacting global legislation and policies. For example, in May 2013, France passed a version of the Sunshine Act requiring pharmaceutical companies to make public the gifts provided to HCPs, and Denmark has required that companies declare payments to physicians for almost 5 years. Critics, however, argue that there are shortcomings to both these legislations that prevent full transparency. There are no equivalent disclosure requirements in other countries within the European Union. In Australia, the Netherlands, and Japan, reporting is voluntary and is being led by industry associations. Adoption of a reporting model similar to the US Sunshine Act will likely be difficult because of the differences in the healthcare systems across various countries.

It is worthy to note, however, that some additional efforts are being made by foreign trade associations in the global push for transparency around relationships between the pharmaceutical industry and HCPs. For example, the industry association of the medicinal products sector of the Association of the British Pharmaceutical Industry (ABPI), which already requires its members to disclose numerous areas of interactions with medical practitioners, recently amended its rules on interactions with HCPs and patient organisations. All 180 members of the ABPI are required to comply with the ABPI Code of Practice for the Pharmaceutical Industry. In addition, the European Federation of Pharmaceutical Industries

and Associations now requires its members to publicly disclose any direct or indirect financial support provided to patient organisations.

There are a number of arguments for and against global implementation of laws similar to the US Sunshine Act. Proponents argue that implementation of a global transparency system would assist companies in developing a comprehensive system across all its business units, in effect including both US and foreign medical professionals. They also state that these activities may improve a company's overall compliance, thereby decreasing the need for enforcement activities over time.

On the negative side is the potential large cost associated with implementing such systems. Companies must develop and maintain data collection processes and systems that will need to be adjusted to conform to the CMS rules. Collecting and reporting such a huge amount of information, especially in the absence of clear CMS guidelines on how spend data should be identified and categorised, will require significant time and dedicated personnel. This would be even more difficult to manage globally given the various and ever-changing standards evolving in different countries around the world.

Impact on healthcare providers: Are unintended consequences looming?

Whether or not the Sunshine Act will have unintended consequences with respect to relationships between physicians and industry remains to be seen. However, there are concerns over the requirements set forth in CMS rules. One concern is that information available publicly might unfairly distort the positive aspects of physicians-industry relationships. Most TOV involve FMV payments in exchange for consulting, education, and research. However, according to John Kamp, Executive Director for the Coalition for Healthcare Communication, the CMS database 'will be a huge target for critics of industry, the press, and plaintiff attorneys seeking to sue industry or doctors'.¹⁶ The dangers of this are all the more disconcerting given serious questions regarding the accuracy of the database that may cause reporting errors.

According to a study conducted by Industry Standard Research, physicians are worried about the impact the Sunshine Act will have on their practice.¹⁷ Of 103 physician respondents, 74% said they were not in favour of sharing these data. If physicians are concerned that interacting with the pharmaceutical industry has a negative connotation, these relationships, which are vital to the public health, could be put at risk.

Limitations on authorship

One particularly growing concern is how authors of industry-sponsored publications may react to reported TOVs for editorial or writing assistance provided by medical communications agencies. This assistance is generally considered important in maintaining quality, accuracy, and timeliness of articles submitted to peer-reviewed journals. It is an accepted practice, provided the nature and funding of the support is fully transparent.

Initial reports indicate that many physicians were not aware that this type of TOV is reportable and are concerned regarding how much TOV will be allocated to an individual physician based on provision of medical publications support. As such, some physicians are beginning to ask that their names be removed from industry-sponsored papers and indicate that they will be less likely to author such publications in the future.

This comes at a time when the *BMJ* has called for legislation in Europe (i.e. a European Sunshine Act) requiring drug companies to declare whom they pay and how much.¹⁸ Additionally, the American Society of Clinical Oncology has taken the issue of transparency to another level by issuing a new conflict of interest policy reflecting a commitment to transparency and independence in the development and presentation of scientific and educational content.¹⁹ The new policy focuses on financial interactions with industry and goes beyond disclosure by imposing restrictions on authors who work for, hold stock in, or participate as a speaker for a pharmaceutical company.

While it is unclear if this kind of punitive approach to forcing transparency around these important physician-industry collaborations will be copied by other journals, many are concerned that such actions will come at a high cost to companies' abilities to report the results of important clinical trials to physicians and patients.

Conclusion

Full transparency in financial relationships between the healthcare industry and HCPs can be a good thing. The goals for transparency are laudable; no doubt we all share the desire to support unbiased and medically sound healthcare practices that are not influenced by financial relationships. At times, legislation developed to enforce transparency can have unintended consequences. For example, will we see a hesitance on the part of clinical investigators to work with industry due to concern for potential misinterpretation of their publicly available financial relationship data? Might this translate

into delays in the publication of industry-sponsored clinical trial results because busy clinicians decide to forgo medical writing support? And finally, will these changes have an impact on medical writers? It remains to be seen whether this, or any other unintended consequences, occur.

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Sunshine spreading across the Atlantic and Over Europe

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Abstract

The quest for transparency in the relationships between life sciences companies and healthcare professionals is quickly becoming a global movement. Reporting requirements for financial interactions have been prevalent in the United States for many years, but the movement is spreading throughout the world to places like Japan, Australia, and Europe. In France, the government passed a law that imposes burdensome reporting requirements. Industry groups across Europe, most notably the European Federation of Pharmaceutical Industries and Associations, are acting aggressively to try to forestall more government laws by adopting industry-developed disclosure systems. These activities will affect many different segments of the European healthcare system.

Keywords: Pharmaceutical companies, Medical device companies, Regulatory compliance, French Sunshine Act, European Federation of Pharmaceutical Industries and Associations, Financial transparency

The trend towards transparency in the relationships between life sciences companies and healthcare professionals (HCPs) is quickly accelerating on a global basis. For many years, the focus of life sciences transparency has been on the United States because of state-level reporting requirements. That focus has only been heightened by the federal government's release of final regulations implementing the Sunshine Act provisions of the Patient Protection and Affordable Care Act, which requires federal-level reporting in 2014. However, the transparency movement is not confined to the United States. It is spreading quickly throughout the world, including Europe.

As this trend extends into Europe, it is accompanied by a debate about how to achieve the goals of transparency. On one hand, supporters of legislation argue that government-imposed disclosure requirements will increase transparency while lowering healthcare costs and reducing corruption. Advocates of this approach point to France's

version of a Sunshine Act as a model for additional legislation. On the other hand, supporters of self-regulation contend that an industry-created reporting system holds greater potential for uniformity across borders and will result in a more efficient transparency system. The most important development for this approach is the June 2013 adoption by the European Federation of Pharmaceutical Industries and Associations (EFPIA) of the *EFPIA Code on Disclosure of Transfers of Value From Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations* (Disclosure Code).¹

It is imperative for all those involved in the European healthcare industry, including medical writers, to be aware of these governmental laws and industry codes, because they will have a significant, wide-ranging impact on many professions.

Legislative approach

In December 2011, France enacted *LOI n 2011-2012 du 29 décembre 2011 relative au renforcement de la sécurité sanitaire du médicament et des produits de santé* (French Act).² The French Act requires pharmaceutical and medical device companies to publicly disclose agreements they have with HCPs and benefits provided to HCPs and various entities. Under the French Act, the details of those requirements were to be included in a decree that was to be in effect by 1 August 2012. Although draft decrees were circulated in 2012, the final decree was not issued until 21 May 2013.³ The French Ministry of Health and Social Affairs also published a Circular, dated 29 May 2013, that provides guidance about the final decree.⁴

The final decree imposes two main types of disclosure requirements on life sciences companies: (1) all agreements, except for commercial sales agreements of goods and services, that they have with defined individuals and entities; and (2) certain benefits given to those individuals and entities. The list of covered recipients includes:

- Healthcare professionals (e.g. physicians, nurses, but the disclosure requirements do not

apply to the reporting company's own employees);

- Associations of HCPs and associations of HCP students;
- Students for relevant occupations;
- User associations of the health system (public or private);
- Health facilities;
- Foundations, learned societies, and consulting companies or organisations in the health sector;
- Publishing companies: press, radio, television, and on-line media;
- Publishers of prescription and dispensing software; and
- Legal entities contributing to the initial training of HCPs.

According to the Circular, the inclusion of the 'publishing companies' category reflects the government's intention to focus on and extend the reporting obligation to the scientific and medical press, as well as the specialist press intended for HCPs.

For agreements, companies must disclose the following information:

- The identity of the parties to the agreement:
 - For HCPs: name, professional address, qualifications, title, specialty, and registration number with the relevant professional board.
 - For healthcare students: name and educational institution.
 - For legal entities, like associations, health institutions, etc.: name, corporate purpose, and registered address.
- The date the agreement was signed.
- The subject matter of the agreement (which should be phrased in a manner to protect confidential and trade secret information).
- If the agreement involves a promotional or scientific event, the program of the event.

For benefits, companies must disclose each of the benefits that they provide, whether direct or indirect, in kind or in cash, to the aforementioned recipients if the benefits are equal to or exceed ten euros, inclusive of VAT. When disclosing benefits, companies must identify the recipient and the recipient's personal information in the same manner as for agreements (e.g. name, address, title); the amount, date, and nature of each benefit; and the time period (either the first six months of a year or the latter six months) during which the benefit was received. The Circular expanded upon the definition of benefits, explaining that in-kind benefits include gifts, donations of equipment, invitations, hospitality

expenses, or payment for trips, as well as commissions, discounts, rebates, or repayment of expenses.

All of this information about benefits and agreements will eventually be disclosed, in French, on a to-be-established public website. A public authority will create and operate the website, and the information will be available for a period of 5 years.

As to timing, companies must report the required information for agreements to the public authority within fifteen days of the signing of the agreement. For benefits, however, the requisite information must be submitted bi-annually: by August 1 for benefits provided from January to June, and by February 1 for benefits provided from July through December of the preceding year. Once the website is operational, the information about benefits provided and agreements made during the first part of a calendar year will be made public by October 1 of that year, and benefits provided and agreements made during the second part of a year will be published by April 1 of the following year.

Because the public website is not yet operational, the decree established an interim reporting process. The decree provides that by 1 June 2013 (ten days after the decree was issued), companies were to submit all reportable benefits and agreements from calendar year 2012 to the appropriate national council of the healthcare professionals association (e.g. National French Medical Association). Companies were then to submit the required information for agreements and benefits covering the first six months of 2013 to the appropriate national council by August 1. All of this information covering both 2012 and the first six months of 2013 was then to be published by 1 October 2013, in two different locations: the website of the reporting company, and the website of the relevant French national council. The next reports are due on 1 February 2014, to cover agreements and benefits for the last six months of 2013.

A number of significant questions remain unanswered, for example, whether the reporting obligation applies only to companies based in France or also to those based outside of France but that do business in France or otherwise interact with French HCPs. Regardless, the act and its implementing decree will have an immediate and enormous impact on transparency reporting in France.

The French experience may also serve as a model for other European countries that are pursuing, or considering, a legislative approach to transparency. For example, Denmark currently has some limited reporting requirements, whereby pharmaceutical companies must identify relationships they have with HCPs, but they do not have to provide

financial transparency information like that required in France. However, the current Danish scheme is expected to be changed by new legislation in 2013. This legislation is expected to apply to both pharmaceutical and medical device companies. Under the anticipated legislative scheme, it is HCPs – not the life sciences companies – who will have the primary obligation to report their financial interactions with industry. Other European countries with existing financial transparency reporting requirements include Portugal, Slovakia, and Estonia, though their current requirements are not as extensive as the French system.

Self-regulatory approach

In contrast to, and, in direct response to, the legislative approach taken by some European governments, EFPIA has been proactive in seeking to implement an industry-driven approach to transparency across Europe. It is important to note that while EFPIA has been aggressive in adopting its Disclosure Code, the medical device industry has not been as active. Unlike EFPIA, which is the representative body of the European pharmaceutical industry, Eucomed, which represents the medical device industry in Europe, has not adopted reporting requirements and has not made any public announcements that it has plans to implement a similar system.

EFPIA's members include 40 pharmaceutical companies and the national industry associations of 33 countries. Before the adoption of its Disclosure Code in June 2013, EFPIA had two relevant codes: (1) EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions With, Healthcare Professionals;⁵ and (2) EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations.⁶ These Codes, like the Disclosure Code, apply to EFPIA member companies, their subsidiaries, and any companies affiliated with EFPIA member companies or their subsidiaries, and they establish minimum standards that national organisations must have in their own national codes.

The EFPIA Code on Interactions with Healthcare Professionals does not contain reporting or disclosure requirements, but encourages companies to make publicly available information about donations, grants, or benefits in kind made to institutions, organisations, or associations comprised healthcare professionals or that provide healthcare or conduct research. The EFPIA Code on Relationships with Patient Organisations contains reporting requirements about support provided to

patient organisations. The disclosure requirements apply to activities commenced as of or ongoing on 1 January 2012, and the first reports were required to be made public by the end of the first quarter of 2013.

EFPIA, however, revolutionized its approach to transparency at its 2013 Annual Meeting when it adopted the Disclosure Code. With the Disclosure Code, EFPIA for the first time is requiring individual-level HCP reporting. Specifically, the Disclosure Code requires companies to publicly report, in 2016, their 2015 financial relations with HCPs and healthcare organisations. The Disclosure Code provides that company disclosures must be made on an annual basis, with each reporting period covering a full calendar year. Companies are required to make their disclosure within six months following the end of the reporting period.

The Disclosure Code requires companies to disclose in one of two ways: (1) on their own website; or (2) on a central platform, which could be developed by the national member association or local public authority. The disclosures themselves must be made in the local language, though companies are encouraged to also make the disclosures in English if that is not the local language.

To assist companies with their disclosure obligations, EFPIA adopted a multi-coloured, multi-column XL spreadsheet template that offers a structure for how all the information should be reported. Companies must report, on the individual level, their transfers of value provided to HCPs (members of the medical, dental, pharmacy, or nursing professions) and healthcare organisations in the following categories:

- Donations and grants (for healthcare organisations only);
- Contributions to costs related to events (registration fees; travel and accommodation, to the extent permissible);
- For organisations only, sponsorship agreements to manage an event ('events' are defined to include all promotional, scientific, or professional meetings, congresses, conferences, symposia and other similar events, like advisory board meetings); and
- Fees for service and consultancy.

The Disclosure Code defines transfers of value to include direct and indirect transfers, whether in cash, in kind, or otherwise. Significantly, transfers of value do not include gifts of medical utility, meals and drinks, medical samples, and money provided by a company to a HCP as part of an ordinary purchase and sale of a medicinal product.

Companies must also report, for the same categories outlined above, the aggregate amounts they spend during the reporting period. Moreover, companies are required to report, on an aggregate basis, their research and development transfers of value to HCPs and healthcare organisations, which includes support relating to the planning or conduct of (1) non-clinical studies, as defined in OECD Principles on Good Laboratory Practice; (2) clinical trials, as defined in the governing directive of the European Commission; and (3) non-interventional studies pursuant to EFPIA's HCP Code.

The Disclosure Code requires formal transposition of these new requirements into the national codes of EFPIA's member associations by 31 December 2013. Member associations are expected to incorporate the Disclosure Code's provisions into their own national codes in full, except when EFPIA's provisions conflict with governing national law. In such instances, e.g. France, EFPIA will permit deviations from the Disclosure Code, but only to the extent needed for compliance with the controlling national legislation.

While EFPIA's activities may have the most significant long-term consequences for transparency within the European pharmaceutical industry, several countries already have experience with transparency reporting. For example, the code of the Netherlands industry group required its members to report in 2013 on amounts spent in support of healthcare practitioners – on an individual level – in 2012. Similarly, members of the British industry group disclosed their relationships with HCPs for the first time in 2013 for 2012 data but, unlike their Dutch counterparts, they only had to report at the aggregate level. As members of EFPIA, however, the Dutch and British industry associations are bound to incorporate EFPIA's disclosure provisions into their codes by the end of 2013.

Impact of transparency laws on medical writers

Many sectors of the life sciences industry in Europe will be tracking whether more governments adopt

transparency laws or whether they will defer action and wait to see how EFPIA's approach is implemented across the continent. One such group will be medical writers, as these types of transparency measures could have a direct impact on their activities. In that regard, France's law explicitly covers agreements made with and benefits provided to publishing companies in the healthcare field. The nature and extent of the impact of the French law on medical writers cannot be predicted at this time, but it will start to become apparent as pharmaceutical and medical device companies grapple with their reporting obligations and recipients react to the public reporting of their financial dealings. Medical writers would also be well advised to monitor whether additional European countries, be it in the form of legislation or self-regulation, require the public disclosure of their financial relationship with life sciences companies and, if it is required, how such public disclosure affects the underlying relationship.

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Bad karma

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Abstract

Bad Pharma provides a hyper-critical account of the pharmaceutical industry's approach to conducting, publishing and using clinical research and development. However, its attack on the drug regulators is unfair and its examination of the medical press uncritical. In consequence, it fails to provide the appropriate solution to making results of trials more widely available. This is to make the rigour of drug regulation available to all, rather than extending the use of that mediocre medium, the medical press.

Keywords: Missing data, Drug development, Publication bias

Gone missing

All who carry out a Cochrane Collaboration (CC) meta-analysis are warned of the importance of identifying all relevant trials. Missing trials are a problem, not just because they represent a loss of information but in particular because the information that is missing may systematically differ from that which is not. Amongst the many sins of which Ben Goldacre accuses the pharmaceutical industry in *Bad Pharma*¹ is that of failing to publish negative studies. However, his critical faculties, ever present when it comes to the pharmaceutical industry, have gone missing when it comes to others. The consequences of his unfair criticisms of drug regulators (the only characters in the book who have a chapter to themselves with the adjective 'bad') and his eagerness to accept whatever journal editors and the CC tell him are that he misdiagnoses the problem and doesn't see the solution.

As one who has dealt with regulators and regularly reviewed for medical journals, I see the difference like this. Regulators are professional, thorough and expert. The FDA, in particular, has played an important role in promoting the study of many methodological issues affecting analysis and interpretation of clinical trials, whether directly by

its own staff or by encouraging, and in some cases commissioning, others to do so. In particular, bioequivalence, non-inferiority, multiplicity, and missing data² are all subjects that have greatly benefitted from regulatory input. Statisticians working for the pharmaceutical industry have also made important methodological contributions to drug development science. Furthermore, the International Conference on Harmonisation E9 guideline on statistical analysis³ is much superior to the alternatives that the journals have to offer. The net result is that the quality of review provided by the regulator far exceeds that provided by journals. The regulators also get to see all the studies, or at least, all the studies for any product seeking a license.

The problem, however, is that it is not only regulators who have to make decisions about pharmaceuticals but also reimbursers, physicians, and patients. Journals provide a visible forum for exchanging results and findings between researchers and for discussing and disseminating them. It is true that peer review makes only a weak contribution to quality but there is not much point lauding the superiority of studies that aren't seen. The first place that any independently based meta-analyst will look for studies is in the medical press. It is thus unacceptable that studies are only seen by the regulators. In a paper I wrote in 2000 entitled 'Statistical quality in analysing pharmaceutical clinical trials'.⁴ I put it like this 'No sponsor who refuses to provide end-users with trial data deserves to sell drugs' (p. 26).

Not surprisingly, the Evidence Based Medicine (EBM) movement has railed against the fact that regulatory studies are not always published. Goldacre suggests that it must be made mandatory for studies to be published within 12 months of completion, 'in summary table form if academic publication has not occurred' (p. 98). Certainly any system that relies on academic publication is unworkable, principally because the medical press is not a single authority but a collection of

competing interests, none of which can be made responsible for publishing any given paper. However, I think that Goldacre underestimates the difficulties. The journals cannot be part of the solution. They are part of the problem. As long as they are seen as being the most prestigious route for dissemination of results, it will be difficult to get all results in a timely manner.

Pluses and minuses

Furthermore, it is quite possible that journals are prejudiced in favour of positive studies. Goldacre dismisses this, describing the journals as ‘blameless’ (p. 34) but his analysis is inadequate and biased. Contrary to what he claims, the experimental evidence, that is to say from studies in which positive and negative versions of the same paper have been submitted to journals, seems to show quite strongly that there is a bias in favour of positive studies. Goldacre sums up this evidence by saying, ‘overall though, even if there are clearly rough edges in some domains, these results don’t suggest that the journals are the main cause of the disappearance of negative results’ (p. 36). However, he is relying on a ‘method’ here, noting that some studies were not significant, that the whole EBM movement rejects. This is not how the CC proceeds. A formal summary of studies is needed and it is not given by Goldacre.

When it comes to the observational studies, then Goldacre accepts uncritically what the EBM movement has concluded, despite the fact that in the paper he deals with in most detail,⁵ it is editors concluding that they are doing a good job. A number of studies have found that if submissions to journals are classified by whether the findings were ‘positive’ or ‘negative’ the acceptance rate is similar. Goldacre then concludes that there is no editorial bias in accepting or rejecting. The fallacy is simple. Goldacre implicitly assumes that the quality of studies submitted is equal. If, instead, authors were submitting by estimated probability of acceptance, not bothering to submit unless this were higher than some threshold, then we might see no difference in this probability but a difference in quality instead, with negative submitted studies having higher quality.^{6,7}

Is there any evidence for this? We all occasionally cite papers only having read the abstract and some perhaps only read the title but here it seems that Goldacre has cited a paper without even having read the title! This paper was, ‘Commercially funded and United States-based research is more likely to be published; good-quality studies with

negative outcomes are not’.⁸ You would have thought that the curious association of ‘quality’ and ‘negative studies’ in the title would have encouraged reading of the abstract, in which one could have discovered, ‘Studies with a negative outcome were of higher quality ($P = 0.003$) and included larger sample sizes ($P = 0.05$)’. In fact, the first of these findings was the most significant one in the article. However, Goldacre seems to have left the ‘mental horsepower’ – that in his chapter *Bad Trials* he warns the reader will be needed (p. 172) – placidly munching hay in the stable.

In other words, to claim that journal editors are not biased against negative studies is like claiming that there is no bias against women in higher education because the same percentage of either sex applying to be promoted to professor is successful, overlooking the higher qualifications of women applicants. An explanation then would be that women were not applying because they knew that the system was biased against them and there was no point applying unless their qualifications were exemplary.

Pious bias

Goldacre’s bias against the drug developers and regulators regularly misleads him and his readers. How many readers, I wonder, not knowledgeable about drug regulation, would learn from reading Goldacre’s section ‘Dodgy subgroup analysis’ (pp. 205–210) that such are outlawed in regulatory submissions⁹ but scarcely policed by the journals? Much of the consulting I do for the industry is concerned with designing watertight, pre-specified analyses to control the type I error rate. (See Senn and Bretz¹⁰ for an example of some methodological considerations.) On the other hand, never in reviewing for the medical press have I been provided with the statistical analysis plan.

In fact, most of Chapter 4 ‘Bad trials’ is pretty much irrelevant to what happens in drug development. Goldacre concedes right at the beginning of the chapter, ‘we should also remember that many bad trials...are conducted by independent academics’, and even admits that when it comes to studies of trial quality ‘...industry trials often come out better...’ (p. 171), but he dismisses all this as irrelevant ‘...for one simple reason: independent academics are bit players in this domain’ (p. 172). Nothing is offered here by way of argument and explanation beyond appealing to pharmaceutical industry dominance. He does not examine the quality scores of studies comparing industry and academic trials. He doesn’t list any indicators

of quality to which he is objecting. Instead he rushes on to discuss bad trials as if they were particularly an industry phenomenon, whereas one could more plausibly argue the reverse is the case.

Goldacre writes, ‘Research reviewing a long series of FDA votes found that experts are slightly more likely to vote in a company’s interest if they have a financial tie to that company’ (p. 126). How many readers will realise that the cited paper stated, ‘excluding advisory committee members and voting consultants with conflicts would not have altered the overall vote outcome at any meeting studied’¹¹ (p. 1921), and that at an individual level a ‘paradoxical’ association was found between conflict of interest for the competitor drug and voting for the index drug?

Future imperfect

Thus, my view is that *Bad Pharma* has contributed to bringing bad karma to a debate in which drug developers, drug regulators, journals, and, indeed, the CC should have been learning from each other. For what it is worth, my proposal for openness is as follows:

- Sponsors should be self-publishing of the results of trials.
- They should produce, as part of the regulatory submission process, a publication plan.
- A license to market should be given only once the plan is fulfilled.

However, there are many difficult details to be worked out in any plan. In particular

- What level of detail should be provided and how in practice will confidentiality be guaranteed?
- In an attempt to control problems of data-dredging, should we require those who want access to data in order to conduct an independent analysis, to pre-specify this analysis?

It is unhelpful to regard either of these last two points as being symptoms of resistance to progress by the pharmaceutical industry. I predict that we will find mistakes made with inadvertent disclosure of confidential data and that we won’t see the EBM movement or the CC coming to the rescue of the industry when this happens. If we don’t do something to address the problem of pre-specification, how will we deal with the problem of missing analyses? And must we require that every researcher requesting data publishes the pre-specified analysis?

If not how can we guard against the problem of selective analyses? How will we police this?

Prosecutor not judge

To return to *Bad Pharma*, my view is that you should regard it as a case for the prosecution with all the bias and selective choice of evidence from such a case that you would expect. That’s fair enough. There is a place for such cases. Unfortunately, however, many commentators seem to have mistaken it for the judge’s summing up. One lesson from *Bad Pharma* is clear: the chattering classes are easily deceived.

Declarations

I consult regularly for the pharmaceutical industry and my career is furthered by publishing. I maintain a full declaration of interest here: http://www.senns.demon.co.uk/Declaration_Interest.htm. The views expressed in this article are mine alone and should not be ascribed to any other party.

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New ICMJE guidelines for authorship

Revised guidelines for authorship have now been published by the International Committee of Medical Journal Editors (ICMJE).¹ As of August 2013, authorship now requires:

1. Substantial contributions to: the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

The last point is the new part – and will be the most difficult one for authors to comply with. In their commentary,² the ICMJE further insists that ‘Each author of a paper needs to understand the full scope of the work, know which co-authors are responsible for specific contributions, and have confidence in co-authors’ ability and integrity’. This was

added because of issues of author misconduct due to authors denying responsibility.

Whether all contributors will be willing or able to comply with these revised guidelines is another story. In my experience, it is already difficult to get most of them to comply with the first three points. Regardless, it is our responsibility as professional medical writers to maintain the highest ethical standards, which includes informing our clients on content and ethics guidelines like those of the ICMJE.

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If a misinformed voice speaks out in the wilderness and no one refutes it, does it make a sound? A call to advocacy

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Abstract

The pharmaceutical industry has been a soft target for many years. Attacks by journalists, politicians, and the lay public tend to be triggered by publications with which professional medical writers are associated. Fault is found, either in the content, perceived obfuscation of content, or on perceived deceptive authorship practices. The term 'ghostwriter' is used with great frequency and is often misapplied, or ill-defined (if it is defined, at all). For the most part, these criticisms have gone unanswered. We must understand that we represent the potential for the strongest and most influential voice in refuting misinformation and misunderstanding about our role. We must educate our critics about the value that we bring to communications about new therapies. We are our own best advocates in ensuring that critics of our profession are brought out of the wilderness.

Keywords: Authorship, Pharmaceutical industry, Medical writer, Medical writing, Ghostwriting, Advocacy

As professional medical writers, we often play a role in developing the materials that are submitted to regulatory authorities, as well as medical journals, industry white papers, and those used in promotion and advertising.

Public perception of the industry and those who work within it can have a profound effect on how the development of new therapeutics is viewed, both by the lay public and by healthcare providers. This, in turn, can significantly suppress participation in clinical studies, raise concerns about the safety of new medicines, and divert attention from, perhaps, more egregious offenses.

These perceptions are shaped by increasingly virulent attacks in the media on Pharma and, by

extension (either implicitly or explicitly) medical writers. It was bad enough back in 2002 when the infamous *TIME* cover story represented clinical trial participants as Guinea Pigs, but there seems to be a new wave. Marcia Angell's book: *The Truth About the Drug Companies*,¹ and other publications and editorials, articles, blogs, and Letters-to-the-Editor – many appearing in prestigious peer-reviewed medical and scientific journals – certainly seem to have fanned the flames. The latest salvo comes from Ben Goldacre in his diatribe: *Bad Pharma*.² While Goldacre makes some valid points on his review of Pharma practices, he goes out of his way to impugn not only the pharmaceutical industry, but medical writers, specifically. He, as do many other critics, conflates professional medical writers with Ghostwriters, failing to distinguish those who provide value in terms of clarity, accuracy, and comprehensibility – with full disclosure, from those who are less transparent regarding their contributions. He drags out the outdated example of the nefarious Ghostwriter and Ghost Publication Manager, creeping behind the curtain. He states, 'In reality, academic articles are often covertly written by a commercial writer employed by a pharmaceutical company, with an academic's name placed at the top to give it the imprimatur of independence and scientific rigour'. '... the entire academic literature, used by doctors to guide decisions – the only tool we have – is ghost managed, behind the scenes, to an undeclared agenda'. It is interesting that someone who is trained in a field depending on empirical evidence defaults (as do many critics) to anecdotal statements. He states that 'Since this activity (ghost authorship) is so hard to trace, it is, I think, legitimate simply to ask people who work with academic authors about their experiences'. Goldacre, and others, ignore the changes that have occurred over the

past five years, including creation and enforcement of authorship standards – including those requiring transparency; establishment of Codes of Ethics for professional associations (including EMWA's); and the attempts at educating all stakeholders about the clear difference between a professional medical writer's disclosed legitimate contributions and 'ghostwriting'.

Most critics are still confused. There are three main unethical authorship practices: ghost authorship, ghostwriting, and guest authorship (Table 1). Regardless of whether these practices occur in industry or academia, they should not be tolerated.

Professional medical writers (NOT to be confused with ghostwriters!) have to comply with a number of guidelines (e.g. Good Publication Practice) or legally binding contracts (e.g. Corporate Integrity Agreements) to ensure that authors do, indeed, meet authorship criteria. For industry-sponsored research, formal authorship agreements, which include authorship criteria, must be signed *before* the authors start developing the manuscript. Professional medical writers must maintain audit trails to document the 'substantial contributions' made by each author. Pharmaceutical companies now impose strict 'firewalls' between their editorial groups and marketing departments.

Although the standards are in-place and widely adopted, there are still challenges involved in determining authorship and for identifying relevant criteria. Annette Flanagan agrees that 'substantial contribution' has not been adequately defined.⁴ She hypothesises that failure to define the term might be intentional to allow wider application of the ICMJE criteria for authorship. For those seeking further clarification, she defines 'substantial contribution' as 'an important intellectual contribution, without which the work, or an important part of the work, could not have been completed or the manuscript could not have been written and submitted for publication'.

For the most part, criticisms of our profession have gone unanswered. We must understand that we represent the potential for the strongest and most influential voice in refuting misinformation and misunderstanding about our role. We must educate our critics about the value that we bring to communications about new therapies. There is a great deal of interest among our colleagues in trying to turn around these public perceptions; however, there have been few formal and coordinated attempts to do so.

The importance of educating the public with respect to the positive value of clinical trials and the value that the industry brings to the public welfare via the development of new therapeutic products cannot be understated. The role and contributions of the professional medical writer, likewise, must be clarified and emphasised.

Given the lack of a concerted voice, I believe that what is required is a grassroots movement to engage in more proactive efforts to try to turn public opinion around. We should discuss how we might create an effective coalition to change the public perception on this key issue.

One collective voice in the wilderness is that of GAPP (Global Alliance of Publication Professionals – <http://www.gappteam.org>). GAPP, a multinational collaboration, advocates for ethical publication practices in industry and non-industry-sponsored research. In particular, GAPP supports professional medical writing and condemns ghostwriting, ghost authorship, and guest authorship.⁵ Over the past two years, GAPP has issued timely and data-supported rebuttals to misguided criticisms of the profession and, in many cases, the efforts to educate our critics have reached the larger audience through the journals in which the responses have been published. Thus, editorials and letters-to-the-editor can effectively use the publication (on-line or hardcopy) as a multiplier for the message.

Table 1: Unethical authorship practices

| Type of contributor | Authorship criteria met? | Identified in manuscript? | Definition |
|-------------------------------------------|--------------------------|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Ghost author | Yes | No | A contributor who meets authorship criteria but is not listed as an author |
| Ghost writer ^a | No | No | A contributor who does not meet authorship criteria but whose involvement is not disclosed (i.e. not listed in the acknowledgments) |
| Guest author (or gift or honorary author) | No | Yes (as an author) | A person who does not meet authorship criteria but is listed as an author. The person may or may not have made any contribution to the manuscript; authorship is 'given' rather than earned |

^aGhost writers are not the same as professional medical writers. Professional medical writers disclose their involvement and funding source (usually in the acknowledgments section), and they adhere to ethical publication practices throughout the manuscript development process.³

Each of us, as professional medical writers, can exercise an effective voice by joining in the chorus of corrective response. In doing so, we should not ignore the many opportunities to discuss the issues with friends, colleagues, and family. They too, once they appreciate our position, may act as effective ‘vectors’ of correct information, spring-boarding the message to the broader audience.

We are our own best advocates in ensuring that critics of our profession are brought out of the wilderness.

Conflicts of interest and disclaimers

The author declares that he has, or does, provide ethical medical writing services to academic, biotechnology, or pharmaceutical clients; neither he nor his spouse have any financial relationships that may be relevant to the submitted work; and that

he is active in national and international not-for-profit associations that encourage ethical medical writing practices. No external sponsors were involved in this study and no external funding was used.

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Relaunch of the Medical University of Innsbruck Master's in Medical Writing

The Medical University of Innsbruck will be relaunching the Master's in Medical Writing in October 2014.

This two-year Master's program will combine on-site summer and winter school in Innsbruck, Austria and distance learning. The course will provide students with the basic medical knowledge required by medical writers and will cover the three main areas of professional medical writing:

- Scientific Writing
- Medical Communications
- Regulatory Writing

Students will be taught by international experts in each field and will have to write and complete two full professional documents, one as a first-year project and a second as a Master's thesis.

Teachers sought

Currently the program is also looking for teachers with expertise in the following areas:

- Drug development and regulatory affairs
- Medical communications
- Advanced English skills
- Quality assurance
- Good clinical practice and medical ethics

For further information or to express interest in teaching, please contact:

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The Big Pharma conspiracy theory

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Abstract

This essay outlines the broad themes of the conspiracy theory that pharmaceutical companies, regulators, politicians, and others are secretly working in consort against the public interest. This so-called Big Pharma conspiracy theory shares a number of features with other conspiracy narratives, but some features make this particular subgenre of conspiracy theory especially intractable and dangerous.

Keywords: Conspiracy theory, Pharmaceutical companies, Paranoia, Vaccines

The so-called Big Pharma conspiracy theory shares a number of features with all other conspiracy theories. First, it shares the same basic plot: a relatively small number of people are working in secret against the public good. Second is a belief that most people are ignorant of the truth and that only a small number of people with secret or suppressed knowledge (the conspiracy theorists) know the real score. Third is the conspiracy theorists' backward approach to evidence: lack of evidence for the conspiracy is evidence *for* the conspiracy, as is any disconfirming evidence. Lastly, the way supposedly confirmatory evidence is handled capitalizes on common mental shortcuts, misperceptions, and non-rational cues, which make the conspiracy theories all the more memorable, compelling, and contagious. This maddening mixture of mistakes makes conspiracy theories very difficult to combat.

Big Pharma conspiracy theories, however, in all their variety, constitute their own genre within the larger category of conspiratorial narratives. In much the same way that the gothic novel has its own conventions (for example, a heroine imprisoned, set in a dark old spooky house riddled with hidden passages, and hints of the paranormal), the Big Pharma conspiracy theory has a number of conventions that set it apart from other conspiracy theories. In this case, the villain is the Pharmaceutical Industry. It's not the *actual*

pharmaceutical industry; rather it is the pharmaceutical industry as they imagine it. In these stories, 'Big Pharma' is shorthand for an abstract entity comprised of corporations, regulators, NGOs, politicians, and often physicians, all with a finger in the trillion-dollar prescription pharmaceutical pie. Eliding all of these separate entities into a monolithic agent of evil allows the conspiracy theorist to mistakenly ignore the complex and conflicting interests that they represent. This agent is, as are all antagonists in conspiratorial narratives, improbably powerful, competent, and craven, and it allows the conspiracy theorist to cast himself in the role of crusader and defender of a way of life, a Manichean dichotomy that was identified in Richard Hofstadter's classic treatise on America's recurring conspiracism, 'The Paranoid Style in American Politics'.¹

Like many conspiracy theories, there may be real tangible facts that undergird the elaborate conspiracy theory. For instance, pharmaceuticals have side effects, many of which are unpleasant, some of which can be fatal. This basic fact of pharmacology, however, has become the basis of blanket claims about the universal dangerousness of pharmaceutical products. Additionally, not all medical interventions are successful, and in our litigious culture people often seem to not understand that sometimes adverse outcomes occur when everything is done correctly. Nowhere are these ideas more prevalent than in conspiracy theories involving cancer treatments. Cancer treatments are often invasive and dangerous, and while the best practices, in the aggregate, improve outcomes for patients, they can still be unpleasant, even traumatic. They may fail certain patients entirely, so that a patient may experience all of the side effects of a treatment and none of the hoped-for benefits. To the conspiracist, ubiquitous advertisements by pharmaceutical companies become 'mind control' or 'brainwashing', while industry lobbying becomes 'corruption'.

Conspiracy theories may be a way to reassure oneself that there is an order to our lives, that calamity and disaster are not meaningless or random.² This in turn enables people to identify an enemy to fight. When patients (and their loved ones) are forced to accept a serious disease, they often experience powerlessness, especially when no cure is available. This may itself trigger a search for a culprit to blame for their suffering. Big Pharma is a convenient target and is often imagined as withholding a cure. Indeed, a major premise of the Big Pharma conspiracy theory is the '*cui bono*' fallacy: he who benefits from misfortune must be the cause of that misfortune. Such logic has been used in other, non-medical conspiracy theories: Franklin D Roosevelt got the war he wanted, therefore, he was behind the Japanese attack on Pearl Harbour; George W Bush and his handlers wanted to go to war in the Middle East, so they brought down the World Trade Centre as a pretence to invade Iraq; European Jews were de-ghettoized as Napoleon swept across the continent—they must have been behind the revolution that led to his ascent to power.

In the case of the Big Pharma conspiracy theory, *cui bono* reasoning appears in a pair of often-levelled charges. The more common charge is that a cure is being withheld to keep people on more expensive, less effective medical regimes. In the case of cancer, the cheap, easy, and 'natural' suppressed cures range from baking soda, to marijuana, to vitamins, to apricot kernels (which are banned because the amygdalin they contain breaks down into hydrogen cyanide).³ The more extreme charge is that diseases are deliberately manufactured molecule-by-molecule or weaponised in labs and released onto the populace in order to give companies an excuse to sell medications. One such high-profile accusation of this, I think, was during the 2009 H1N1 swine flu outbreak. Mike Adams, an inexplicably popular online health guru (he calls himself the 'Health Ranger') who advocates nearly every conspiracy theory, made this charge in 2009 in a bizarre little rap called 'Don't Inject Me (The Swine Flu Vaccine Song)':

Don't you know the swine flu was made by
man
Pharmaceutical scam
[...]
All you parents grab your kids
And shoot 'em up just like guinea pigs,
Inject your teens and your babies in the crib;
And when they get paralyzed,
That's when you realize
There's no way to undo what you did.

The big drug companies are makin' a killing
Collectin' the billions and gettin' away like a
James Bond villain
Cause they're willin' to do almost anything
Just to make money with the flu vaccine.

Adams actually embraces both *cui bono* claims, that all you need is vitamin D to ward off the swine flu (but that drug companies can't charge as much for it) and that the flu was manufactured in order to sell the vaccine. He also manages to invoke a global depopulation conspiracy alongside creating a market for vaccines: two agendas that are hard to reconcile, as one involves killing people and the other saving as many people as possible by selling them vaccines. This is a typical feature of conspiracist thought – a 2012 study by Wood, Douglas, and Sutton found that the 'endorsement of mutually incompatible conspiracy theories are positively correlated'.⁴

Anti-vaccine conspiracy theories play on many of the same fears that run-of-the-mill Big Pharma conspiracy theories do – including fears over side effects, 'unnatural' substances in them and a general suspicion of the profit motive in health care – but these theories are often supercharged by the fears of parents. Parents who believe that their children are 'vaccine-damaged' and who are struggling to understand and assign blame for an intractable, life-changing disease with no cure, have created one of the most stubborn and dangerous conspiracy theories. Following the widespread attention received by Andrew Wakefield's entirely fraudulent 1998 *Lancet* article linking the MMR vaccine to autism (withdrawn by the journal in 2011), childhood vaccination rates plummeted below levels needed to support community immunity in many areas, and children started to contract diseases that many younger physicians had never seen. The resilience of the conspiracy theory targeting vaccine manufacturers and researchers can be seen in the fact that it persists despite over a dozen studies demonstrating otherwise, including one Cochrane review that had a sample size of about 14.7 million children.⁵ The theory is as popular as ever and is still pushed by the likes of Jenny McCarthy, Generation Rescue, and innumerable alternative medicine practitioners. Fear, it seems, is more contagious than reason.

So, what can be done to combat the Big Pharma conspiracy theory? Sadly, the theory will always be around because peddlers of alternative medicine find Big Pharma to be a useful adversary in their quest to sell their questionable remedies and because of the role that belief plays in people's lives. Furthermore, once the theory has taken root in someone's mind,

it's often impossible to dislodge it, as the conspiracy theory turns those who argue against it into 'paid shills' or 'sheeple'. It is best to catch people before they fall into conspiratorial beliefs. Secrecy and ignorance beget conspiracy theories; they are best combated by education and transparency.

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theories and other extraordinary claims, as well as veterans' combat narratives.

Fun with medical studies

What a shame this study has finished, as judging by the protocol I would have quite liked to have enrolled...

'Applications will be done by massage until complete penetration by the medical staff'.

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Editorial

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Pharmaism

Criticising the pharmaceutical industry is a type of sport, and it is astonishing what nonsense people will believe about it. For example, it has been said that pharmaceutical companies will only conduct a clinical trial against another product that will show their own product in a favourable light. This is a facile criticism. Of course pharmaceutical companies do not run clinical trials that can be predicted to have a negative outcome. Clinical trials are expensive and a pharmaceutical company is a commercial business. It does not make sense for any company in any industry to spend money advertising another company's product. What does make sense is for the competitor company to pay for the trial that shows their own product to be better; *ipso facto* the company with the better product pays for the trial.

It is probably the fact that pharmaceutical companies make a profit from selling drugs to treat our ailments that underlies people's antipathy towards it. The alternatives to having the development of potential new medicines funded by a business include for governments to fund the work (i.e. for us to pay through our taxes), for drugs to be developed by charities (i.e. for us to pay through our donations), or for no further research to be done (i.e. we keep our money and hope we do not develop an illness for which there is currently no effective treatment). None of the alternatives are viable or acceptable and the pharmaceutical industry continues to thrive.

The media paints a picture of the pharmaceutical industry as being populated by overweight executives in dark suits, jet-setting around the globe making business deals that line their own pockets and those of their friends, the shareholders. These ogres are responsible for publishing positive data, hiding negative data, and misleading the vulnerable.

Any company that develops any product has to advertise and sell that product otherwise the company will be in business for a very short time. The pharmaceutical industry is no different and criticising the industry for its marketing is just target

practice. All advertising material for all industries must comply with advertising codes, which include the requirement to hold documentary evidence to prove all claims, whether direct or implied, and not to be misleading. In the particular case of the pharmaceutical industry, the company's medical director is at personal risk of criminal prosecution for any breaches of the advertising code, which is an effective incentive (if one were needed) for ensuring that any claims made in marketing materials can be substantiated.

Not publishing negative data is not the same thing as hiding it. The worst that the pharmaceutical industry can reasonably be accused of is putting a positive spin on its products by highlighting the positive aspects. This is not a news story and it's not 'bad' behaviour; it's just marketing. Imagine an advertising campaign in which the actor uses a shampoo, shrugs his shoulders and says, 'It's alright I suppose'. Or Mrs Average Housewife looks at the bottle of ketchup handed to her and says, 'I'm sure it's very nice but I buy the supermarket's own brand because it's cheaper'. We do not see advertisements for breakfast cereals that bring the sugar content of the products to our attention. There is nothing new or unusual about advertising materials promoting the positive, unique selling point of a product.

To suggest that an industry is good or bad is to suggest that each person employed in that industry is good or bad. This is stereotyping. A company is an entity in law but it is composed of individual people. It is like saying that the British go to Ibiza on holiday and get very drunk. Of course there are people for whom this is an accurate description of their behaviour but they represent a tiny percentage of British people. Like a country, a company can have a culture but we cannot assume that every person who works for the company agrees with the culture, or feels comfortable with it. On the contrary, many employees have a healthy scepticism of corporate mission statements and values.

The pharmaceutical industry is a success story, creating employment, contributing to gross domestic product, and developing new treatments for

disease. People who work for the industry are employed in manufacturing, drug discovery, information technology, distribution, formulation research, human resources, administrative support, clinical research, catering, marketing, cleaning, sales, administrative support, and so on. A pharmaceutical company is not a sentient creature; it is a conglomeration of normal people who are also The Public and often The Patient. In all walks of life, people want to earn a living, preferably doing work that they enjoy, so that they can have enough money to eat, be warm and dry, spend time with family and friends, have a few nice things and go on holiday now and then.

We can draw an analogy with the negative publicity about bankers' bonuses, which gave us the impression that everyone who works for a bank is rewarded annually with an enormous bonus that is higher than most of us will earn in our lifetime. If this isn't terrible enough, these are the people who are responsible for the current global economic crisis. In reality, very few employees of banks are investment bankers. Most bank employees earn a modest wage and will be lucky if their bonus (if they get one) is enough for them to afford to buy a new washing machine.

Author information

Wendy Kingdom is a freelance medical writer with more than 25 years of experience in clinical research and medical writing.

Most of us who work in or for the pharmaceutical industry do our work diligently, honestly, and responsibly. We take pride in our work, we take the regulations seriously, and we work to high ethical standards because we believe that it is the right thing to do. We know that it is impossible to hide data from the Regulatory Authorities; any attempts to hide data would require a conspiracy worthy of a bestselling novel. We might have come across one or two individuals who have not made us feel proud to be working for the same company – as with all stereotypes, there is a grain of truth in there somewhere. Nonetheless, stereotyping has more to do with what people want to believe than what is necessarily factually correct, logical or reasonable. History should teach us to be wary.

As for the shareholders, the major ones are usually pension companies. We should all wish them many happy returns on their investments.

Disclaimers

Wendy Kingdom is a freelance medical writer for the pharmaceutical industry. The views expressed in this article, including any errors, are entirely her own and do not represent the views of EMWA.

Legal remedies for medical ghostwriting: Imposing fraud liability on guest authors of ghostwritten articles

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Introduction

There are persistent concerns about the influence of the pharmaceutical and device industries on the medical literature, and particularly on the reporting of clinical trials, which can include the distortion of the true evidence base of medical interventions and overestimation of the clinical benefit of a drug used to treat patients.¹ An especially problematic issue involves the industry practice of publishing studies prepared by hired medical writers but signed by academic 'guest authors' who are invited to add their names without fulfilling authorship criteria. In this case, 'guest authorship' is accompanied by 'ghostwriting', which occurs when a published article fails to acknowledge the original writer or writers' contributions.²⁻⁴ Ghostwriting can also occur when an academic research group uses a professional writer to draft an article based on data generated by the group. When the research group retains control of the data and the final analysis, however, there is less of a concern about possible bias in the reporting of the results, and the appropriate remedy in that case is to report explicitly the role and contribution of the medical writer in the article. Here, we concentrate on ghostwriting and guest authorship in industry-controlled research, where several examples have revealed the use of ghostwriters to insert concealed marketing messages favourable to a company's product, and the recruitment of academics as 'guest' authors despite not fulfilling authorship criteria.⁵⁻⁹

Commentators have condemned the practice as unethical and unacceptable and have discussed the harms resulting from this form of medical ghostwriting, recommending that journal submissions be policed more aggressively and that the 'guest authors' be suitably sanctioned by journals, academic institutions, and regulatory agencies.¹⁻¹⁴ However, these recommendations have not yet been widely embraced by the academic institutions, medical journals, and medical licensing organizations that would seem to have the most at stake in curbing this practice. Here, we discuss some of the reasons for this lack of response and suggest that the law may offer a solution, given these other institutions' failure to impose sanctions.

Concerns about guest authorship

Guest authorship is a disturbing violation of academic integrity standards, which form the basis of scientific reliability.¹⁵ The scientific base guiding clinical practice and decision-making is to a large degree formed by the peer-reviewed medical literature. Indeed, pharmaceutical sponsors borrow the names of academic experts precisely because of the value and prestige attached to the presumed integrity and independence of academic researchers. In turn, academics receive considerable credit for publication, thus providing an incentive for their willingness to act as 'guests'.

In the legal setting, peer-reviewed articles are credible sources of evidence that may be used in lawsuits to support claims about safety and effectiveness, and hence to determine liability.¹⁶ Industry-controlled publications that are prepared by ghostwriters or that use guest authors may distort perceptions about current knowledge concerning a product's safety and effectiveness. For legal purposes, publication in peer-reviewed journals

is one of the criteria that help to make a scientific theory or method admissible as evidence, according to the standards set out by the United States Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals*.¹⁷ By facilitating publication in peer-reviewed journals, guest authorship creates the impression that standards of academic independence and integrity have been satisfied even when they have not, and makes it more likely that the research will be treated as legally admissible even when this is inappropriate.

Publications on which academics appear as guest authors also give credibility to these authors in the legal setting. These articles are sometimes used to establish an expert witness's authority, even when the validity of the research in the article is the very issue under dispute. As a result, the treatment of the guest author as a legal expert may prevent scrutiny of the practice that is being challenged for contributing to serious harm. Numerous studies have shown that industry-sponsored clinical trials are often biased in favor of the sponsor, sometimes in ways that can be detected only with access to the original data and study protocol.^{8,9,18–22} Often, the manipulations that influence the outcome are not visible to the guest author, whose role in the study or article may be minimal and may fall short of authorship criteria that would require involvement in the development and conduct of the study, and final approval of the paper. Thus, guest authors help create the appearance that a study reflects the kind of 'scientific methodology' that is required to render evidence admissible under the Daubert standard, and in the process they credentialize themselves as expert witnesses who can speak authoritatively about a product's efficacy and safety.

Curbing ghostwriting practices

The International Committee of Medical Journal Editors (ICMJE), in establishing leading standards for biomedical publications, has sought to curb inappropriate and unethical authorship practices by requiring that journals ask detailed questions about what exactly each author has contributed to an article.²³ Editors and editors' associations have a significant interest in preserving the integrity of their journals, and some have detailed sanctions. For example, the World Association of Medical Editors (WAME) says that ghostwriting is 'dishonest and unacceptable', and recommends that on detecting the practice, a journal should '(1) publish a notice that a manuscript has been ghost written, along with the names of the responsible companies

and the submitting author; (2) alert the authors' academic institutions, identifying the commercial companies; (3) provide specific names if contacted by the popular media or government organizations; and (4) share their experiences on the WAME Listserve and within other forums'.²⁴ Similarly, the Committee on Publication Ethics (COPE) recommends that journal editors 'adop[t] authorship or contributorship systems that promote good practice (i.e., so that listings accurately reflect who did the work) and discourage misconduct (e.g., ghost and guest authors)' and recommends that when the integrity of research is corrupted, '[e]rrors, [and] inaccurate or misleading statements must be corrected promptly and with due prominence'.²⁵

Summary points

- Ghostwriting of medical journal articles raises serious ethical and legal concerns, bearing on the integrity of medical research and scientific evidence used in legal disputes.
- Medical journals, academic institutions, and professional disciplinary bodies have thus far failed to enforce effective sanctions.
- The practice of ghostwriting could be deterred more effectively through the imposition of legal liability on the 'guest authors' who lend their names to ghostwritten articles.
- We argue that a guest author's claim for credit of an article written by someone else constitutes legal fraud, and may give rise to claims that could be pursued in a class action based on the Racketeer Influenced and Corrupt Organizations Act (RICO).
- The same fraud could support claims of 'fraud on the court' against a pharmaceutical company that has used ghostwritten articles in litigation. This claim also appropriately reflects the negative impact of ghostwriting on the legal system.

Some journals, such as PLoS Medicine, have called for bans on future submissions by authors who act as guests, formal retraction if unacknowledged ghostwriting is discovered after publication, and reporting of authors' misconduct to institutions.²⁶ This may have an impact on academics concerned about their status and future publication options. However, it is unclear whether journals can or even want to monitor the practice adequately. Some editors have stated that their journals are not responsible for policing authorship practices.²⁷ And because medical journals may gain significant revenue from lucrative advertisement contracts

and from selling reprints (including of ghostwritten articles), which industry may use for off-label promotion,²⁸ it is unlikely that medical journals will effectively seek to prevent these practices.

Commentators have also called for academic sanction.^{12,29} But while several established academics have been associated with ghostwritten publications, no public sanctions appear to have been enacted for their behaviour. Various reasons explain an institutional reluctance to take this route: the guest's role in the ghostwritten publications may be unclear; academic institutions may be challenged by their dual commitments to safeguard academic integrity while also protecting their employees against unjust accusation; and universities in particular tend to approach authorship questions with understandable prudence, considering the serious potential impact on academic careers. Academic institutions may also be reluctant to act because ghostwriting cases often involve successful academics who hold positions of power due to their prestige, academic status, publication record, and grant support.

Moreover, institutions may decide not to act because the practices involved in ghost and guest authorship may not be far removed from other common publication practices in academic medicine where laboratory directors, departmental chairs, and supervisors often claim authorship on publications because of those institutional roles rather than by standard authorship criteria.² Some clinician-investigators even insist on co-authorship when providing access to patients or samples. Pursuing sanctions for ghostwritten articles may open a Pandora's box, leading to scrutiny of other authorship practices in academia, or to anxiety-laden efforts to justify those practices.³⁰

Professional organizations, such as State Medical Boards in the US, Colleges of Physicians and Surgeons in Canada, and the General Medical Council in the United Kingdom, could also intervene when evidence of guest authorship by licensed health care professionals is uncovered, particularly if it involves outright misrepresentation of data.¹ When a physician falsely claims to have analysed and adequately reported safety and effectiveness data, this can be considered a violation of professional integrity standards and of the commitment to patients and good health care; physicians should know that this may impair clinical care and endanger patients, and they should be sanctioned accordingly.¹

However, these professional organizations have so far failed to issue serious sanctions in the rare cases when an organization has looked into

allegations of authorship violations.³¹ The reasons for the lack of action may include their general inertia in reacting to new professional challenges and the fact that they may be more preoccupied with other, more traditional violations of professional standards of care, violations of conflicts of interest, and financial fraud. There has also been much criticism of these organizations for their perceived tendency to protect the profession.^{32,33} Finally, for the same reasons as the academic institutions, professional organizations may be uncomfortable about confronting problems of guest authorship and ghostwriting that damage their members.

In light of the lack of institutional responses to curb the practices of ghostwriting and guest authorship and in light of the significance of these practices for the legal system, we suggest that a firm legal response is appropriate.

Legal liability for ghostwriting

An important starting point for a legal response involves the ICMJE uniform guidelines²³ and the authorship forms used by many medical journals based on those guidelines. The theories outlined below apply specifically to journals that require authors to complete and sign such a form as a condition of publication. The guidelines were designed to ensure that authorship credit is reserved to those who have played a significant role in the study's design, conduct, and analysis, and writing of the article. The guidelines set out three criteria, and a person seeking credit as an author must satisfy all three:

1. Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
2. Drafting the article or revising it critically for important intellectual content; and
3. Final approval of the version to be published.²³

Medical journals typically require all authors to confirm in writing that they have satisfied these criteria. 'Guest authors' often fail both of the first two requirements, as suggested by evidence that has been revealed in recent class actions involving drugs such as Vioxx (rofecoxib), Prempro (combined estrogen/progestin), and Paxil (paroxetine).^{6,7,27} For example, an individual who reads an article and/or offers minor comments has offered nothing substantial under criteria 1 and 2.

The authorship requirements are known not only to named authors but also to readers. The warranty

of authorship is an important factor in ascertaining an article's integrity and quality. To see this, we need only ask how readers would react to an article prefaced with a statement that a lead author has refused to sign (or has repudiated) the authorship warranty, and now wishes to clarify the contributions of an industry-based medical writer. Such a statement would significantly undermine the article's credibility.³⁴

Guest authorship as fraud

The above thought experiment, involving a guest author who admits to playing that role, shows that a false affirmation of authorship is an example of fraud. Fraud occurs when a person makes a knowingly false representation in order to acquire something of value, and harm occurs as a result.³⁵ In its basic structure, a claim of civil fraud on this basis would take the same form in many countries.³⁶ However, such a claim is more likely to yield significant damages if numerous plaintiffs can join together to sue in a class action, which may be done more easily in the US than in many other jurisdictions. We therefore draw on US law in this section. Here, the guest's false claim—asserted in the authorship warranty—induces the journal to publish the article, and misleads readers about the scholarly care and scrutiny lavished on the research. The journal gives the guest credit for an article that may serve as a valuable credential, by impressing academic merit committees, grant agencies, conference organizers, and others including judges and juries if the guest later acts as an expert witness.³⁷ Such recognition may carry reputational and financial value. Arguably, each repetition of the false warranty (implicitly asserted on a CV presented to any of these audiences) is an independent fraud. The journal loses the opportunity to publish an article that would legitimately have satisfied the authorship requirements. The subscribers lose the opportunity to read a legitimate article, and may be led to believe, rely on, and use data from a fraudulent article. If the journal became aware that the lead author was a mere guest, and that the journal's authorship requirements had not been satisfied, the journal would not publish the article.

The characterization of guest authorship as fraud has received limited but important recognition in suits involving the False Claims Act (FCA), which imposes liability on those who cause fraudulent claims to be presented to the US government.³⁸ For example, in *Strom ex rel. U.S. v. Scios, Inc.*, the US government alleged that the defendants' activities

led to the presentation of false Medicare claims.³⁹ These activities included sponsoring ghostwritten articles purporting to validate off-label use of Natrecor (nesiritide) and, through press releases and the promotional efforts of sales representatives, recklessly encouraging doctors to prescribe the drug for uses that were not medically accepted. Without deciding the merits, the court held that the allegations, if proved, would be sufficient to state a claim under the FCA. In *Strom*, it appears that the unwarranted claims made in the ghostwritten articles, rather than their fraudulent authorship, helped to support the allegations of fraud. This approach has great potential, but it will not always be easy to prove the falsity of ghostwritten research.

As *Strom* shows, the fraud underlying these articles cannot be attributed solely to the guest author, who after all has responded to an invitation. Pharmaceutical companies and medical communications agencies are well aware of the journals' publication requirements. Soliciting and facilitating fraud may amount to conspiracy, and may incur liability on the same grounds as the fraud itself.⁴¹ Such conduct may also constitute fraud under the Racketeer Influenced and Corrupt Organizations Act (RICO).⁴¹ RICO applies to conspiracies involving at least two prohibited acts within a 10-year period, if those acts 'have the same or similar purposes, results, participants, victims, or methods of commission'.^{41,42} The predicate acts for RICO liability include mail and wire fraud, which occur when a fraudulent statement is sent through the mail or by email. If a guest lends her name to two or more articles for the same product, she may satisfy the RICO criteria in several different ways, because the purposes, results, participants, and methods of commission are the same. Civil RICO liability allows plaintiffs to seek treble damages from those violating the statute.^{41,42}

Because a journal's readers are all harmed by the fraud, they may sue the guest in a civil RICO class action.^{43,44} One of their harms involves the value of the journal subscription. The subscription price represents the value of a year's worth of articles that conform to the guidelines. Readers would not willingly pay for the fraudulent articles, as shown by the hypothetical example of a guest author who disclaims responsibility for authorship. Whether or not they read the article in question, its publication deprives them of the opportunity to read an article satisfying the journal's requirements, and thus diminishes the value of their subscription. The harm may be measured by reducing the subscription price in proportion to the space devoted to the

ghostwritten article. If the subscription costs \$100, and the journal publishes 100 articles per year, it could be said that each subscriber suffers a \$1 loss from a fraudulent article. The individual loss is small, but the aggregate loss to all subscribers may be significant—particularly if the cost is trebled under RICO.

In addition, some readers access articles on a pay-per-view basis. These readers, too, will assume that the article meets the journal's requirements, and they would also be unlikely to pay if they first saw a disclaimer of authorship responsibility. These purchasers might constitute a distinct subclass in a RICO class action, with damages based on the cost of the download.

To prevail, the plaintiffs would not have to prove individually that they relied on the guest's fraudulent claim. In 2008, the US Supreme Court held that when plaintiffs allege fraud under RICO, they are not required to show that they relied on the defendant's assertions, so long as they were harmed because someone else relied on the fraud (such as the journal editors).⁴⁵ Once a plaintiff establishes that the article was ghostwritten, and shows that he or she paid for a subscription or a download, she has sufficiently established fraud, reliance, and harm for the whole class of RICO plaintiffs.

Why should this approach be directed against guest authors, rather than the others who are complicit in the same fraud? RICO fraud could be added to the claims raised against pharmaceutical companies in negligence suits, but the damages would be low, as against those already available in such cases. But the combination of monetary sanctions and reputational harm might deter academics, and might also deter the medical communications agencies that design these studies and seek impressive names for the byline. Here is a case where the threat of liability—and the uncertainties and distractions that it brings—may be sufficient to discourage those who are not normally sued for harmful drugs, but who help to legitimate the studies that publicize these products.

Guest-authored articles as 'fraud on the court'

As to the pharmaceutical companies, we propose another approach, also grounded in fraud. Just as the integrity of medical research is a key factor in recognizing false authorship warranties as fraud, the courts' concern about the integrity of their proceedings is key to the doctrine of 'fraud on the court'. This doctrine takes a similar form in England, Australia, Canada, India, and many

other countries;⁴⁶ we focus on US law here because, as explained below, the doctrine had its start in a case that involved a ghostwritten article. A recent formulation of the doctrine defines it as 'conduct: 1) on the part of an officer of the court; that 2) is directed to the judicial machinery itself; 3) is intentionally false, wilfully blind to the truth, or is in reckless disregard for the truth; 4) is a positive averment or a concealment when one is under a duty to disclose; and 5) deceives the court'.⁴⁷ This definition would apply to the use of ghostwritten articles when they are cited by lawyers for those who helped to create the articles or by expert witnesses for those parties. Expert witness testimony comes into court through the agency of lawyers, who are officers of the court. When a pharmaceutical company helps to produce ghostwritten articles and its lawyers cite them in court, the lawyers are, at the very least, reckless about the falsehood and they have a duty to disclose the truth. Remedies for fraud on the court may include a default judgment for the opposing party (when the fraud is revealed during a proceeding), nullification of a judgment or a legal entitlement that was secured with the aid of the fraud, and disbarment of counsel who facilitated the fraud.⁴⁸

For a more concrete sense of the doctrine, consider *Hazel-Atlas Glass v. Hartford-Empire Co.* (1944), which seems to be the only ghostwriting case decided by the US Supreme Court.⁴⁸ The facts are worth reviewing, because their significance is easily misunderstood—and to the best of our knowledge, the case has not been cited by any commentators on medical ghostwriting. In 1926, Hartford tried to patent a method of molding glass. Faced with skepticism from the Patent Office, Hartford's employees wrote an article lauding their method as an important advance, and then found an author for it in William Clarke, president of the Flint Glass Workers' Union. After publishing the article in a trade journal, Hartford cited it in their patent application, and the patent was granted. In 1928, Hartford sued Hazel, a competing glass manufacturer, for infringing the patent, but lost at trial. On appeal, Hartford leaned heavily on the spurious article. Hazel doubted its legitimacy, and interviewed Clarke, but he refused to acknowledge the truth. The court of appeals ruled for Hartford, quoting from the article as evidence of the patent's novelty and utility. The truth came to light 9 years later, when Hartford disclosed its files during an antitrust action. In 1944, the Supreme Court vacated the prior judgment, sanctioning Hartford's use of the article as a fraud on the court. The Court also nullified Hartford's patent, and the

Hartford lawyers who had used the spurious article were disbarred from practice before the Patent Office.⁴⁹

In explaining why Hartford's actions merited sanction, the Supreme Court offered several observations that apply with equal force to current examples of medical ghostwriting. The Court stated that using spurious claims of authorship to legitimate claims before the Patent Office and the courts 'is a wrong against the institutions set up to protect and safeguard the public'.⁴⁸ Precisely the same could be said about ghostwritten articles published in medical journals through false warranties of authorship. The courts are among the institutions wronged by such practices, which may lead judges to treat the ghostwritten publications as evidence that is legally admissible according to the *Daubert* requirements, as noted above.¹⁷ Hartford argued that it was impossible to prove that the article was responsible for their legal victory, but the Court rejected that argument: 'Hartford's officials and lawyers thought the article material. They ... went to considerable trouble and expense to get it published [T]hey urged the article upon the Circuit Court and prevailed. They are in no position now to dispute its effectiveness'.⁴⁸ We might expect pharmaceutical defendants to minimize the evidentiary role of ghostwritten articles today, and the same answer would be appropriate.

Ghostwritten articles are not created and developed primarily for legal purposes; rather, they are used to publicize and market drugs. However, a restriction on the legal use of articles to which guest authors have added their name could significantly diminish their overall value. They are often used in litigation to support the manufacturer's arguments about a drug's efficacy and safety, or to establish a record of scientific acceptance for *Daubert* purposes, or to credentialize an expert witness. Each of those uses, if attempted by a party that had helped to create the article, could risk sanction. The articles could still be used to promote drugs, but if litigation should arise, the defendant's arsenal of responses would be limited.

Conclusion

The false respectability afforded to claims of safety and effectiveness through the use of academic investigators risks undermining the integrity of biomedical research and patient care. This integrity also underpins the use of scientific evidence in the courtroom. Whether publications with academic guest authors are factually accurate is irrelevant. In

Hazel-Atlas, Hartford insisted that the article's claims were true, attribution issues notwithstanding. The Supreme Court found this argument unavailing: 'Truth needs no disguise. The article, even if true, should have stood or fallen under the only title it could honestly have been given—that of a brief in behalf of Hartford, prepared by Hartford's agents, attorneys, and collaborators'.⁴⁸ Today, as in 1944, one might expect the sponsors of ghostwritten articles to treat the question of false authorship as an insignificant detail that merits no legal sanction. The US Supreme Court's comments provide a sufficient rebuttal to such claims.

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Author contributions

Wrote the first draft of the manuscript: SS TL. Contributed to the writing of the manuscript: SS TL. ICMJE criteria for authorship read and met: SS TL. Agree with the manuscript's results and conclusions: SS TL. Jointly developed the structure and arguments of the paper: SS TL. Wrote the first draft of sections 1 and 2, and had primary responsibility for the discussion of concerns associated with ghostwriting: TL. Wrote the first draft of section 3, and had primary responsibility for the discussion of fraud: SS. Made critical revisions and approved the final version: SS TL.

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Medical Writing Jumble # 9

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

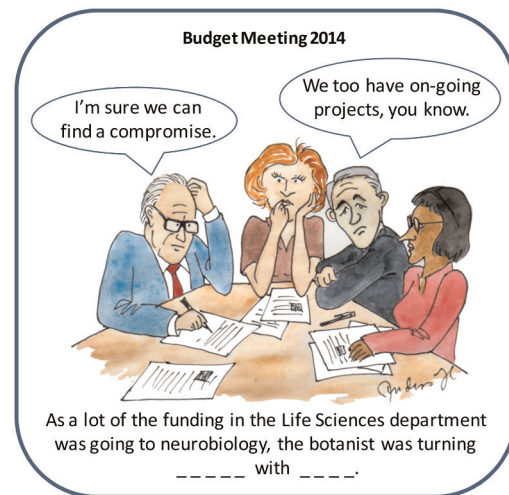
Illustration: Anders Holmqvist

TEENV

SEYNAU

GRAUS

CEFTEF



Answer: WITH

See page 316 for the answers.

A decade of change: A new ISMPP has arrived

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Abstract

Founded originally as a not-for-profit society to provide education, advocacy, and best practices for those involved in medical publication planning, the International Society for Medical Publication Professionals (ISMPP) has grown in size to over 1300 members throughout the world. As ISMPP approaches its 10th Annual Meeting, significant changes are occurring within the industry, as well as in the organisation's operating structure, including the hiring of a full-time President and Chief Operating Officer to help drive the vision and mission of the organisation and provide a 'visible' face to ISMPP. Additional changes include a reassessment of key elements of ISMPP's vision and mission, increased organisational collaborations, and more proactive positions across numerous areas of interest in support of its members. At the same time there are significant concerns across the industry regarding initiatives that undermine the credibility and intrinsic value all publication professionals hold dear, which is transparent and ethical scientific exchange.

Keywords: Chief Operating Officer, International Society for Medical Publication Professionals Board of Trustees, Value proposition

Founded originally as a not-for-profit society to provide education, advocacy, and best practices for those involved in medical publication planning, the International Society for Medical Publication Professionals (ISMPP) has grown in size to over 1200 members throughout the world. More significantly, ISMPP has evolved beyond a core group of pioneers and is now becoming increasingly recognised for its contribution in establishing ethical and transparent publication practices and standards, for advocating and taking a leading position on issues facing our profession, and for the creation of educational content and tools that provide value to its members globally.

New President and Chief Operating Officer

A recent significant change in ISMPP's structure was the creation of a full-time Chief Operating Officer position, which I proudly assumed in October of this year. This new role was designed as a basis to lead the permanent ISMPP office staff and is accountable to the ISMPP Board of Trustees (Figure 1). The creation of this role will allow for a more concentrated focus on organisational leadership, strategy development, external affairs, and organisational management. Additional advantages include a more visible external 'face' for ISMPP, continuous and recognised leadership, the possibility of increased and more strategic organisational collaboration, reduced role strain on volunteer Board of Trustees officers, and by moving from an implementation model to a governance model, an optimised Board of Trustees.

A growing value proposition

ISMPP's growing stakeholder base includes representation from medical writers, publishers, journal editors, academics, medical communication professionals, and individuals from pharmaceutical, biotechnology, and medical device companies. While these groups may not have been fully aligned based on historical relationships, the value proposition we offer healthcare providers and patients can and should be aligned. All stakeholders believe that research should be conducted in the most objective manner through application of scientific methods. In addition, all groups believe that research results be developed in an objective and transparent manner and subsequently published in peer-reviewed journals. These are important areas of alignment because the peer-review literature is one of the most important sources of information for healthcare providers and directly influences patient care.

Many established ISMPP activities and benefits support the above value proposition. These

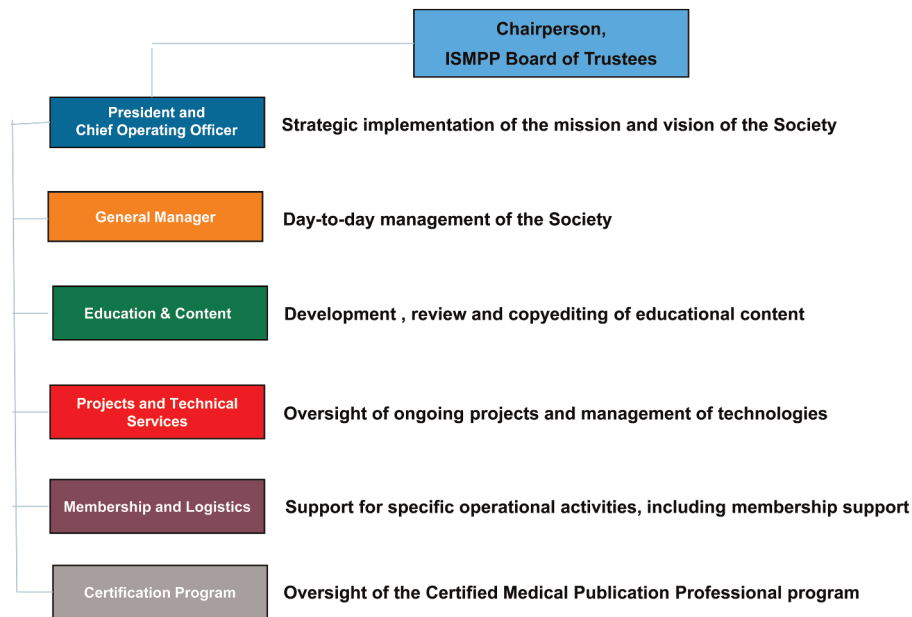


Figure 1: ISMPP organisational structure.

include the Annual and European Meetings, Good Publication Practice for Communicating company Sponsored Medical Research (GPP2), monthly ISMPP University webinars, ISMPP Educational Archives, Code of Ethics, and ISMPP's Ambassador and Research Grant initiatives. The Certified Medical Publication Professional credential, which is earned by passing a 150-item examination, provides a validated qualification of medical publication professionals' expertise and promotes integrity and excellence in the profession by demonstrating knowledge of, and encouraging adherence to, best-practice standards across the industry. New initiatives underway to further ISMPP's commitment to our shared value proposition include leading the development of Good Publication Practice 3 (GPP3), a Code of Conduct, a Publications Standards Handbook, and Asia-Pacific specific educational training, just to highlight a few.

Collaboration and leadership

While attending the September 2013 *International Congress on Peer Review and Biomedical Publication*, I was struck by changes in attitudes that had occurred since the meeting 4 years ago in Vancouver. There was more open collaboration among various stakeholders, in addition to a greater diversity in the poster and oral presentations. Although not perfect, this is hopefully one example of a more

collaborative approach to sharing information and working to bridge differences, while adding to our shared value proposition. As ISMPP continues to grow over the coming decade, it will seek to further develop its leadership position by creating unity and strength in collaboration with various organisations. This will include taking a proactive stand on key issues (e.g., Sunshine Act recommendations), further expanding our geographic footprint into Asia-Pacific and other regions, providing accessible educational platforms and tools, and doing all we can to advocate for the highest possible ethical standards in medical research and biomedical publishing.

Conclusion

While still in its formative stages, ISMPP has accomplished a tremendous amount in its first 9 years of existence. Its new organisational structure, combined with a rich resource of volunteers from its membership ranks, will be critical in collaborating with other stakeholders as a basis to move the profession forward. Equally important, ISMPP will more proactively assess and react to important issues to ensure the validity and credibility of our efforts, support and establish standards globally, and will work to further establish an aligned value proposition with all stakeholders involved in medical research, publishing, and scientific exchange.

Author information

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the strategic goals and vision of the Society. He has previously been the head of publication teams at sanofi-aventis, Boehringer Ingelheim and Celgene Corporation.

Oxford English Dictionary literally kills debate about contentious word

There can be few words in the English language that cause more discussion and anger than 'literally'. The following remarks from footballer-turned-football pundit Jamie Redknapp illustrate the issue:

*These balls now – they literally explode off your feet.
In his youth, [ex-England footballer] Michael Owen
was literally a greyhound.*

Now, I'm no football expert, but I've never heard of exploding footballs or players that used to be dogs. When Redknapp uses the word 'literally' it is to emphasise what are figurative statements. His aim in the above examples is to convey just how bouncy the new footballs are and how quick Owen was as a kid.

Use of 'literally' in this way causes annoyance in some quarters, mirth in others. I personally have always found it pretty amusing. And it's not as if it's something new, as these quotations from 19th-century literature show:

*His [...] body [was] literally worn to the bone –
Charles Dickens (Nicholas Nickleby)
The land literally flowed with milk and honey –
Louisa May Alcott (Little Women)*

Now, thanks to the Oxford English Dictionary, I no longer have any reason to smile when sports

commentators and others use the word in this way.¹ In a change that sparked outrage in the British press, the OED now includes a new definition of 'literally' as 'Used to indicate that some [...] metaphorical expression is to be taken in the strongest admissible sense'.

This is an interesting move that can be interpreted as an admission that dictionaries do not control language so much as reflect the way it is used. Although 'literally' is not really used in medical writing, its fate neatly illustrates the fluid nature of language. Medical writers need to be aware of changes in definitions, as well as the meanings of relevant new words (e.g. generalisability, stemness).

As for the 'language police', they will just have to find something else to get worked up about. Perceived misuse of the word 'like', perhaps? It's, like, so annoying.

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Selling evidence over the counter: Do community pharmacists engage with evidence-based medicine?

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Abstract

Community pharmacy has been recently criticised for selling products which do not have a rational or robust evidence base. Available evidence suggests that pharmacists understand and are willing to embrace the concepts of evidence-based medicine (EBM), but it is not often utilised in the community pharmacy setting. Community pharmacists appear to rely more on consumer feedback and personal experience than clinical trial evidence when making over-the-counter recommendations, a practice at odds with the principles of EBM. Limiting factors for the uptake of EBM include a lack of resources and time, as well as a lack of skills in appraising scientific papers. Solutions may include improving pharmacists' awareness of existing EBM information resources, improving critical appraising training, and providing information tailored to the community pharmacy environment.

Keywords: Pharmacy, Community pharmacy, Evidence-based medicine, Non-prescription drug

Traditionally, products sold over the counter (OTC) in a pharmacy may have been guided more by commercial gain than rational, evidence-based medicine (EBM). Even those products that are licensed may not have a robust evidence base for their effectiveness. Irrational combination products, cough medicines, and unproven complementary medicines line the shelves of most stores, leading some prominent promoters of good science to recently criticise pharmacy as a 'quack trade'.¹

As the role of the pharmacist evolves, it is becoming more and more imperative for the profession to distance itself from quackery and embrace EBM. This is particularly important in the face of deregulation of prescription-only medicines, the potential for self-selection of pharmacy medicines by patients,

and a general public that is increasingly willing to take responsibility for its own healthcare.²

The cornerstone of EBM is the ability to locate, appraise, understand, and communicate clinical evidence. Pharmacists often act as the front-line interface between the patient and the healthcare service and as such require the skills to translate complex statistical health information into language which patients are likely to understand and engage with.³

Opportunities for EBM in the community pharmacy

An effective OTC encounter in a pharmacy is a step-wise, logical process of elimination, using good questioning and knowledge to narrow the available products suitable for an individual patient. The first step involves the use of careful, structured questions, usually following a mnemonic (see Table 1), to establish the symptoms and check the diagnosis. Symptoms that require referral are identified and patients directed to appropriate services where required. Once the diagnosis is identified, the range of OTC products available to treat it will be borne in mind by the pharmacist. Knowledge gained from questioning about the patient's medical history and drug history is used to eliminate any products which are inappropriate for the individual patient due to cautions, contra-indications, or drug interactions. The pharmacist may then recommend a product based on a number of factors. Counselling points on how to use the product effectively and safely should then be conveyed to the patient.

As some of the most easily accessible healthcare professionals, community pharmacists often deal with patients presenting with health- and medicines-related questions, which may be prompted by sensationalist media reporting or information gathered from friends, family, or the Internet.

Table 1: Common mnemonics used in pharmacy OTC consultations¹²

| WWHAM | ASMETHOD |
|------------------------------------------|-----------------------------------------------------------------|
| Who is it for? | Age/appearance |
| What are the symptoms? | Self or someone else |
| How long have the symptoms been present? | Medication |
| Action taken | Extra medicines |
| Medication being taken | Time persisting History Other symptoms Danger symptoms |

There are therefore clear opportunities within daily community pharmacy to utilise clinical trial evidence in accordance with the principles of EBM.

The evidence for a lack of evidence

A survey conducted in 2005 amongst pharmacists from all sectors in Illinois by Burkiewicz and Zgarrick found that 90% of 323 pharmacists held positive attitudes towards EBM.⁴ In a more recent survey of community pharmacists in Northern Ireland conducted by Hanna and Hughes, 88.3% of 205 community pharmacists stated that they were familiar with the concept of evidence-based practice.² This is indicative of a profession that understands the underlying concepts of EBM.

In spite of these studies, there is an overall lack of robust evidence examining community pharmacists' attitudes and uptake of EBM, and the currently published evidence is limited by small sample sizes and methodological flaws. However, the qualitative studies which do exist offer an interesting insight into the considerations when selecting an OTC preparation.

Hanna and Hughes conducted a series of surveys into pharmacists' attitudes to OTC sales.² They found that the over-arching concern when selecting a product was patient safety, with 91.8% of pharmacists agreeing or strongly agreeing that safety was their main concern. Effectiveness of the product was of secondary interest. Pharmacists cited patient and colleague feedback, along with personal or family use, as the most common methods to determine a product's effectiveness, with clinical trial data appearing to be a less important consideration. This would seem to be at odds with the principles of EBM, and suggests that while pharmacists are broadly in favour of EBM, their ability to use it in their everyday job is limited. Over 60% of respondents agreed that evidence-based practice is more difficult for community pharmacists compared to other healthcare professionals.²

In May 2013, the consumer magazine *Which?* performed an undercover investigation of the quality of advice given in a sample of 122 community

pharmacies in the UK. The report found that unsatisfactory advice was given by pharmacy staff in 43% of visits.⁵ While this report has been widely criticised due to its small sample size,⁶ it may be indicative of a wider problem which may be improved by increased uptake of EBM. *Which?* also investigated the evidence for claims made for a variety of health-care products, and has published a list of 10 popular and widely available pharmacy products for which no good evidence of benefit exists. This includes well-known brands such as Benylin™ and Covonia™ cough medicines, Bach's Rescue Remedy™, Bio-Oil™, and Boots™ Cold and Flu Tablets.⁷

Reasons for the lack of EBM uptake

In the 2005 study by Burkiewicz and Zgarrick,⁴ 45% of all pharmacists cited lack of time as the main factor limiting their ability to practice EBM. In a community pharmacy setting, the proportion is likely to be even greater, given the fast-paced, unpredictable nature of the retail environment.⁴ Constant interruptions and juggling many tasks whilst maintaining an open, appointment-free approach to healthcare can lead to a lack of time available for the pharmacist to read and interpret clinical data.

Community pharmacies can be under-resourced to effectively practice EBM. Trusted medical information resources such as Micromedex and Medicines Complete may be too expensive for the average community pharmacy to feasibly access, and can be difficult to navigate in the community pharmacy environment. With the delivery of advanced clinical services such as Medicines Use Reviews – an initiative to improve medicines adherence in the UK by providing support to patients with long-term conditions who are taking multiple medicines⁸ – along with an ever-increasing dispensing workload, the pressures on a community pharmacist's time are vast and many.⁹

The availability of new OTC products and the deregulation of prescription-only medicines can lead to an overwhelming amount of extra training and research for a community pharmacist, on top of their usual daily workload. At present, OTC training tends to take the form of industry-sponsored training packs aimed at enabling community pharmacy staff to sell new products. In my experience, these training packs tend not to address any shortcomings in clinical evidence or proof of benefit, but instead focus more on practical selling points. Whilst they may be adequate to allow pharmacy staff to safely sell a product OTC, they do not always include enough information to allow a pharmacist to make an unbiased, evidence-based assessment of a new product. Moreover, in

Hanna and Hughes' study, only 38% of community pharmacists agreed that they knew how to perform a literature review and critically appraise research papers.² This highlights a gap in the knowledge of community pharmacists and an important training need. Whilst critical appraisal is covered in pharmacy degree courses and pre-registration training, it may not be used often enough in everyday practice to allow community pharmacists to maintain and hone their skills sufficiently.

Patients appear more likely to rely on personal experience or anecdotal evidence than robust clinical trial evidence when choosing an OTC product, and seem on the whole ambivalent about the need for evidence of effectiveness.¹⁰ This, coupled with advertising and the policy in the retail environment that the 'customer is always right', means that patients may be unresponsive to messages about lack of evidence from the pharmacist. In an Australian qualitative study, pharmacists reported that advertisements for OTC medicines opposed their professional advice, leading to a sense of disempowerment.¹¹ In the face of consistent rejection of scientific, evidence-based advice, it may be understandable that many pharmacists give up attempting to convey such information.

Solutions

Somewhat alarmingly, Hanna and Hughes² found that only 23.9% of community pharmacists in their survey were familiar with the work of the Cochrane Collaboration, one of the world's foremost independent organisations for the dissemination of information about the effects of healthcare interventions. Improving community pharmacists' awareness of (and access to) reliable sources of medicines information is crucial to improving uptake of EBM in the sector. Pharmacists may not have the time or skills to interpret clinical trial data themselves, so need to have access to robust, concise resources from organisations skilled in the interpretation of evidence. Primary care guidelines such as the Clinical Knowledge Summaries provided by NICE (the National Institute for Health and Care Excellence) in the UK and the guidelines provided by Patient.co.uk can be helpful resources for dealing with minor ailments, but there is a lack of high-quality, independent guidelines for OTC medicines.

Greater collaboration between the pharmaceutical industry and accredited pharmacy training providers may be one solution. An independent review process similar to peer review, but tailored to OTC needs, could be implemented to ensure that any potential biases in industry-sponsored training packs for

community pharmacy are reduced. The standardisation of such packs, and inclusion of information on clinical data and its limitations, may improve the ability of pharmacists to make evidence-based decisions.

Greater awareness and utilisation of medicines information services (see Box 1) amongst community pharmacists may be helpful, as these provide a rapid and efficient evidence-based enquiry answering service, allowing community pharmacists to use their time to deliver other services. Staff in medicines information centres are specially trained in the retrieval, interpretation, and appraisal of evidence and can act as a go-between to interpret clinical trial data and apply it to a clinical situation.

There is a clear need for independent training on critical thinking and appraisal skills that is tailored specifically towards community pharmacists. The ability to disseminate complex safety and effectiveness data to patients is a valuable skill that the pharmacy profession could focus on. Questions remain about how best to close the gap between patients' reliance on advertising and anecdotes and more reliable clinical trial evidence, and any future research in this area will be extremely valuable.

Box 1: Medicines information services

Medicines information services aim to support the safe and efficient use of medicines by providing evidence-based information and advice on their use. They may be publicly or privately funded. In the UK, publicly funded medicines information services are organised into a three-tier virtual network called UKMi, which ensures ready access to MI services for all National Health Service health professionals.

The core work of medicines information services is enquiry answering. Healthcare professionals, and in some cases patients, may contact the service with a query, which is then researched by medicines information staff. The staff have access to a wide range of resources, and are specially trained in the retrieval, interpretation, and appraisal of information.

Medicines information services may also provide information proactively in the form of newsletters and publications, as well as being involved in training, formulary work, and a wide range of other activities.

Selling honestly: a personal perspective

I worked as a community pharmacist for many years, and can identify with the use of patient feedback and personal use as the main means of informing OTC product selection. Bombardment with information about new products, along with the highly pressured

and stressful job of managing a pharmacy day to day, can be so overwhelming that it can be virtually impossible to keep up with emerging evidence. It becomes easier to rely on more immediate, passive methods of differentiating between products than evidence appraisal.

After moving into a job in the medicines information field, I have improved my skills in finding, appraising, and communicating complex trial information. When undertaking locum shifts in community pharmacy, I have found that this in turn improves and informs my ability to advise OTC. Having more confidence to seek out and question evidence, as well as encouraging critical thinking and evidence communication, allows me to improve an engaged patient's ability to make an informed choice. I have found patients to be variably receptive to this, with reactions ranging from gratitude, satisfaction, and engagement, through to impatience and, rarely, anger. For the most part, I have found that being honest about the lack of evidence for OTC products increases trust, as patients can see that I am not there primarily for commercial gain, but instead to provide them with good-quality health and medicines advice.

Conclusion

Community pharmacy has an inherent conflict of interest, given its situation as both a retail outlet and a professional healthcare service. Commercial interests may have traditionally outweighed the need for high-quality, evidence-based OTC advice, but a sea change is required to ensure the profession remains a respected part of the wider healthcare community. Other aspects of the healthcare system (and pharmacy) are adopting and implementing EBM, and there is an increased focus on the importance of clinical trial data in the health and popular media following the AllTrials petition (an initiative led by Ben Goldacre, and various other groups, which is calling for all past and present clinical trials to be registered and their results reported). This in turn is exposing the gap between reliable, robust evidence of benefit and how OTC products are currently being sold. Improving understanding of the importance of clinical trial data amongst community pharmacists will be a key step in converting pharmacy from a quack profession into what could more comfortably be considered 'good pharma'.

Author information

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pharmacist. She has a Master's degree in Pharmacy, as well as a Diploma in Therapeutics. She has a keen interest in scepticism in healthcare.

Good regulatory practice and the role(s) of a regulatory affairs professional

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Abstract

Good Regulatory Practice is a regulatory affairs quality standard that is based on trained people who understand their professional role and work in an environment that follows standards and processes. This article illustrates the diversity of roles represented by a regulatory affairs professional and explains the importance of focused training of personnel, and of generating departmental regulatory intelligence. Good Regulatory Practice is a prerequisite for achieving an optimal balance between regulatory requirements, anticipated target profile, and time to market.

Keywords: Good regulatory practice, Regulatory intelligence

If you are a (Drug) regulatory affairs (RA) professional, you would certainly be familiar with standards such as Good Manufacturing Practice, Good Laboratory Practice, or Good Clinical Practice. And as a person interested in medical writing, you probably consider the principles of Good Writing Practice in your daily work. But what about a quality standard within RA itself? How about establishing a Good Regulatory Practice (GRP)?

There is no officially published or legally binding GRP standard. Therefore, it is up to the individual RA department or RA professional to define what GRP means in their particular environment. My understanding from the point of view of a global pharmaceutical company is that GRP is:

- To comply with legislation, internal and external standards and policies, as well as the scientific, ethical, and administrative requirements.^{1,2}
- To fulfil the responsibilities of an RA professional.

Legislation, standards, and policies are usually well-defined and easily accessible, but the responsibilities

of an RA professional need to be correctly understood for the proper implementation of GRP.

Role of an RA professional

One of the responsibilities of an RA professional, at least in a large R&D company, is to provide strategic and technical guidance throughout the life cycle of a product (Fig. 1), right from the discovery of new molecules, via proposals for new development projects, to full product development and obtaining marketing authorisation for a new product.³ In addition, maintaining existing licences and developing existing products further is crucial to ensure the company's sales over many years until a product is eventually phased out and replaced by a newly discovered one.

One of the core activities of an RA professional is to monitor trends and changes in the regulatory environment and to keep track of the ever-changing legislation with a view on its implications on product development and maintenance.² During the development of a new product, a lot of studies are performed and heaps of data and information are generated. However, even the most scientifically complete study and the best results do not guarantee the granting of a marketing authorisation of a product if the regulatory authority is unwilling to accept the way the data are presented. The RA professional compiles all the relevant technical documents during product development and at the time of submission ensures an appropriate presentation of registration documents to the regulatory agencies. The RA professional also ensures that submission timelines are met and that questions from the regulatory agencies are addressed within the given deadlines. Thereby, the RA professional seeks an optimal partnership with the regulatory agencies to guarantee a smooth running of all registration procedures – allowing for a timely launch.

RA is increasingly becoming an important interface with almost every discipline within a

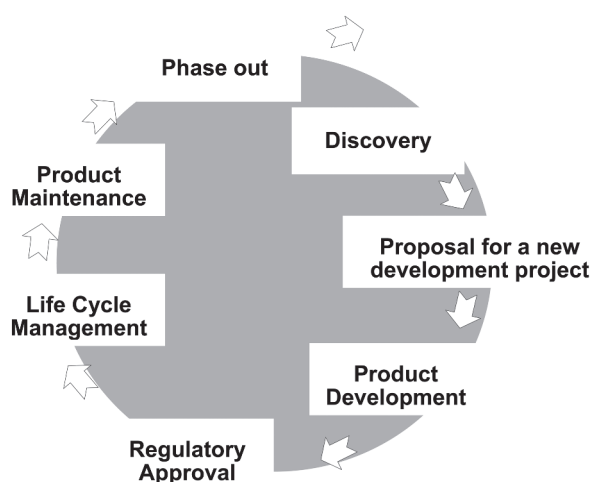


Figure 1: Product life cycle in the pharmaceutical industry.

company. It is also becoming important in external functions. The RA professionals are responsible for:

- Reviewing study protocols and final reports generated by the R&D department of the organisation, and maybe for archiving such documents.
- Accompanying the development of the active ingredient, the formulation and the analytics, as well as the preclinical and clinical development, and the finished product manufacturing.
- Being in contact with the marketing department for the life-cycle management of existing products and development of new ones.
- Being an active member of relevant industry associations.

This central function of RA is nicely illustrated in an article called ‘The Hub of the Wheel’ by Peter Lassoff.⁴ He compares RA with the hub of a big wheel, meaning that RA is not the group to say ‘No’ to new ideas as it might have been perceived in the past, but one to ‘make things happen’, to keep the wheel turning.

Regulatory intelligence

A prerequisite to be able to handle the different hats that an RA professional needs to wear is continuous training, and building up what is called regulatory intelligence. An often used definition of intelligence is ‘the transformation of information into knowledge’. Information is everywhere but knowledge is very specific to a certain task or role.⁵ This specific knowledge can be gained, for example, by a focused training of the RA professional and a targeted development of specific skills such as those in medical writing, sensitive cross-cultural

communications, or negotiations.² Such skills cannot be gained simply by attending training courses. It is crucial for junior RA staff to actively participate, ideally together with an experienced colleague, in negotiations, teleconferences, industry associations, etc. This hands-on approach is the only way to practice communication skills, to get to know people (e.g. regulators) in person, and to learn from mistakes.

Continuous communication is also very important, not only within the team but also with colleagues from the industry or directly with regulators. The RA department needs to build up experience of new staff and effectively collect know-how of experienced colleagues. There should be a system to retrospectively capture the lessons learned from past experiences – from good and bad experiences, and from the right and wrong decisions.

Good regulatory practice

On the basis of the foregoing discussion, GRP can be described as a quality system of the RA department wherein RA professionals understand their professional role and work in an environment that allows capturing of regulatory intelligence.

The fundamental aspects of any quality system are usually standardised work processes, detailed instructions, and a customised infrastructure. As GRP is not a legal prerequisite, it can be dealt with in a much more relaxed manner and tailored to suit the needs of an RA department, and the company size. The head of the RA department can define, maybe together with the whole team in case of certain issues, the details of GRP as applicable to their functions. In any case, processes should be agreed upon and documented, and should be adapted to the workflows and the organisational structure. Interfaces between functions should be identified and communication pathways at these interfaces should be organised. Furthermore, it should be verified that all systems support the processes. Systems and processes should be reviewed periodically, and where necessary, amended.

As mentioned before, all personnel in the department need to understand their role as RA professionals and to commit themselves to their functions. And, last but not least, in a department that follows GRP, all regulatory activities should support the company strategy.

Summary

To summarise, GRP is a quality standard defined by and for the RA department of a company. Its

implementation requires continuous training of RA professionals, establishment of standardised processes, and generating regulatory intelligence. GRP aims at supporting the development and licensing of safe and effective drugs that are of high quality, while keeping an optimal balance between regulatory requirements, anticipated target profile and time to market.

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Combating impact factor misuse: The San Francisco declaration on research assessment

As a measure of journal quality, the journal impact factor should not be used to assess an individual article or its authors. Indeed, the IF's creator, Eugene Garfield, strongly advises against its misuse in this way.¹ In spite of this, it is routinely used to decide who should get faculty positions at research institutions and who should be awarded research funding.

Concerned by this continuing problem, a group of journal editors and publishers met at the Annual Meeting of The American Society for Cell Biology in San Francisco in December 2012 and developed the San Francisco Declaration on Research Assessment,² a set of recommendations on the appropriate evaluation of research, including the use of impact factors.

As well as specific recommendations for funding bodies, research institutions, researchers, and publishers, the declaration includes the following general recommendation:

Do not use journal-based metrics, such as Journal Impact Factors, as a surrogate measure of the

quality of individual research articles, to assess an individual scientist's contributions, or in hiring, promotion, or funding decisions.

Launched with the backing of 82 stakeholder organisations, the declaration had at the time of writing been signed by 9305 individuals and 381 organisations. I for one am hoping it has the kind of impact its architects are presumably keen to see.

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Profile

An interview with Dr Gustavo A Silva on the concept of public health in medical writing and translation

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We often tend to consider the different branches of medical translation as unique islands of knowledge. We may imagine translators specialising in single areas such as oncology, ophthalmology, gynaecology, and so on. Nevertheless, there are indeed other fields of medical translation that may require a much broader knowledge base and training, such as translation related to public health.

Not many translators have a better understanding of these differences than Dr Gustavo A. Silva. He is one of the founding members of the International Association of Translators and Editors in Medicine and Allied Sciences (Tremédica). He was also head of the Translation Services Department of the Pan American Health Organization (PAHO) in Washington, DC for several years. He is currently working as a translator and reviser at the Spanish Translation Unit of the World Health Organization (WHO) in Geneva, Switzerland.

Dr Silva has kindly agreed to answer a few questions for Medical Writing (MEW).

Medical Writing (MEW): What exactly is 'public health'?

Dr Gustavo A. Silva (G.A.S.): You can define it by comparison: medicine deals with individuals and is more focused on disease; by contrast, public health deals with populations and is based on health promotion, disease prevention, and rehabilitation.

MEW: Which other areas does public health include?

G.A.S.: If you think of public health as a field of professional practice, it covers a host of other scientific disciplines such as medicine and all its specialties and paramedical careers (nursing, psychology), as well as epidemiology, veterinary medicine, biostatistics, demography, ecology, sanitary engineering, sociology, economics, or actuary, to name a few.

MEW: Is translation of public health texts any different from translation of medical texts?

G.A.S.: It is very different since medicine only covers a part of what public health is all about. Having said that, a medical background helps a lot in understanding the nuances of public health texts. Overall, these texts usually do not go into great medical details; instead they deal with issues about epidemiology, preventive and community

medicine, development, sociology, and economy. After all, collective health is closely linked with the social and economic conditions in which human populations live. That is why public health is mostly a duty for government.

MEW: Are organisations such as the World Health Organization (WHO) and the Pan American Health Organization (PAHO) actually dictating our writing rules and terminology or obeying international linguistic standards set by others?

G.A.S.: Not at all. The main role of both international organisations is offering technical, regulatory and policy guidance to their Member States (represented by the national ministries of health) so that they can deal with public health issues. For instance, about issues such as child immunisation schedules, control of outbreaks and epidemics, essential drugs, training and distribution of health professionals, eradication of diseases (e.g. smallpox, poliomyelitis, and measles), environmental health, and many other.

WHO does have a terminological duty in terms of the INN (International Non-proprietary Names)? This is a list of recommended drug names in the six official languages of the Organization (Arabic, Chinese, English, French, Russian, and Spanish) plus Latin. Its purpose is to identify a single name for each selected drug in order to allow a common understanding since many drugs have different names in different countries even in the same language. A typical example would be paracetamol (an INN), a drug known as acetaminophen in the United States and elsewhere. The use of INNs by national health ministries facilitates communication among the countries; besides, these names are always used in all official documents of WHO and PAHO. In addition, WHO produces a 'family' of nomenclatures, namely the International Classification of Diseases (ICD), which is 'the standard diagnostic tool for epidemiology, health management and clinical purposes. This includes the analysis of the general health situation of population groups. It is used to monitor the incidence and prevalence of diseases and other health problems'.¹ It assigns each disease a unique alpha-numeric code that allows comparisons for statistical purposes. 'It

is used to classify diseases and other health problems recorded on many types of health and vital records including death certificates and health records. In addition to enabling the storage and retrieval of diagnostic information for clinical, epidemiological, and quality purposes, these records also provide the basis for the compilation of national mortality and morbidity statistics by WHO Member States'.¹

In other words, it does not matter whether we call the disease 'liver cancer', 'hepatic cancer', or 'cancer of the liver', we will always be able to recognise it by the code assigned in the ICD.

To conclude, translation in public health is an extremely broad field of specialisation and Dr Gustavo A. Silva, having such a wide expertise, has guided and inspired hundreds of translators and writers in Spanish all over the world.

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PubMed vs. Google Scholar

I use PubMed to retrieve medical literature. I always have. But should I?

Researchers in Canada recently compared the abilities of PubMed and Google Scholar to find relevant research articles.¹ In an elegantly designed study, Shariff *et al.* used 100 systematic reviews in the field of nephrology to derive 100 research questions (one per review). They then presented these questions to practising nephrologists and asked them for the search terms they would use to find literature to answer them. Finally, using these search terms the researchers searched PubMed and Google Scholar for relevant articles – defined as the 1574 articles cited in total in the 100 systemic reviews.

While PubMed and Google Scholar returned similar overall numbers of relevant articles, Google Scholar returned a greater overall number of articles (relevant plus irrelevant). The proportion of relevant articles was thus lower for Google Scholar than for PubMed. On the other hand, Google Scholar returned a greater number of articles for which the full text was available free of charge.¹

Intriguingly, the results were very different when the analysis was limited to the first 40 articles returned – the maximum number of citations 80% of nephrologists reported scanning for relevance in a previous study.² When this limit was imposed, Google Scholar retrieved twice as many relevant articles as PubMed, as well as three times as many relevant articles with free full text.¹

Importantly, PubMed and Google Scholar had similar coverage of relevant articles, containing 80 and 83% of them in their respective databases.

So, is Google Scholar better than PubMed for retrieving relevant medical literature? Previous comparisons of the two in other fields – including sarcoma³ and respiratory care⁴ – do not reveal a consensus. I guess the answer depends on a number of factors, including how many citations you are willing to trawl through and the importance of obtaining free content.

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AuthorAID: An international service and chance to serve

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Abstract

Medical and other researchers in developing countries conduct much valuable research. Yet difficulties in writing and publication often prevent this research from being widely known. AuthorAID (<http://www.authoraid.info>), a project of the International Network for the Availability of Scientific Publications (INASP), was established in 2007 to help address this problem. Aspects of AuthorAID include on-site and online instruction, a resource library, a blog, an e-mail discussion list, small grants, and mentorship. Medical writers can contribute to AuthorAID by volunteering as mentors and assisting in other ways. In addition, AuthorAID resources can help medical writers and the researchers worldwide with whom they work.

Keywords: Capacity building, Developing countries, Mentorship, Publishing, Research, Writing

Medical and other research from developing countries often remains largely unknown. One main reason is that many researchers in developing countries lack training in research communication, lack familiarity with publication and presentation procedures, and lack confidence in their ability to publish and present. The AuthorAID project of the International Network for the Availability of Scientific Publications (INASP) is designed mainly to help researchers overcome these barriers and thus to build capacity in communicating research.

The AuthorAID concept originated about a decade ago when Phyllis Freeman and Anthony Robbins, soon to become editors of the *Journal of Public Health Policy*, recognised such barriers and sought a way to give developing-country researchers guidance on writing and publishing. Over the years, others had given medical and public-health researchers in developing countries a variety of workshops and courses

on scientific communication. Freeman and Robbins, however, envisioned supplying such guidance largely through the Internet, which was increasingly accessible in developing countries. In particular, they viewed the Internet as a vehicle for one-on-one mentorship in scientific writing.

In 2007, INASP, a charity that focuses on supporting global research communication, established what has become the most extensive and visible of the projects using the generic designation AuthorAID. AuthorAID projects not associated with INASP have included AuthorAID in the Eastern Mediterranean and the AuthorAID project of the International Society for Environmental Epidemiology. In keeping with common usage, this article will refer to AuthorAID at INASP simply as AuthorAID.

AuthorAID (<http://www.authoraid.info>) is intended to serve developing-country researchers in all disciplines and geographic regions; however, medical researchers and professional medical communicators constitute sizeable parts of the AuthorAID community, as they do in research and scientific communication as a whole. Funding for AuthorAID has come mainly from the UK Department for International Development (DFID) and the Swedish International Development Cooperation Agency (Sida). AuthorAID has evolved to include several main components: on-site and online instruction, a resource library, a blog, an e-mail discussion list, small grants, and mentorship. Overall direction of AuthorAID is provided by Julie Walker, who manages the publishing support activities at INASP. The other main members of the core team are INASP Associates Ravi Murugesan (a consultant in India) and I, who each devote part of our time to the project. A variety of volunteers and others contribute to specific aspects, for example by providing mentorship or translating AuthorAID materials.

AuthorAID components

On-site and online instruction

Starting in 2008, AuthorAID has held several research-communication workshops per year in developing countries. Researchers from the host country and sometimes elsewhere in the region attend. INASP's local coordinators in its partner countries have been of great help in arranging the workshops. Among countries where one or more AuthorAID workshops have occurred are Bangladesh, Colombia, Ethiopia, Ghana, Kenya, Nepal, Nicaragua, Pakistan, Rwanda, Sri Lanka, and Tanzania. Some workshops have been held jointly with partners, such as the International Foundation for Science and the Pan Africa Chemistry Network, or have occurred in conjunction with conferences.

Typically, AuthorAID workshops last 2–5 days and include both lectures, which are intended to provide core content, and small-group activities, which are intended to help participants assimilate the content and start applying it to their own work. Previous workshops have focused mainly on how to write and publish journal articles; topics of lectures have included approaching a writing project, the content and organisation of the parts of a scientific paper, and the publication process. Workshops commonly also include material on related topics, such as preparing poster presentations, giving oral presentations, and writing grant proposals; some workshops have dealt mainly with writing grant proposals. In addition, the workshops generally include presentations on effective scientific writing in English and on resources for further use.

In addition to a workshop leader from AuthorAID, each workshop generally has one or more local co-facilitators. Among other things, these co-facilitators help relate the workshop content to the local context and learn to give such workshops themselves.

All attendees are encouraged to share the learning with their colleagues and students. Increasingly, AuthorAID workshops have been followed by train-the-trainer workshops to help in this regard. Several co-facilitators and attendees have gone on to give AuthorAID workshops, and others also have shared content.

As well as imparting knowledge, skills, and confidence, the workshops help publicise AuthorAID, serve as direct opportunity to assess needs, and offer chances to test teaching materials. A limitation, however, is that the workshops reach relatively few researchers per year and that researchers in some high-priority countries lack the opportunity to

attend the workshops. To help extend the workshops' reach, AuthorAID has begun giving online courses based on the workshops. The first online course, which was on research writing, was pilot tested in autumn 2011 with participants at the National University of Rwanda. This course is now run two or three times per year. An online course on grant proposal writing was given for the first time in summer 2013.

The AuthorAID online courses, which run for about 5 weeks, use the Moodle platform and are moderated. The number of participants is limited, in order to permit ample interaction and feedback. In some cases, there is a call for applications; in others, candidates meeting given criteria are invited to participate. A specialised version of the research writing course, on writing about research in environmental health, has been held in collaboration with the Blacksmith Institute, an international charity concerned with alleviating pollution problems in low- and middle-income countries. The first offering of the grant proposal-writing course was for women researchers who had applied for AuthorAID grants. Participants in the online courses both complete lessons and participate in a discussion forum; those who satisfactorily complete all assignments, as almost all do, receive a certificate at the end of the course.

For sustainability, AuthorAID is now emphasising the embedding of instruction in developing countries. In other words, it has begun working intensively to prepare researchers and others in such countries to provide research-communication instruction themselves. The first country to be the focus for this embedding is Sri Lanka. Efforts to embed instruction there began in the first half of 2013 with a workshop on teaching research writing online and a more general workshop on teaching research communication. The embedding initiative also will include mentorship and other guidance in Sri Lanka and elsewhere.

The AuthorAID online community

The AuthorAID community extends far beyond the researchers served by workshops and courses. In particular, AuthorAID offers a variety of online resources, including a resource library, a blog, and an e-mail discussion list. A Spanish-language version of the AuthorAID website debuted in June 2011.

As of October 2013, the AuthorAID resource library contained more than 600 items. Among them are presentations (largely from AuthorAID workshops), articles and links thereto, and links to relevant websites. The library includes translations

of AuthorAID presentations into Arabic, Chinese, French, Portuguese, Spanish, and Vietnamese; translations into additional languages are being sought. The resource library is searchable by subject area, language, and medium (e.g., article, presentation, video, or weblink).

The AuthorAID blog began in 2007, became weekly in 2008, and now contains three posts per week: a general post on a research-communication topic, a tip of the week, and a resource-of-the-week post. Many of the general posts provide advice on communicating research. Others report on AuthorAID activities, introduce AuthorAID opportunities, or present highlights of relevant conferences. Increasingly, the posts are by researchers in developing countries. All past blog posts are archived in the news section of the AuthorAID website.

The resource library and blog posts are openly accessible, without registration. However, users can benefit from registering on the AuthorAID website. Through registration, one can sign up for AuthorAID's e-mail discussion list, through which researchers can request advice, seek resources, and share information. Registrants also can sign up to be notified by e-mail when new AuthorAID blog posts appear. In addition, registration lets one contact other AuthorAID registrants through the AuthorAID website, for example to obtain a mentor or mentee or to ask questions.

The number of AuthorAID registrants has steadily increased over the years, and as of October 2013, there were more than 7600 registrants, from 183 countries. On registration through the AuthorAID website, each registrant identifies from a standardised list one or more subject areas in which he or she works. Sizeable proportions identify medically related subject areas. As of October 2013, about 1500 registrants had chosen 'Biological Sciences', 1300 'Medicine and Dentistry', 1000 'Subjects Allied to Medicine', and 700 'Veterinary Sciences, Agriculture and Related Subjects'.

During the year from August 2012 through July 2013, there were nearly 64 000 visits to the AuthorAID website, from nearly 34 000 unique visitors. Nearly half of the visits were from returning visitors. The 10 countries from which the most visits came were, in descending order, the United States, India, Nigeria, the United Kingdom, Kenya, Bangladesh, Uganda, Nepal, Pakistan, and Ethiopia. Other sources of at least 1000 visits during the year were Mexico, Canada, Sri Lanka, China, and South Africa.

Small grants

Since 2011, AuthorAID has periodically offered small grants. They are of two types: workshop

grants (to give workshops on research communication) and travel grants (to give presentations accepted by conferences). The workshops can employ AuthorAID materials but are not required to do so. The grants are limited to applicants from countries specified as high priority by INASP and its funders; as of mid-2013, eligible countries were Bangladesh, Bolivia, Cuba, Ecuador, El Salvador, Ethiopia, Ghana, Honduras, Kenya, Lesotho, Madagascar, Malawi, Mozambique, Nepal, Nicaragua, Pakistan, Rwanda, Sierra Leone, Sri Lanka, Tanzania, Uganda, Vietnam, Zambia, and Zimbabwe. Competition is stiff, with dozens of applicants for the few grants in each category.

Mentorship

Mentoring was a distinguishing feature of the initial vision for AuthorAID, and it remains an important part of the array of activities. Prospective mentors and mentees can identify and contact each other through the AuthorAID website. In addition, members of the AuthorAID team have helped match prospective mentors and mentees. Once a mentor and mentee decide to work together, they can continue contact through the AuthorAID website or interact through one or more other media, such as e-mail, Skype, and (where feasible) face-to-face meetings. The mentoring relationships can range widely in content and duration. Commonly, the activities centre on helping the mentee write or revise a paper for submission to a journal.

Mentoring resources on the AuthorAID website include an explanation in the form of a comic strip ('The Mentoring Journey'), a brief guide for mentors, and a mentorship learning agreement that mentors and mentees are encouraged to complete and submit. Because the reporting of AuthorAID mentoring relationships is voluntary, and because privacy issues have limited the monitoring of mentorship activities, only limited information currently is available on the scope and outcome of mentorship. Case studies and individual reports indicate that some AuthorAID mentoring relationships have been rewarding and productive indeed. Efforts are now under way to characterise more extensively the mentorship activity that has occurred and to build on it.

AuthorAID and medical writers: Giving and gaining

One thing that does seem clear is that unmet demand for mentors exists. As of October 2013, about 5500 AuthorAID website registrants had indicated that they felt they could benefit from

mentorship, but only about 900 had indicated that they were interested in becoming mentors; for registrants designating the field 'Medicine and Dentistry', the respective figures were about 1000 and about 100. Anecdotal evidence suggests that professional medical writers and editors have been some of the most committed and productive mentors. Serving as an AuthorAID mentor is a chance for medical writers and other medical communicators to provide substantial, and satisfying, international service. It can also be a way for early career medical writers to gain experience, broaden their horizons, and build their curricula vitae.

Medical writers wishing to be of international service also can contribute their expertise to AuthorAID in other valuable ways, some of which need not be very time-consuming. For example, the AuthorAID resource library always is seeking resources on research communication, including ones on medical writing. Suggestions of existing resources, and offers to develop new ones, are gratefully received. Medical writers proficient in languages other than English can help by preparing translations of AuthorAID materials to include on the website. Medical writers can enrich the AuthorAID blog by suggesting topics, posting comments, and offering to write guest posts. Those who subscribe to the AuthorAID discussion list have frequent chances to share their knowledge. On occasion, opportunities may exist for medical writers to help facilitate AuthorAID workshops or online courses. All such contributions are deeply appreciated. Medical writers interested in helping in these or other ways are invited to contact AuthorAID at authoraid@inasp.info to explore possibilities.

Likewise, AuthorAID materials can be resources for medical writers to use and share. The resource-of-the-week post can alert medical writers of new or existing resources to use themselves or to suggest to researchers with whom they work. Similarly, the AuthorAID resource library contains much that medical writers can pass on to researchers wishing to refine their communication skills. Medical writers whose activities include providing workshops or other instruction can employ or

adapt teaching materials in the resource library, and junior medical writers may find materials in the resource library helpful in learning the craft. Similarly, the AuthorAID news archive – which as of autumn 2013 contained more than 600 blog posts – has much that medical writers can use themselves or supply to others. Searching the AuthorAID website can reveal materials on a wide range of topics in or related to medical writing. Although AuthorAID was developed to help researchers in developing countries, much of the content can aid individuals anywhere who are interested in skilful research communication.

If you already are involved in AuthorAID, we thank you for your participation and hope you will remain active or become more so. If you are not involved, we would very much welcome your participation. For both medical writers and the researchers they work with, AuthorAID can be both a service and a valuable chance to serve.

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India as a hub for ethical and evidence-based medical communications

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Abstract

Ethical and evidence-based medical communications are gaining increasing importance in emerging pharmaceutical markets, outside of North America and Western Europe. In large pharmaceutical companies resources are limited, and small and mid-sized companies may lack the infrastructure and technical knowhow to provide these services for emerging markets. Required skills and competencies include scientific knowledge, communication skills, analytical skills, and awareness of global as well as regional legal and ethical requirements for pharmaceutical product information. India is already a preferred destination for outsourcing medical writing for regulatory documents and has the potential to become a 'hub' for medical communications services. Skilled medical writers in India can help global pharmaceutical companies to reach out to healthcare professionals and patients in the emerging markets with evidence-based information related to their products.

Keywords: Medical communications, Emerging markets, India, Medical information, Medical writers, Evidence-based

Emerging markets and the pharmaceutical industry

The focus of the pharmaceutical industry is steadily shifting towards the emerging markets of India, China, South East Asia, Latin America, Africa, Russia, Eastern Europe, and the middle-eastern countries.¹ These markets, with their growing economies, large patient pools, increasing middle-class populations, expanding healthcare coverage (governmental and personal) and improving healthcare facilities are increasingly attractive to global pharmaceutical companies. The stagnation of developed markets (North America, Western Europe, and

Japan), due to expiring patents and generic competition, together with the challenges of new drug innovation, is also pushing the pharmaceutical companies (both big and small) towards the emerging economies. It is expected that, despite the lower spending capacity of patients, the emerging markets will contribute 30% of the global spend on medicines by 2016, primarily due to larger patient numbers.²

As a result, most innovator companies have established dedicated units for research and development, sales, marketing, and medical affairs in some of the countries that represent emerging markets. Alternatively these companies may have partnerships with contract research organisations (CROs) or other specialist outsourcing organisations within such countries. Pharmaceutical companies are positioning themselves in the emerging markets by marketing their established products, which have gone off-patent, at lower prices or through the acquisition of existing generic brands in these markets. Several established and not-so-old products (new to these markets) are being launched every year. These product launches require medical communications and medical information support. Additionally, clinical and observational studies and medical surveys are being undertaken in many of these countries with the prospect of a large number of journal articles that need to be drafted. Delivery of this new medical communication requires effective compliance standards, operating procedures, guidelines, and work instructions specific to the emerging markets.

Scope of medico-marketing and medical information services for emerging markets

Ethical and evidence-based communication for promotional (medico-marketing) and non-promotional

(medical information services, publications) material is needed to support the effective and successful launch of established or new products in emerging markets and to report clinical trials in peer-reviewed international journals. To launch new products in new territories, companies may use either a 'group of countries at the same time' or a 'one country at a time' approach. In either case, they need to create materials to inform and educate local healthcare professionals (HCPs) about the key features, benefits, and risks of the products specifically with reference to the local or regional population. This information may be gathered from local clinical or observational studies and medical surveys, and can be communicated through product monographs, brochures, slide kits, leave-behind literature, sales aids, continuous medical education (CME) slides, training modules, key opinion leader documents, conference posters, abstracts, and journal articles.

Following the launch of a product, pharmaceutical companies require a dedicated team of medical information scientists to answer unsolicited inquiries from HCPs through standardised or customised responses to inquiries about labelled or off-label use,³ efficacy and safety of the product. This requires a strategy-based literature search in peer-reviewed literature databases⁴ to identify relevant articles and create customised responses. Appropriate medical communication is based on fit-for-purpose material customised both to the scientific and ethical positioning of the product and to the local requirements.

Challenges faced by pharmaceutical companies in emerging markets

Major challenges faced by pharmaceutical companies while catering to the emerging markets are:

- Diversity in demography, culture, and language
- Variations in local government health policies and regulations
- Differences in medical infrastructure (healthcare facilities, insurance policies) in different countries
- Paucity of local staff with up-to-date domain knowledge
- Gaps in infrastructure and technological support
- Lack of knowledge of disease profiles of the population

There is also competition between innovators amongst themselves, and between innovators and

generic companies for a share of the market. Pharmaceutical companies with no previous experience in these markets need to understand the business and healthcare requirements of each country. Large pharmaceutical companies have established marketing and sales departments in many emerging countries but these may not be adequately staffed and the existing staff may also be involved in other essential activities. Medium-sized and small companies face additional challenges since they may not wish to invest in building a captive operation with a fairly comprehensive skill set in these countries. Pharmaceutical companies are trying to find ways to reduce their marketing expenditure. One useful approach is to create a central hub (a 'centre of excellence') for medical communications to produce a repository of common material for all products and to disseminate the material across all markets, with customisation for local marketing needs (e.g. translation).

'Hub in India' model for emerging markets

In India, medical writing started in the late nineties against the backdrop of economic liberalisation, the boom in information technology and potential for growth in the field of clinical research services.⁵ This was helped by English being one of the official languages and the only language of science in India.⁶ These factors, along with the cost-effectiveness of services delivered from India, encouraged several pharmaceutical companies to open their first offices here (e.g. Pfizer, Novartis, Sanofi Aventis, GSK). CROs, IT-based business process outsourcing organisations, medical communications agencies, and specialised service providers also followed.⁷ At this juncture, India did not have its own innovator products and the drug regulatory body of India was evolving. Indian companies initially contributed to the fields of medical communications and health journalism. They increased their presence by drafting peer-reviewed journal articles and then entered the field of regulatory writing (e.g. clinical study reports and other clinical trial-related documents and aggregate safety reports for post-marketed products) for innovator companies, based on data that were primarily from the developed world. In the initial years Indian outsourcing companies lacked adequate experienced personnel and training programs, and showed a lack of clarity and perspective among medical writers.

Over the past few years, however, Indian companies have increased their status as a preferred destination for all categories of medical writing, along

with related activities (such as biostatistics and drug safety).⁸ Accurate estimates of the scope and volume of medical writing done from India are not available, but several hundred medical writers are now based in India. These writers produce substantial numbers of regulatory, clinical, and scientific trial reports and post-marketing documents both for innovator and generic drugs, and for all the developed markets. Indian medical writers have more recently entered the fields of medical information, CME, product labelling, pharmaceutical research analytics, and health economics.

A survey of Indian medical writers (49 respondents; 2008) provides preliminary information on educational qualifications and job profiles of medical writers in India.⁹ The recently formed All India Medical Writers Association accounts for about 250 registered medical writers from all over the country.⁸ However, accurate information is not yet available about the number of medical writers in India, their distribution in full-time jobs versus freelancing, their engagement in regulatory, clinical, or medical domains, their qualifications and experience or their career progression. Another survey of medical writers in India is needed to provide insight into some of these aspects.

In the past few years, many Indian and international professionals with higher education and work experience from North America or Europe have been returning to India or joining firms based in India, and are thus contributing to the development of specialised domains.¹⁰ Collaborations and professional networks with such individuals are creating stronger bridges between the medical writing community in India and those in other countries.

In addition, medical writers in India are learning from and working closely with their international colleagues, and are instrumental in timely submissions of regulatory documents to the FDA, EMEA, and other regulatory agencies. They are part of international medical communications teams and participate in writing manuscripts and other clinical documents mostly for North American and European markets. Of late, generic companies, with a bigger focus on developed markets, are also bringing their writing projects to Indian writers.

Both promotional and non-promotional medical communications in emerging markets require significant background work to identify, analyse, and present health-related data in local populations. This involves collecting epidemiological data for different diseases in emerging markets to determine whether the needs of the local population differ

from those of the established markets, collecting information about local regulatory requirements and health economics, and finding innovative yet simple and cost effective ways to reach HCPs and patients. Medical communications demand strong engagement of medical writers with HCPs from different countries working in a range of settings (e.g. hospitals, private clinics). Medical information services require high-quality standards because even small errors could have serious consequences for patients. Indian medical writers can play an important role in providing medical information and communications support because of their medical/scientific knowledge, analytical skills, experience with literature databases, exposure to data management systems, and global experience. Their experience of working with the most mature regulatory bodies of the world has assisted the development of appropriate and efficient quality control and quality assurance strategies.

Writers in India understand the needs of non-native English-speaking countries. Due to the global influence and awareness of opportunities, many Indians also learn other languages, including those of some of the emerging market countries. Thus translations of English documents into local languages of emerging nations may also be a future area of opportunity for India. They have experience of working in a range of environments (pharmaceutical companies or specialist service providers) and have acquired expertise in different types of medical writing through job transitions. In the early part of their careers, medical writers in India typically start with service provider organisations on specific and well-defined writing assignments or preparing documents with stringent style guides and time lines through collation of contributions from several clinical and regulatory personnel from pharmaceutical companies. The complexity, quality, and variety of medical writing in India have consistently increased.

Conclusion

The central hub model is ideal for the medical communications documents that are the subject of this article. Tremendous synergies can be realised by preparing common material that can be customised for local consumption. Considering the progress made and the experience gained by medical writers in India, the pharmaceutical industry may strongly consider the 'hub in India' model for reaching out to HCPs and patients in emerging markets with information about clinical trials and information required for product launches. Over the last decade medical writers in India have developed

the capability to meet this challenge through their training and work experience. They can add value in reaching out to emerging markets through their knowledge of the culture and infrastructure of such markets.

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Providing value for medicines in older people

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Abstract

The global population is ageing, but inequalities remain in older people's access to treatment, especially people 75 years of age and older. These people receive less frequent interventions and lower quality medical treatment than their younger counterparts. Explanations for these inequalities include ageism, a lack of testing of medicines in older people, unclear diagnoses resulting in hesitancy to institute treatment, polypharmacy, and a general lack of concordance and compliance. In Europe, responsibility for improving this situation lies with the pharmaceutical industry, the European Medicines Agency, national regulatory agencies, prescribers, dispensing pharmacists, and the patients or consumers themselves. Clinical trial and health economic data are needed to assure the effective and safe treatment of older people.

Keywords: Elderly, Ageism, Special populations, Pharmacovigilance, Safety

Owing to declining global birth rates and increased longevity, the global population is ageing. In 2000, one in nine people was 60 years or over, but by 2050, this figure is expected to rise to one in five.¹ This has and will continue to have an large impact on healthcare.

The European Review on the Social Determinants of Health and the Health Divide, Older People 2012 indicates that although the needs for healthcare services increase with age, older people – especially those aged 75 years and over – receive less and lower quality treatment.² They also receive less expensive treatments than younger people for the same illness. Some studies indicate that the number of prescriptions of recently introduced, non-substitutable pharmaceuticals tend to be proportionally lower in the younger part of the oldest age groups. Also, diagnostic procedures are often less intensively used among older people than

younger adults. Mammography is an example, partly because this diagnostic procedure has not been adequately tested in older women.

Furthermore, the review indicates that older people are less likely to be prescribed and receive target doses of relevant medications. For example, several country-specific studies have shown that older people were less likely to receive antihypertensive drugs. The number of prescriptions of angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, and anticoagulants declined sharply in the 75- to 85-year age group. In addition, some studies have shown that older people are less likely to receive statins, angiotensin-converting enzyme inhibitors, and calcium channel blockers. In general, the review showed that for women with breast cancer, less treatment was administered to older women than to younger women.

Finally, treatment of older people has been shown to be symptom-based rather than diagnosis-based.³

Factors accounting for inadequate or inappropriate drug treatment of older people

Many factors contribute to inadequate or inappropriate drug treatment of older people, including ageism; a lack of clinical data, proper diagnosis as a basis for treatment, concordance, and compliance; and polypharmacy.

Ageism

Ageism was defined in 1969 by Larkin and Butler as a type of discrimination that involves prejudice against people based upon their age.⁴ Similar to racism and sexism, ageism involves holding negative stereotypes about people. This is not limited to older people; adolescents and children can also be discriminated against because of their age.

Ageism, like racism and sexism, is difficult to combat. One step towards improving the situation is the approval of the proposed 2008 EU Directive

against age discrimination,⁵ which not only covers work and education but also access to goods and services, healthcare, and social welfare. Approving the EU Directive will convey the message that it is not acceptable to deny older people the healthcare they need because of their chronological age and that the importance of the benefit of a treatment must be weighed against the risks for the individual patient in all people, regardless of age. The proposed directive is currently being considered by the Council of the EU.

On an individual level, people should also react and act when encountering ageism in all its forms. It is unacceptable to be denied a treatment, a subscription for a mobile phone, or a bank loan just because of chronological age.

Lack of clinical data in older people

Unlike medicines for children,⁶ specific legal requirements do not exist for the development of medicines for use by older patients. The EMA has reacted to this and has prepared a document on quality aspects of medicines for older people.⁷ Older people represent a heterogeneous population who react to medicines in different ways. Some may have difficulties in taking their medicines, for example, difficulties swallowing tablets, opening packages, or reading the patient information leaflet. In addition, many older patients have comorbidities, and physical changes such as renal or hepatic impairment or altered gastrointestinal motility are important when evaluating the benefit-risk profile of a medicine. The fact that many older patients use several medicines at the same time makes it difficult to design clinical trials where resulting data will not be confounded by polypharmacy. Ethical aspects must also be considered, including how to best obtain informed consent from persons who suffer from dementia and how to test new medicines in fragile individuals.

Lack of a proper diagnosis as a basis for treatment

Lack of a proper diagnosis as a basis for treatment contributes to inappropriate treatment of older people. For example, a survey by Boëthius and Westerholm⁸ found that one-fifth of patients treated with hypnotics for insomnia were inappropriately receiving the medication because they had originally asked for it to treat feelings of loneliness even though they did not articulate this to the prescribing physician.

Lack of concordance

Concordance is defined as an agreement reached by negotiation between a patient and a healthcare

professional that respects the beliefs and wishes of the patient regarding whether, when and how medicines are to be taken.⁹ This term and its practical effects have been questioned. Some patients want clear straightforward advice, while others want to discuss the pros and cons of a treatment. However, concordance should be sought for patients who show a need and want such discussions.

Lack of compliance

Lack of compliance is very common. It can be remedied by using various compliance aids such as tablet dosing boxes, watch alarms, and medication reminder charts.

Polypharmacy

Polypharmacy means that a patient is being treated with many different medicines. In Sweden, in 2011, people 75 years and over were treated with an average of five medicines at the same time, which is regarded as polypharmacy.¹⁰ In the same year, 11% of all people 75 years and older were treated with 10 or more medicines at the same time, and 10% were being prescribed medicines that should be avoided in older persons.¹¹ Polypharmacy is known to be the main risks for adverse drug reactions in older people.^{10,12,13} This might be due to the patient having many health problems that require medication. Other contributing factors include multiple prescribers for the same patient, different platforms for maintaining medical records, multiple names for the same medicine, and lack of consultation time for the patient.

Improving the treatment of older people

The responsibility for improving the treatment of older people with medicines lies with the pharmaceutical industry and, in Europe, the EMA, as well as prescribers, pharmacists, and even patients themselves.

The pharmaceutical industry

The pharmaceutical industry plays an important role in that all medicines, old and new, should be tested in the age groups in which the medicines will be prescribed. The overall cost of medicines is increasing, and as more new expensive medicines enter the market, both the economic and clinical value of medications need to be documented. In addition, to help elderly patients, comprehensive patient information leaflets should be produced in large print, and advertising should follow the codes of ethics set out by the WHO and national

rules. Additionally, during the life cycle of medicines, the benefit–risk ratio in elderly patients should be re-evaluated.

The EMA

In Europe, the EMA is responsible for following the development of emerging medicines via clinical trials and through the on-going evaluation of licensed medicines. This includes evaluation of whether the medicine can be safely and effectively used in the patient groups to which the medicine is thought to be prescribed – in this instance, older people. The EMA has developed a geriatric medicines strategy⁷ and established an expert group for the evaluation of medicines for older people (The Committee for Medical Products for Human Use Advisory Group on Geriatrics). Via this body, the EMA will ensure that medicines used by geriatric patients are of high quality and appropriately researched and evaluated throughout their life cycles. The EMA is also working on improving the availability of information on the use of medicines for older people, thereby assisting with informed prescribing (Product Information and European Public Assessment Reports). The EMA also interacts with stakeholders via the Patients and Consumers Working Party. Finally, the EMA is responsible for the Pharmacovigilance Programme, which includes reporting adverse reactions and medication errors.¹⁴

Medication errors are the single most common preventable cause of adverse events in medical practice. Thus, reporting of medication errors is a new and very important task in evaluating the safety of medicines because. The World Alliance for Patient Safety has estimated the annual cost of medication errors to be between €4.5 and 21.8 billion per year.¹³ An estimated 19–56% of all adverse drug events among hospital patients are caused by medication errors that could have been prevented. New pharmacovigilance legislation that came into force in July 2012 acknowledges medication errors as a major public health burden. The legislation explicitly foresees reporting of suspected adverse reactions associated with medication errors.

Prescribers

Prescribers must base their prescribing on knowledge about the causes of the patient's health problems, the benefit–risk profile of the medicine, and the other medicines that the patient is prescribed. To avoid errors, one physician should be responsible for the medication of the patient and should coordinate prescriptions given by other physicians. The physician needs the time to inform the patient about the diagnosis and to discuss the medication

with them. Finally, the physician should assess the patient's reactions to treatment, evaluate them, and if necessary, adapt therapy, also known as 'therapeutic auditing'.

Pharmacists

Pharmacists are responsible for checking that the correct medicine is delivered. They should signal the prescriber when medicines not to be used by older people have been prescribed and when interactions might occur. Moreover, the pharmacist should allow time for the patient to ask questions.

Patients: The Swedish example

In Sweden, a project was started in 1999 that has now developed into the 'Master your drugs' campaign. The two major organisations for older people, the National Pensioners' Organisation and the Swedish Association for Senior Citizens, comprising some 700 000 members, are responsible for this activity.

Seminars and study circles about medicines are organised for the members in which they are shown how to weigh benefits and risks. The members are given a list of questions to ask their doctor, including:

- Why are you prescribing this medicine for me?
- For how long should I take it?
- What are the most common adverse effects?
- Can I use it together with other medicines and herbal products that I take?
- Is it good for me to take this medicine, bearing in mind how old I am?
- Has this medicine been tested in older people?

The members are also provided with a list of medicines contraindicated in older people, and if prescribed any of these, they are recommended to ask their doctor: 'The information on the list I have here says it is contraindicated in older people. Why are you prescribing it for me?'

This campaign was originally funded by the National Pensioners' Organisation and the Swedish Association for Senior Citizens, but the Swedish government found it so interesting that it is now financing the project. The programme is being assessed on an on-going basis, and the results will be presented in 2015.

Effective medicines are currently lacking in some indications such as rare diseases, Alzheimer's and Parkinson's disease, and osteoporosis, and new antibiotics are needed for infectious diseases for which bacterial resistance has become a problem. Such issues present challenges for the pharmaceutical industry.

In addition, re-evaluation of preventive medicine is needed. The lack of effective health economic evaluation is a problem that must be addressed to allow changes to current practice to be monitored. Data on number needed to treat to save one life are needed for different age groups. The question of whether it is right to treat large populations with medicines that may cause adverse effects to save one life is difficult to answer.

Conclusion

Older people receive less and lower quality treatment than younger people. This is due to several reasons, and the responsibility for improving the treatment of older people lies with the pharmaceutical industry and, in Europe, the EMA, as well as prescribers, pharmacists, and even patients themselves. Medicines need to be not only clinically effective but also cost effective, bearing in mind the increasing number of older people needing medical treatment.

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Author information

Barbro Westerholm is a medical doctor and pharmacologist. She is a long-standing member of the Swedish Parliament and former Professor of Drug Epidemiology; Head of the Division for Approval of New Medicines in Sweden; Director General of the Swedish National Board of Health and Welfare; and Vice President of the Executive Board of the World Health Organisation (WHO). Professor Westerholm established adverse drug reaction monitoring in Sweden; built up the national prescription register and organised postgraduate education for doctors on the rational use of medicines. A prolific publisher in the fields of clinical pharmacology, health care, politics, and ethics, she addressed EMWA in May 2013 on the subject of providing value for medicines in older people.

In the Bookstores

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Scientific Style and Format: The CSE Manual for Authors, Editors, and Publishers

by the Council of Science Editors;
Council of Science Editors, 2006 (7th edition).

ISBN: 978-0-977-96650-9.

35.00 GBP. 658 pages.

Comprehensive guidance on scientific style and format from a truly authoritative source

This book is regarded by many as the holy grail of reference manuals. For those not familiar with the great tome it contains a massive amount of information regarding 'publication style and format for scientific papers, journal articles, books, and other forms of publication'. Many of our day-to-day working style guides and information contained within them have their basis in the rules and information contained in the 658 pages of this great book. First issued by the Council of Science Editors in 1960, the current 7th edition was published in 2006. In the latest edition, style is defined as 'publication style: the conventions related to punctuation, abbreviation, capitalization, symbolization and referencing'. Clearly with the amount of information covered there is a requirement for it to be well organised and to this end the book has a four-part structure.

Part 1 is 35 pages long and entitled 'Publishing Fundamentals'. This first section of the book includes information on publication policies and practices as well as copyright and types of publications. The section cross-references other relevant sources of guidance like the American Medical Association Manual of Style and the International Committee of Medical Journal Editors. However, this is a fast moving subject area with much new guidance and information being issued, re-issued, and revised. Although the information in this section is useful, it should be considered that this edition was published 7 years ago and readers would be well advised to consult other sources on the web for more up-to-date information.

Part 2 of the book is around 160 pages and entitled 'General Style Conventions'. The 11 chapters making up this section provide guidance on many topics including alphabets, symbols and signs, punctuation and related marks, spelling, capitalisation, and abbreviations. Chapter 7 is dedicated to prose style and word choice, with a helpful list concerning 'imprecisely applied words'. This list presents pairs or groups of scientific and science-related words that can be misused. For example, assess, determine, evaluate, examine, and measure are often used interchangeably but each has a precise meaning and should be used only when the situation being described merits the use of the word. Covering about 10 pages, useful examples of many imprecisely applied words, together with illustrations of their correct usage, are provided. Another practical chapter (Chapter 12) concerns numbers, units, and statistics. This chapter gives guidance and advice on when to use numerals rather than words when expressing whole or decimal numbers; it also provides detailed recommendations for writing using the International System of Units (also called SI units), including those to use when presenting statistics.

Part 3 of the book is the longest at approximately 235 pages and relates to 'Special Scientific Conventions'. Although some of the chapters in this part cover topics that medical writers rarely deal with, like 'Astronomical Objects and Time Systems' and 'The Earth', there are many relevant chapters. Important chapters provide guidance on 'Chemical Formulas and Names' (Chapter 17), 'Drugs and Pharmacokinetics' (Chapter 20), 'Taxonomy and Nomenclature' (Chapter 22), and 'Structure and Function' (Chapter 23). 'Genes, Chromosomes and Related Molecules' (Chapter 21) illustrates gene family nomenclature using the cytochrome P450 gene family as an example and provides useful summaries for 'the major conventions' required for human gene nomenclature.

Part 4 is 177 pages in length and consists of six chapters. These chapters are concerned with the 'Technical Elements of Publications' and the information covers styles and formats required in books and manuscripts. As an example, one

chapter (Chapter 29) deals with 'References' and the correct method of citing references, both in the text and at the end of the text in the reference list. Another hugely important chapter (Chapter 30) describes the style and formatting of tables, figures, and indexes, providing guidance on when presenting data in a table is appropriate and how to construct the table in a clear and precise way. Similarly, general considerations relating to the use of figures are also presented in this chapter.

A list of cited references in support of the recommendations and additional evidence to reinforce the guidance is provided at the end of each chapter. For those with the responsibility of writing and maintaining style sheets or guides, this book and the supporting material are an invaluable resource. If, on the other hand, you do not have a style guide and you use at least some of the recommendations contained in the book you know you are following a recognised and authoritative source.

The book consists of information-dense chapters and I have only scratched the surface in this review, but much of the information contained

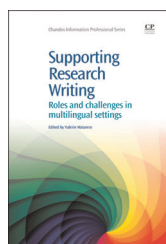
within each chapter is extremely important when writing regulatory documents as well as journal manuscripts or book chapters. As a freelance medical writer, I work mainly with the different style guides supplied by clients and it is of great interest to understand the basis of many of their requirements.

You may already be working in an environment where style sheets are readily available, and may never therefore need to check on any point covered in the book, but I recommend that you familiarise yourself with at least some of the fascinating content.

However, a note of warning: reading this book has parallels with social media. You begin by flicking through the pages and are distracted by little gems of fascinating information and before long, more time than you realise has passed....

You can also follow the Council of Science Editors on Twitter (@CscienceEditors), where they offer additional advice.

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Supporting Research Writing: Roles and challenges in multilingual settings edited by Valerie Matarese; Chandos Information Professional Series, 2013. ISBN: 978-1-84334-666-1 (paperback). 52.50 GBP. 285 pages.

A MUST for anyone who supports research writing through editing, translation, or teaching

A collection of 15 papers aimed at illustrating and leveraging how language professionals (editors, translators, and teachers) can help authors who use English as an additional language to write and improve their research articles.

This comprehensive and useful book was developed from a panel discussion that took place during a MET (Mediterranean Editors and Translators) meeting in 2009. The original discussion was aimed at clarifying and defining the full spectrum of roles and responsibilities involved in research writing support services and in making such services more visible at a European level. The former translator, reviser, translation manager,

and editor, Emma Wagner, at the European Commission (retired), states the following in one of the three forewords in the book:

For many authors it comes as a surprise that complexity is not an essential prerequisite of a convincing document – that in fact the reverse can be true: clear, simple texts have more credibility. This message comes across loud and clear in many of the papers in this collection, showing how authors, editors and translators can best work together to produce effective texts that will get published and will ultimately attract and interest readers.

As a medical writer who translates and edits, but also 'takes an author's ideas and helps to craft them into an appropriately presented text' (to use the words of Greg Morley, who wrote a chapter in the book), I often feel that it would have been quicker and easier to start from scratch.

The book has four parts: the first three reflect the main areas of writing support – education, translation, and editing – while the fourth part explores means of combining these activities. According to the editor, Valerie Matarese (biomedical scientist-turned-editor), hybrid services are needed when

manuscripts are far from publishable. The authors suggest that especially in the research and academic settings, use of a unifying label for those who provide writing support could help to raise their profile. The term 'language professional' is inspired by 'IT professional' and is the chosen term for providers of the three main activities (editing, translation, and teaching) covered by the authors of this book. The typical medical writer role is presented as different from that of a language professional. Some authors use the term 'non-native English speakers' while others use the more positive term 'authors who use English as an additional language'; for this review I have chosen the latter (apart from in direct citations).

Part I, 'Teaching non-native English speakers how to write in English', opens with an overview of how academic writing is taught in European universities. Implications of teaching approaches based on different perspectives are discussed, i.e. focusing on the text and its linguistic forms and patterns, the writers and their cognitive processes, reader expectations (the discourse community), and the writer's first language and language culture. Writing process research is nicely summarised, techniques of genre analysis and corpus linguistics are introduced, and interesting advice is given on how these techniques can be used together to help writers produce texts that more closely match reader expectations.

Studies of effective writers show that they are more aware of the fact that changes in details affect the whole and that a circular approach to writing is needed rather than a linear one. They are also more focused on reader expectations than on words and sentences; in short, they have a more holistic approach. The editor, Matarese, describes a course she gives to doctoral candidates on strategic critical reading of scientific literature, which benefits both research and writing. The main didactic methods in that course – small-group learning and moderated critical discussion with peers – represent the current best practice in science education. Matarese also presents the useful concept 'the reading-research-writing continuum'. It serves to remind us of the effective writers' holistic approach to manuscript writing – the circular rather than linear way of writing.

Part 2 is about helping authors who use English as an additional language to publish through translation. It was a pleasure to read in-depth articles that cover so many of the processes and dilemmas involved in translation, all written by highly competent authors. The challenges of

translation – cultural mediation and knowledge creation – are underestimated. I believe that these chapters can contribute to increased understanding of the processes involved and perhaps even elevate translation's status. One chapter in Part 2 concerns bilingual publication of academic journals. Little has been written about this area, and I must say that I would have been thrilled to find this overview when I was involved in discussions about bilingual publication of a Norwegian journal.

Part 3 is about facilitating publication through editing and writing support. It provides us with a useful overview of many definitions of editing, which clearly means different things to different professionals. It is not difficult to agree with the advice from author Joy Burrough-Boenisch that

... one should not give an author the impression that copy-editing and substantive editing can be done simultaneously, because the two activities require a different approach and entail different sorts of concentration on the task.

The fifteenth and last chapter presents details of a successful mentoring programme for authors who use English as an additional language, in which the key contributors were a journal editor, a language professional, and a researcher on writing for publication in a global context. The term 'anglophone centre journals', i.e. academic journals published in the medium of English in the UK and the USA, is introduced. Having publications accepted in these anglophone centre journals tends to be associated with the highest status, but also with considerable competition. The programme arose from the need to address inequalities in academic publishing, and has so far included 55 authors and lasted for over 4 years.

In my opinion, the authors of this book have succeeded in meeting their goal to clarify and define the full spectrum of roles and responsibilities involved in research writing support services and in making such services more visible at a European level.

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Do you have any comments on any of the book reviews published in *Medical Writing*? Are there any books that you think we should review? Would you like to write a book review yourself? If so, we would love to hear from you.

Excerpts from *European Science Editing*



Comments on the San Francisco Declaration on Research Assessment

The August 2013 issue of *European Science Editing (ESE)*, the journal of the European Association of Science Editors, included a couple of articles relating to the San Francisco

Declaration on Research Assessment, on which I comment elsewhere in this issue of *MEW* (see page 273). Briefly, the Declaration aims to change the way in which research is judged, challenging the reliance on the journal impact factor (IF). Writing in *ESE*, Werner Marx of the Max Planck Institute outlines some of the shortcomings of the IF for assessing research and discusses alternatives such as the Relative Citation Rate (RCR, the 'observed citation rate of an article divided by the mean expected citation rate').¹ Highlighting a problem inherent to both the IF and the RCR – the lack of normalisation of number of citations according to subject and publication year – Marx describes a 'percentiles' method, which 'gives an impression of the impact [an article] has achieved in comparison to similar items in the same publication year and subject category', to overcome these limitations. This percentiles method was previously presented in an earlier *ESE* article.²

In the same issue of *ESE*, R Grant Steen describes the Declaration as 'a sprawling document that attempts to serve a variety of needs, but may serve none of them well', criticising it for bashing the IF without proposing an alternative.³ While acknowledging that the IF is flawed, and indeed listing its flaws, Steen argues that it can in fact be used to assess research quality, highlighting a study of 979 papers by the Wellcome Trust which found that expert assessment of importance (non-blinded) was strongly correlated with IF of the journal of publication.⁴ Though he accepts that the IF should not be used to assess individual papers or an individual researcher's output, he questions whether the alternatives are as good.

Other articles of interest in 2013 issues of ESE

- **August 2013:** Nikhil Pinto highlights some of the more common style errors in scientific

papers in an excellent short article.⁵ Among other things, Pinto describes the difference between 'cases' and 'patients' and explains why one should write petri dish, gram-positive, graafian follicle, western blotting (lower case), Gram stain (upper case), data are (plural), and Parkinson disease (no apostrophe).

- **May 2013:** This issue included short pieces outlining the benefit of statistical knowledge for copy editors working with academic publications⁶ and describing patchwork plagiarism (in which text from multiple sources is weaved together in a new article),⁷ including its detection and avoidance.
- **February 2013:** In an opinion piece on authorship,⁸ R Grant Steen explains the vulnerability of the old ICJME criteria for authorship (since revised) to misuse. He argues for a new criterion: 'free and unfettered access to all raw data'. Elsewhere in the same issue, Denys Wheatley lists what he considers to be some of the commonest clichés in scientific papers,⁹ and Hasan Shareef Ahmed and Armen Yuri Gasparyan explore potential solutions to some of the problems surrounding peer review.¹⁰

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Good pharma: a linguistic approach

There are different definitions of the adjective 'good', e.g. morally excellent; satisfactory in quality, quantity or degree; of high quality; excellent; well-

behaved; etc. as the web dictionary tells us. In 'good pharma' the meaning of 'good' is most probably a moral one. 'Good pharma' corresponds more to the morally outstanding performance of the pharmaceutical industry and less to the quality of pharmaceutical products or financial performance of the industry. However, if you think about a 'good medical writer' the term 'good' does not stand for a morally excellent professional but for a person doing his or her job very well. Thus, 'good' seems to change its meaning when used in connection with different words. This is the semantic information carried within the phrase which is – by the way – mostly ignored by automatic translation systems. There is a whole research area focusing on dictionaries or systems that do not only translate the words one by one but also the meaning they carry – even for proverbs. An impression on semantic translation is contained here:

https://en.wikipedia.org/wiki/Semantic_translation.

The linguistic measure known as 'mutual information' provides information about how strongly two words are linked, i.e. indicating how often they are used together in the same document (e.g. 'London' and 'UK' score high on this measure). The measure itself is a statistical probability for the occurrence of one word after the other appeared in a text. For those who are eager to read more about this, I can recommend this site – even if it looks a

little bit like a complex math explanation, it presents some useful examples:

<http://nlp.stanford.edu/IR-book/html/htmledition/mutual-information-1.html>.

One can only guess how strong the mutual information ratio between 'good' and 'pharma' might be. However, picking up the example of 'good medical writing', 'good writing' is obviously not the same as 'correct writing'. Beside orthography there are many more factors that contribute to 'good writing' – and these are necessary to make a text useful or interesting or simply entertaining for the intended readers. A short discourse about these factors – probably not new but nice to remember – is given here:

<http://grammar.about.com/od/yourwriting/a/characteristics.htm>.

Eventually, a Google search on 'good pharma' gave a few sites of pharmaceutical companies with a name composed of these two terms – as well as a book 'bad pharma' and an article 'good pharma, bad pharma'. The above mentioned dictionary defines 'pharma' as a pharmaceutical company or pharmaceutical companies when considered together as an industry. Thus the word 'pharma' is the short form for pharmaceutical. According to another definition, 'good pharma' also relates to good pharmaceutical products, e.g. effective and safe drugs. In this context – and as a reward to those who managed to struggle through all this linguistic stuff – a humorous approach to the topic can be found here:

<http://www.pharmamanufacturing.com/articles/2012/145.html>.

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Regulatory Writing

Full publication of clinical trial data: Opening Pandora's box?

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Abstract

The European Medicine Agency's draft policy on the publication of clinical trial data for consultation (POLICY/0070, EMA/240810/2013) is causing quite a stir. The draft policy provides for the publication of large parts of the clinical

study reports included in a common technical document submission, along with the accompanying summary documents and overview. The varied stakeholders (pharmaceutical companies, patients) will have different opinions on the draft. The European Federation of Pharmaceutical Industries and Associations, a major representative of the pharmaceutical industry, have been particularly critical. While greater transparency is to be welcomed, inappropriate analyses of the data causing unwarranted public alarm and identification of anonymised information remain major concerns.

Keywords: EMA, Clinical trial data, Publication

On the 24th June of this year, the European Medicines Agency (EMA) issued its draft policy on the publication of clinical trial data for consultation, after lengthy interaction with different stakeholders (see http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/06/WC500144730.pdf). The draft forms part of a drive towards greater transparency, a new buzzword in many different institutions that serve the public.

What is being proposed

In the draft policy the EMA would commit to proactively publish (as of March 2014) modules of the common technical document in a submission (along with the individual clinical study reports themselves included in module 5) on their website, regardless of whether or not approval has been granted. Certain parts, for example, the module on biopharmaceuticals are regarded as containing commercially confidential information and will not be made available. Other parts, mainly the patient

level data in the individual, will be designated as 'controlled access' (where the gatekeeper would be the EMA, following as yet poorly defined procedures and criteria for release of this information).

The policy is a complement to the existing 'Policy on access to documents (related to medicinal products for human and veterinary use)' (POLICY/0043)(EMA/110196/2006), which came into effect in 2010 (note the 4-year delay between the publishing of the policy and its coming into effect - the EMA hasn't always moved quickly on its promises of greater transparency).

Main industry worries

The devil, as always, is in the detail. The European Federation of Pharmaceutical Industries and Associations (EFPIA), which agglutinates national pharmaceutical industry associations and leading pharmaceutical companies, has set out its opposition to many of the details of the draft policy (see http://www.efpia.eu/uploads/EFPIA_comments_on_EMA_draft_policy_access_to_CT_data_FINAL.pdf). According to this industry association, the three main worries are that the proposed policy might not fully safeguard patient confidentiality, that the policy may undermine trust in the regulatory approval system and so act as a disincentive for investment, and that commercial secrets may see the light of day, with the ensuing disincentive to fund innovative research.

Will patient confidentiality be preserved?

As mentioned above, patient level data will be subject to 'controlled access'. Any entity or person wishing to have access to such data should agree to a legally binding data-sharing agreement designed to ensure that the intended use is in the interests of public health (the requestor will have to explain in detail what the information will be used for, for example a meta-analysis) and in line with the spirit of informed consent. In addition, the requestor will have to agree not to try to identify patients through linking to other databases or programs (for example, hospital discharge records

might enable identification of patients in SAE listings).

The draft policy also states that the data will be appropriately 'de-identified' (presumably by the EMA) in a similar fashion to the recommendations for publishing raw clinical data in journals.¹ The EFPIA questions whether such de-identification would be sufficient in light of rapid advances in re-identification technology and would prefer to have more control over how and what is released (that is that the requestor is referred to the company with the EMA as interlocutor). With the vetting system proposed by the EMA, it is hard to determine the likelihood of that the anonymity of patient data, collected after the patient has signed an informed consent guaranteeing their privacy, is broken and the data re-used for purposes other than the lofty ideals of improving public health. The EFPIA also suggests that it should not be possible for data to be downloaded. However, many of the (legitimate) uses for such data would be in meta-analyses or re-analyses, which would be extremely tedious if this was the case.

A final point on confidentiality is that, according to the draft policy, data on investigators and other trial staff (names, addresses, appointments, qualifications, and clinical duties) should be fully available. I would hope that by address, the draft policy is referring to business address and not home addresses (which may appear on CVs included in clinical study report [CSR], appendices). Certainly the EFPIA considers that there is dubious legal basis for this, and cite a number of EU regulations to support their point of view. I suppose a worry here is that some investigators and patients, if they know that personal information may be compromised, will be less inclined to participate in a study.

Trust in the regulatory approval system and disincentives for investment

The question of whether implementation of the draft policy will undermine trust in the regulatory approval system will probably have a very different answer depending on whether or not you are part of the pharmaceutical industry. In the eyes of the general public, the credibility of the system has taken plenty of hits recently and books such as *Bad Pharma*, by Ben Goldacre, have generated plenty of discussion. With the new proposal, sceptics will be able to see data on which an approval or rejection is based, and come to their own conclusions as to whether the decisions are consistent across applications and appropriate. Such a utopian vision could generate greater trust in the system (provided

of course that appropriate decisions are being made). A potential danger though is that data may be used to generate flawed analyses that generate undue public alarm. Going further, would it be such a far-fetched scenario to imagine companies funding investigators to trash competitors' programmes? It is hard to predict how this will play out.

Pharmaceutical companies, moreover, are very used to confidential dealings with the health authorities and the thought that much of their submission dossier may be readily perused by one and all must be disquieting. The ready availability of such information could be a disincentive for investment. Although not explicitly stated by the EFPIA, a worry must be that this release of information will benefit generics companies over innovators. It is interesting to note that since implementation of the existing policy on release of clinical trial data (POLICY/0043)(EMA/110196/2006), more than 1.6 million pages of clinical trial data have been released,² with most of the requests for disclosure of information coming not from healthcare professionals or members of the public, but from pharmaceutical companies. Presumably these requests were made to gain competitor information and not with the public good in mind. There is a big difference though between having to interact with the EMA to procure information under the current policy and having much of it freely available on the Internet as per the current proposal. With the information more readily accessible individual investigators and small start-ups may also use the information available as stimulus to launch truly innovative projects that will attract investment. Thus, the overall effect on innovation is hard to predict.

Benefits for medical writers

Much of the debate about this greater transparency has focussed on the overall interests of pharmaceutical companies themselves. As medical writers, on the level of doing our jobs, we may actually stand to benefit from having ready access to what could develop into a huge repository of regulatory writing. At present, we only have access to regulatory documents from the companies we work for but we have no idea how other companies may be approaching similar challenges. And although a quick look on the Internet can usually retrieve the applicable guidance, there are very few actual examples of text from real documents. So if you are not convinced that your company is taking the best approach in their CSRs, then you will be able to go to the published trials and see what other companies have done. Wondering to what extent others

cross-reference the protocol in the materials and methods of a CSR? It will now be possible to find out. Examples of clinical summaries and overviews will also in principle be freely available. In the long term, the opportunity to see what others have done could well lead to greater harmonization of approaches, as the ones that work best are copied and gain predominance.

Conclusions: Are we opening Pandora's box?

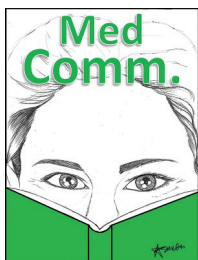
The policy on publication and access to clinical trial data is still in draft form and it is impossible to know the extent to which the final form will differ from the present one. As it stands, the policy may improve

access to data for legitimate purposes, but there are also risks of inappropriate usage. The revised policy may well alleviate some of these concerns. Nevertheless, once the policy is in effect, the EMA would be advised to be on stand-by for rapid action in case the law of unintended consequences applies.

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Dear all,



I received a very positive response to the article that Sarah Richardson wrote (published in this section a couple of issues ago) about writing meeting reports from audio recordings and slides. The article also triggered a response

from our latest contributor to the Medical Communications section.

Elisabeth Heseltine is an extremely experienced and well-published writer, who teaches globally and is also a freelance translator, editor, compiler, workshop leader, report-writer, précis-writer, and indexer for various organisations including the WHO, the International Agency for Research on Cancer, and Interpol.

Elisabeth contacted me after seeing Sarah's article, and I thought it would be really interesting for

EMWA members to understand a bit more about what she does. Elisabeth's article is a fascinating insight into the world of the précis-writer – a world that I admit I knew little of, but demands quick thinking, impeccable language skills, and creativity in its own right. Elisabeth describes the qualities needed and explains why she enjoys the work and the environment so much. For anyone lucky enough to have more than one language, I think this would be a very exciting area to work in, and I would encourage the many EMWA members with these skills to investigate this career path.

It only leaves me to wish you the very best of this season's greetings – I hope Santa is kind, and your mistletoe bountiful. Long may your wine be mulled and your stockings stuffed.

Have a great and well-earned Christmas break all, and see you in the New Year!

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More on meeting reports – writing reports for the United Nations system

Meeting reports are an aspect of 'medical' and other technical writing that has had little discussion. The following might be of interest to medical writers asked to provide rapid, reliable, objective reports of various types of meeting.

The United Nations, its agencies (including the World Health Organization, WHO) and other international bodies, have over the past 70 years developed a sophisticated system for recording the proceedings of working groups, meetings, assemblies, and conferences. Until recently, the records were written by people who were in the meeting room; now, with the financial restrictions affecting all organisations, they are being written more and more often at home from sound files. The details of the procedure are as follows.

First, two kinds of record are produced. One is what are known as 'summary records', which are written by 'précis-writers' (described below). These summarize the intervention of each speaker in a few lines, unless a series of speakers simply agreed with another one, in which case, the text would

read, 'The delegate of Germany, supported by those of Algeria, Bhutan and Cambodia, said....' For a 3-h meeting, a summary record might be 20 pages or more. The other kind of record is a report, in which the gist of the debate on each topic discussed is summarised, usually without mentioning the names of either delegates or countries, unless this is specifically requested. A report of a 3-h meeting would be no more than 7–10 pages.

A 'précis-writer' is someone who writes an abridged version of a statement. The term, from French, has been used in English since the beginning of the nineteenth century. Until recently, part of English language teaching in English schools involved learning how to write a representative summary of a piece of text.

The system has been perfected to ensure that the record can be published as soon as possible after the meeting. Originally, this meant the next day, so that the discussion from the previous day could be taken into consideration in the deliberations. In most organisations, this is no longer the case, as there are endless rounds of verification and re-writing by staff, who sometimes insert what they wish

they'd said! This often means that summary records become archives and not working documents. However, the original concept was to produce an immediate, clear record of the proceedings in a form that is understandable even by people whose first language is not English.

When précis-writers or report-writers attend a meeting in this system, they do so successively. Thus, a team of up to four writers will cover one meeting, with enough overlap to ensure equal coverage once the actual length of the meeting is known, i.e. if it finishes early or goes overtime. The number varies from organisation to organisation. Increasingly, however, one or two people are expected to cover an entire meeting. Having more than one person allows the others to write up immediately, which is an important consideration, as the technique of writing either précis or a report is to write up your notes as soon as possible, while you can still read your writing and remember what went on. Most people write their notes in their own brand of shorthand, while others use actual shorthand; some now take notes on a portable computer. In any case, to capture the essence of a debate, it is essential to work from one's notes.

When the system first began in the 1940s, précis-writers had no back-up. They had no recordings, no transcripts, and no notes from speakers (who actually *spoke*, without reading from a prepared text). The précis-writers listened to the speaker or, if they did not know the language, to the interpreter, took down the important points and turned them into a clear record. Now, sound files are available in both the original language and the English interpretation, and there are also transcripts in languages other than English. The speakers' prepared texts are made available as well. Précis-writers and report-writers are expected to know at least two of the official United Nations languages besides English (Arabic, Chinese, French, Russian, and Spanish) so that they need to depend on the interpretation as little as possible.

One advantage of actually being at a meeting is that one can obtain every bit of paper being discussed, for example documents at the back of the room that people introduce into their intervention. Another is to see exactly how a person's talk goes

with their PowerPoint (whether they have a logical 'walk through', or whether they flip back and forth among their slides). The main advantage is being immersed in the general ambiance and, as at every meeting, seeing what goes on in the corridors. I was once absolutely illuminated by a conversation overheard during a coffee break, when the implications of a rather mysterious statement made during the meeting became clear.

This luxury is, however, becoming rare, and working from sound files is becoming the norm. I agree with Sarah Richardson that the techniques of 'live' précis-writing must be maintained: précis-writers or report-writers must read all the relevant documents, sit down and listen to the recording, with any slides and documents, and take notes, as if they were in the meeting room. Typing everything out and editing down the transcript can lose immediacy and result in a record that does not reflect what actually happened.

The qualifications needed to enter this profession are:

- A good command of English that is understandable to an international audience, as probably 90% of the readers of the report will have English as only their second, third, or fourth language;
- A working knowledge of at least three of the official United Nations languages;
- The ability to discern relevant parts of a statement and the assurance to leave out those that are irrelevant; and
- The ability to write clear text rapidly, with minimal revision required.

Almost all précis-writers and report-writers in the United Nations system are freelancers. Getting onto the circuit is not easy, as in any profession, but it would be worthwhile contacting an organisation such as WHO to see whether they need précis-writers for one of their large meetings, such as the annual World Health Assembly. Once one has a foot in the door, networking with colleagues is the best way to obtain further contracts.

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A guideline for manuscript flow. Part 2 – The methods

New medical writers and medical writing students are often unsure how to start writing a manuscript and need help organising their thoughts.

How to link the sections and information within them is what I call 'manuscript flow'. This article is the second in a series on the flow of information in a manuscript. The first article, published in the March 2013 issue,¹ discussed how to organise the introduction. Here, I explain how to organise the methods.

As described in my previous article 'What are the most common reasons for a manuscript to be rejected (and how can they be avoided)?',² the methods is the part of a manuscript most likely to be the cause of rejection. This is mostly because the methods frequently do not provide enough detail to allow others to interpret the true significance of the results. Inadequate methods can be—or at least may be viewed as—a sign of problems in the study design.

Manuscript content guidelines (e.g. CONSORT) and ICMJE recommendations have been developed to help authors prepare articles whose methods are complete.³ The journal's instructions for authors may also have detailed requirements for the methods section. Writing a clear, well-organised methods section that satisfies all of these instructions can be a challenge.

Described below and summarised in Figure 1 is a general structure that fulfils the requirements of complete reporting of methods. This is only one possible way to organise the methods, but it is one I have arrived at after writing manuscripts for more than 10 years and it seems to work. The structure is in no way rigid—you may find that a different flow works better for you—but this is a good place to start.

The examples I give are for clinical studies because they are what I and most medical manuscript writers work on. A similar flow can be used for all other kinds of articles or studies, although obviously some of the information will be irrelevant and specific guidelines will need to be followed for each article type.

Start with the overall study design and key details

I like to start the methods with a section called 'Study design'. This section gives the reader an overview of the kind of study performed, along with details of when and where it was performed. Begin this section with a sentence describing the overall design of the study, and give the clinical trial registration number if there is one. Follow it with a sentence describing the dates and location of the study. Finally, provide the study objectives, with an indication of the primary and secondary outcome measures. For example,

This was a phase II randomized, double-blinded, multicenter study in adults with severe Crohn's disease (ClinicalTrials.gov NCT00109473). The study was performed between May 12 and August 12, 2011 at 6 centers in Austria. The primary objective was to demonstrate whether 30 µg xamimumab is superior to 20 µg xamimumab for the treatment of severe Crohn's disease as measured by the CDAI. The secondary objective was to compare the safety of 30 µg and 20 µg xamimumab.

Ethics

Next, describe the ethical considerations, including approval by ethics committees, ethical guidelines that were followed, and a statement about informed consent. This can be described in a separate section or combined with the study design section. For example,

The study was approved by the local ethics committee of each institution and was conducted in compliance with the Declaration of Helsinki (as amended in Tokyo, Venice, Hong Kong, South Africa, Edinburgh, Washington and Tokyo), the International Conference for Harmonization Guideline for Good Clinical Practice (January 1997), and all international and national laws and regulations. All subjects gave written informed consent before being included in the studies.

Patients (or Subjects)

Once you have given the above generalities, describe how the patients or study subjects were selected. First make it clear who was considered eligible

and then follow with the reasons for exclusion. This should be done in a single paragraph. For example,

Adults 18–50 years of age were eligible if they had a history of moderate to severe seasonal allergic rhinitis during at least the 2 previous years, a positive skin prick test (wheal diameter ≥ 3 mm) to any seasonal pollen, and a pollen-specific immunoglobulin IgE level >0.7 kU/L. Subjects were excluded if they were taking systemic corticoids; had severe seasonal asthma requiring long-acting beta agonists or inhaled steroids; or had a vital capacity $<80\%$ and a FEV₁ $<70\%$ of the predicted value. Women could not be pregnant or lactating.

This section would be structured in the same way for an observational study. If the article was a systematic review or meta-analysis, this section can be replaced with a description of how the articles were selected, and if the study was in cells, animals, or tissues, this section should describe what these are, how they were handled, and how or from whom they were obtained.

Study conduct

Study conduct should form the middle part of the methods because the study design and population need to be described first. For an interventional study, start by explaining what was done to the patients or subjects. This includes how they were split up or randomised into groups, what the subjects were treated with, how the treatment was administered, and what assessments were made. For example,

Patients were randomized 1:1 to receive a single subcutaneous injection of 30 μ g zipitone (Anonymous Drug Company, Felix, NC) or an equivalent volume of 0.9% NaCl (placebo). Subjects were randomized to treatments using an interactive web response system, with randomization lists generated by SAS version 9.2 (SAS Institute, Cary, NC). Treatments were provided in identical, numbered glass vials so that both subjects and investigators were blinded to the treatment type.

You may wish or need to describe the treatments in detail in their own paragraph or section, especially if they have not been described before or are not commercially available. The following example could be a paragraph within the ‘Study conduct’ section or could be a section of its own entitled ‘Vaccines’:

All vaccines were split virion and contained the A/Solomon Islands/3/2006 (H1N1), A/Wisconsin/

67/2005 (H3N2), and B/Malaysia/2506/2004 strains. The investigational intradermal vaccines contained either 15 μ g or 21 μ g of HA per strain in 0.1 mL in a prefilled Toluva™ microinjection device. The high-dose vaccine contained 60 μ g of HA per strain in a ready-to-use 0.5-mL syringe. The standard-dose vaccine contained 15 μ g of HA per strain in a ready-to-use 0.5-mL syringe.

Next, describe the assessments, measures, or assays. For each technical method, if it has been previously published, you only need to give a single sentence providing the citation, although if you think it important, a sentence or two summarising the method can be included. If not previously published, describe the method in full. In all cases, be sure to describe the limits of detection and sensitivity for the method as well as the source of any materials or equipment used. For example,

Quality of life was assessed on day 28 using the HAQ (12).

The following is a more detailed section that should be presented as a separate paragraph or section entitled, for example, ‘Immunogenicity’:

Blood samples were collected before vaccination (day 0) and 28 days after vaccination. Hemagglutination inhibition (HI) titers were measured using a standard assay (12). The serum HI antibody titer was defined as the reciprocal of the highest serum dilution that completely inhibited hemagglutination. To calculate geometric mean titers, samples with HI not reaching 100% at the lowest serum dilution tested (1:10) were assigned a titer of 5. Seroconversion in a subject was defined by either a pre-vaccination HI titer $<1:10$ and a day-28 titer $\geq 1:40$ or by a pre-vaccination titer $\geq 1:10$ and a minimum four-fold titer increase at day 28. Seroprotection was defined as a pre- or post-vaccination HI titer $\geq 1:40$.

For clinical studies where safety was assessed, you may want to create a separate section called ‘Safety’ describing in detail the assessments of adverse events, severe adverse events, and scoring of solicited reactions (expected adverse events).

Sample size

For interventional studies, describing the sample size calculation is essential. This information puts the results of statistical tests in context. For example, the relevance of statistical tests will be unclear if too few subjects were included to detect



Figure 1: Summary of flow of the methods.

a meaningful difference. Even if a power calculation was not performed, an explanation of how the sample size was selected can help put the results in context. This information about sample size can be combined with the statistics section, but it can also be effective as an independent section, especially when it has an important bearing on the interpretation of the results. I like to include a section on sample size just before the section on statistics. For example,

A total of 1600 subjects (800 subjects 18–60 years of age and 800 subjects >60 years of age) were estimated to be needed to provide 95% power to detect the primary objective, assuming a one-sided alpha level of 2.5%, a non-inferiority margin for the geometric mean titer ratio of 1.5, a standard deviation of log-transformed titers of 0.7, and 90% of subjects evaluable.

Statistics

The statistics section should explain the software used, the statistical tests used, specific populations

or subgroups, and general statistical considerations, such as how statistical significance was defined and whether (and how) missing data were replaced or imputed. For example,

Statistical analysis was performed using SAS version 9.2 (SAS Institute, Cary, NC). Missing and incomplete data were not replaced and no imputation was performed. Safety was assessed in all subjects treated. Immunogenicity was assessed in all subjects who were randomized and treated, had a valid post-vaccination serology result, and completed the study according to protocol. Non-inferiority was assessed in subjects completing the study according to protocol and superiority was examined in all vaccinated subjects with a post-vaccination blood sample. For non-inferiority, the age-stratified confidence interval was calculated using an analysis of variance model of log-transformed titers, with age group (18–60 and >60 years) as the stratifying factor in the model. Non-inferiority was demonstrated if the lower limit of the age-stratified two-sided 95% confidence interval of the ratio of day 21 geometric mean titers was >0.667. The frequency of solicited reactions was compared between groups using Fisher's exact test. Differences were considered statistically significant if the p-value was less than 0.05.

Conclusion

To avoid having your article rejected because of an inadequate methods section, you must include all information required by the appropriate content guidelines (e.g. CONSORT) and the journal's instructions for authors, and everything needed for readers to put the study in context and to allow the results to be interpreted. The flow described here can accomplish this and is one way of logically organising the information, although you should adapt it to the specific needs of your article.

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Out On Our Own

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Editorial

The EMWA autumn conference is always so well placed in November, giving us the chance to meet friends and colleagues before the onslaught of traditional end of year festivities. Barcelona's conference was no exception. We were

pleased to welcome new and old friends alike to the Barcelona Freelance Business Forum (FBF). The FBF minutes are now on the EMWA website (www.emwa.org) in the Freelance Resource Centre (FRC), so do take a look if you missed the meeting. Remember that the FRC is your resource. Log in to the 'members only' section, click 'Resources' then 'Freelance Resource Centre' and browse - you may be surprised at the range of business- and medical writing-related content available. Do spread the word to your non-freelance colleagues; the content is open to all EMWA members.

In this year-end issue of Out On Our Own, Anne tells us about her first experience of taking a free (yes, free!) 'Massive Online Open Course' (MOOC). With content relevant to our profession, as well as plenty of alternative material to choose from, the sky (or probably more realistically, our available time) could be the limit to our learning. Perhaps MOOC will find its way onto a few New Year's resolution lists...

Jane's second article in her series on Social Media (SoME) develops the theme of using SoME as a business and marketing tool. Jane's practical use of SoME platforms to maintain continuity of workflow

illustrates the intelligent side of SoME use and balances out the side we are more used to reading about in the papers!

Hurray - Tool Box is back after Raquel took a well-earned rest in September 2013. This time, Raquel tells us about ORCID - an authorship attribution platform that gets around the problems of authors moving jobs or changing their names. From those of us who published material before marrying, chose to take our partner's name, and continued to publish afterwards, we salute you!

We close for 2013, but not before asking you to add another resolution to your list:

Contact us with any material or ideas you'd like to contribute to OOOO. More varied content and a wider pool of authors is good for us all. Remember that the exposure is particularly good for freelancers and your business.

We thank all our contributors for the wonderful material you have sent us in 2013. You know who you are, but we love you so much for getting involved, that we'd like to mention you again:

Ann Bless, Amy Whereat, Aylsia Battersby, Claudia Frumento, Jane Tricker, Anne McDonough, Paul Woolley, Anne Cunningham, and Raquel Billiones.

Hmmm - strange - not many men! Come on guys, get involved in 2014...

All the best to you all for the seasonal holidays, and we'll be back in March 2014.

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Is a MOOC for you?

I am, by nature, a late adopter when it comes to technology, but as a freelancer I know I need to keep up with important innovations. Fortunately I have tech-savvy friends, and when one of them blogged last year about taking a Massive Online Open Course (MOOC), I knew this must be the next big thing. She was ahead even of the *New York Times*, which

in November 2012 deemed that year 'The Year of the MOOC'.

What's a MOOC?

A MOOC is a class (usually at the university or advanced degree level) that is available over the

internet and into which anyone can enrol. Over the last year or so, several providers of MOOCs have started up – both for-profit and not-for-profit. Coursera (www.coursera.org) seems to be the most established and offers a wide variety of courses from prestigious American universities such as Johns Hopkins, Harvard, and Stanford and from universities in many other countries such as Mexico, Israel, Australia, India, Taiwan, France, and Germany. Here are a few examples of courses that might appeal to medical writers:

- Clinical Terminology for International and U.S. Students
- Case-Based Introduction to Biostatistics
- Design and Interpretation of Clinical Trials
- Writing in the Sciences
- Drugs and the Brain.

The MOOC business model is not entirely clear to me, and I don't believe the rampant hype that MOOCs are a viable alternative to traditional university-based degree courses. They may, however, present an excellent opportunity for the freelance medical writer to advance his or her professional knowledge – particularly because they are free. Yes, you read that correctly – FREE.

How was my experience with a MOOC?

Last spring I signed up for Drug Discovery, Development, and Commercialization offered through Coursera by the University of California – San Diego. Since I have worked in drug development for over 20 years, I did not expect to learn a great deal of new information from this course; my objectives were to consolidate the knowledge I had gained from experience, fill in some gaps, and gain a better understanding of the trendy new technologies being used in discovery.

I registered for the course online and received a welcome e-mail from the instructor with a link to the course materials. By the time the course started, over 14 000 people had registered. Apparently such a large enrolment is not uncommon, and MOOCs often have tens of thousands registered. Of course, fewer start the course, fewer still complete it, and only a small number of participants complete the assessed work.

The structure of the course was 2 hours of lectures (given via PowerPoint slides with voiceover) per week for 10 weeks. The lectures were released on Friday mornings and were available to view online or download; the instructor also provided PDFs of

the slides for download. Each topic was covered by a different presenter, and each presenter provided high quality, though slightly overlapping, content. The instructors also provided an online discussion forum and made themselves available in Google Hangouts. I initially found that as a busy freelancer it was quite difficult to find even 2 free hours a week, but I caught up after a few weeks. Once I was able to incorporate the time into my schedule every week, I really enjoyed the break from my work.

Quizzes after each lecture and a final project comprised the assessment component of the course. The final project could be completed individually or in a small group and was graded by peer assessment, a practice that seems to be the standard in the MOOC world. Participants who completed both of these activities received a Statement of Accomplishment. A Verified Certificate could be earned with the same work plus registration in the Signature Track (requiring payment of a US \$50 fee and provision of identity details). Sadly, I was not the recipient of either document because, although starting with the best of intentions, I gave up on the final project in the end. Because of my hectic schedule, I had planned to complete the project on my own, but found it was a bigger piece of work than I could manage in a reasonable amount of time.

Would I recommend a MOOC to other freelancers?

Absolutely! My main piece of advice is to decide early on the level at which you want to participate. Will you just listen to the lectures, or will you complete the work to attain a Statement of Accomplishment or Verified Certificate, participate in the forums, and attend hangouts? Both approaches are valuable, I think, but, if you want to achieve the latter, some planning and commitment will be required to keep up and complete the work. If you are looking for more of a refresher or taster, a MOOC provides a great deal of flexibility in fulfilling those objectives. In fact, for at least some courses, an archive of course materials is available online, so you do not even need to wait for the course to begin to look at them. Overall, I think MOOCs provide a great resource that you can tailor to your needs, interests, and availability.

Would I take another MOOC?

Again, absolutely! I was very satisfied with my experience and have just signed up for another

course related to my work. I'm also ready to try something new. As important and challenging as it can be for freelancers to keep their knowledge current, it can be equally important and challenging to switch off from work. Anyone want to join me in

Roman Architecture or Exploring Beethoven's Piano Sonatas?

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Using social media for self-promotion and business development

In the September 2013 issue of Out on Our Own I explained how I use social media for connecting and networking within the medical communications industry and wider afield. In this second article I will describe how I use social media to help ensure that I have a constant stream of work through self-promotion and business development. I am not a social media expert, but I have developed an interest in it in the last few years, and been fortunate to have access to experts who have been generous with their hints and tips.

LinkedIn™

My first foray into social media was with LinkedIn. Although my first aim was to use it to network with other medical writers and editors, as time went on I began to appreciate that LinkedIn could expand my business horizons – both within medical communications (as people that I was connected with moved on to new jobs), or because people from outside our industry needed a medical writer for a one-off project. Deciding to use LinkedIn as a promotional tool, rather than as a networking opportunity, however, meant engaging with it on a different level.

I was advised to make my LinkedIn profile as complete as possible to improve my 'discoverability' and to encourage searchers to contact me. Over time I have continued to refine and add to my LinkedIn profile, usually at LinkedIn's prompting, to ensure that it stays 95–100% complete. My intention is that my LinkedIn profile should contain enough information to allow a potential client to make the decision to shortlist me for a project.

Another aspect of engaging with LinkedIn was to start to use it to give status updates – particularly when I'm attending meetings (in case some of my contacts also are attending) – and to follow status updates (to identify opportunities to renew a personal contact – for example, when a contact moves to a new job). I also started to join in with discussions in LinkedIn groups that I belong to: sometimes, if someone else has managed to crystallise my thoughts, and I can't add anything more of value, I'll just hit the 'Like' button, occasionally I contribute my own thoughts and experiences – however, I'm always

conscious that I could do myself more harm than good by saying something silly or by writing something that would identify a client. I have noted an upturn in the number of people viewing my profile, and have received invitations to connect with other group members, after taking part in a discussion.

I would say that in terms of social media, LinkedIn is my most important tool for self-promotion and business development.

Twitter™

I joined Twitter just before my website went live in 2010. At that time, my only reasons for joining were the benefits that I was told it could bring to my website – and I will return to that later. As with LinkedIn, though, I soon started to see other possibilities. I followed the example of a fellow freelancer and started to post occasional Tweets (without mentioning clients or products) about the type of work that I was doing, and highlighting unusual projects or in-house interim contracts, for example, with the hope that the audience would see a versatile and flexible medical writer working in a range of therapeutic areas.

As with LinkedIn, Tweeting about (or sharing other people's Tweets about) new developments in medicine, news stories about the pharmaceutical industry, meetings that I am attending (in the real world or in cyberspace) etc., informs potential clients that I am here and taking an interest in issues relevant to the industry.

I believe that Twitter has its uses in direct self-promotion and business development, but its greater value is in networking, continuing education (a theme I will develop in my next Out On Our Own article), and indirectly supporting other business development efforts.

Google+™

This is a 'work in progress' for me, as I have only recently set up my Google+ account. I have completed my profile and started to build some circles, but I'm still exploring what to do with it. As in my early days with Twitter, my primary aim for Google+ is to drive traffic to my website.

All social media paths lead to www.freelancemedicalwriting.co.uk

My website is the most important part of my business development strategy. It presents a more detailed breakdown of services that I can offer potential clients than my freelancer listings allow; it contains testimonials from clients and – through a link to my blog site – potential clients can see examples of my writing style. However, the time and money invested in my website would be wasted if it was undiscoverable by people searching the internet.

Although some changes have occurred since my website was developed, search engine optimisation (SEO)¹ still relies on creating good backlinks (links from other websites) to improve search engine results page (SERP) rankings. As they carry a lot of SEO ‘weight’, I have linked my freelancer listings on EMWA.org and medcommsnetworking.co.uk, and my profiles on LinkedIn, Twitter, Google+, and WordPressTM to my website. In addition, my

Twitter feed is plugged into my home page, so, as long as I Tweet regularly, that page is continuously updated, giving internet bots² more reason to re-index it and helping to improve its SERP ranking. Thus, the work done by my social media sites in pushing traffic to my website and improving its discoverability in internet searches, is at least as important as the direct opportunities that they present for self-promotion and business development.

¹SEO is designed to improve the chances of your website appearing higher on the results page than those of your competitors – consult a specialist for more information and guidance.

²Internet bots are software applications that run high speed, simple and structurally repetitive tasks – in this context they fetch, analyse and file information about the pages held on the web server that they are assigned to.

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Tool Box

ORCID: The key to correct attribution

National censuses show that the likelihood of two unrelated people sharing the same family name is high.¹ Ask anybody with the last names Johnson, Patel, Lee, or Garcia and they will tell you how their frequently occurring surnames can often lead to mix-ups in their private as well as professional lives.

Attribution and authorship

Attribution is defined as the act of attributing or ascribing, i.e. ascribing a piece of work to a particular person. Is this a Monet or a Manet? Was that Bach’s or Beethoven’s?

In academic institutions, accurate and reliable attribution of research outputs (e.g. publications) is of prime importance. And because in most cases multiple authors are involved, the order of attribution and the individual researcher’s contribution in a publication also need to be clearly defined.² After all, attribution is not only about getting the credits and honours but also about responsibility and accountability. The example below illustrates how common surnames can complicate academic authorship:

Yu XM, Wang L, Li JF, Liu J, Li J, Wang W, Wang J, Wang C. Wnt5a inhibits hypoxia-induced pulmonary arterial smooth muscle cell proliferation

by downregulation of β -catenin. *Am J Physiol Lung Cell Mol Physiol.* 2013;304(2):L103–11.

ORCID and publications

In 2012, ORCID (Open Researcher and Contributor ID) was launched to provide a unique identifier for researchers, thus addressing the problem of correct attribution of scientific publications. This ‘machine-readable, 16-digit unique digital identifier’³ is similar to a barcode and aims to link researchers with their academic output, regardless of a change of affiliations or names.

The ORCID is far from the first of its kind in attempting authorship disambiguation. Over the years, many publishers have issued log-in names or unique IDs to submitting authors. There is also the ISO-certified International Standard Name Identifier (ISNI) which is the ‘global standard number for identifying the millions of contributors to creative works and those active in their distribution, including writers, artists, visual creators, performers, researchers, producers, publishers, aggregators, and more’.⁴ ORCID is the academic or scholarly equivalent of ISNI and the two systems have issued a joint statement on interoperation.⁵

Claiming uniqueness ‘in its ability to reach across disciplines, research sectors, and national boundaries and its cooperation with other identifier

systems',⁶ ORCID is supported by major players from different sectors including universities, research organisations, scientific societies, and publishers. Most publishers, including Wiley & Sons, Nature Publishing Group, Elsevier, and Thomson Reuters have integrated ORCID in their electronic submission process of peer-reviewed manuscripts.

ORCID, research outputs and databases

However, ORCID is not just used for tracking peer-reviewed publications but also less prestigious, but nevertheless important, outputs such as conference abstracts and posters, researcher contributions that may not qualify for authorship status and even social media posts. ORCID can be linked to other pre-existing publications ID such as Scopus Author ID and ResearcherID, or to a LinkedIn account. Online bibliographic databases such as Ovid (ovid.com) and Europe PubMedCentral (europepmc.org) are also now linked to ORCID.

ORCID and grant applications

Finally, ORCID is not just for researchers and publication tracking.

In January 2013, the US National Institutes of Health (NIH) subscribed to ORCID and started testing the ID's use in their grant application workflows.⁷

Another funding agency, the Wellcome Trust, is actively involved in the ORCID board. According to Liz Allen, Head of Evaluation at the Wellcome Trust:

*ORCID promises to provide funders a means to better track research and understand the impact of our funding while reducing the burden for researchers of reporting the products of their research.*⁷

With this step, ORCID completes the circle of linking researchers with their grants and outputs.

In the future, we may expect ORCID to become a gold standard in research and lead to the development of new quantitative metrics for the evaluation of scholarship and scientific merit.²

You can get your unique ORCID for free at orcid.org (Figure 1). In the next issue, we will bring you some tips on how to use your ORCID to optimise your professional profile online.

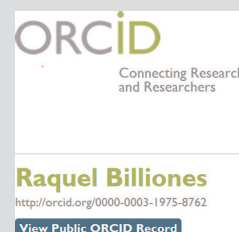


Figure 1: Getting an ORCID is quick, easy and free of charge. Screenshot is used with permission from ORCID and the Creative Commons license.

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Freelance Foraging

Kathryn White saw this unusual menu item in Mallorca over the summer. Served in a bun with chips is perhaps the best place for them!



Erratum

In the Bookstores, *The Spirit Level* Reviewed by Sam Hamilton

<http://dx.doi.org/10.1179/2047480613Z.000000000123>

We would like to acknowledge an error in the above book review published in Vol. 22 No. 3. The correction has been made to the online version of the article. The review author should have been listed as:
Sam Hamilton

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The Light Stuff

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A call to abandon the useless anachronism of the 'define at first use' rule for abbreviations

Definitions

CTD - Common Technical Document (dossier submitted for marketing authorization)

eCTD - Electronic Common Technical Document

QC - Quality Control (process of checking consistency in documents just prior to finalization)

I was asked to give a workshop recently which involved discussing the eCTD and how this differed from a paper CTD. It occurred to me that although I haven't worked on a truly paper CTD in many years and we live and work as medical writers in what is an essentially completely electronic environment, it is astounding how many writing habits we all have which are surviving anachronistic remnants of the paper age. Although there are a number of these, today I would like to draw your attention to one of



the most pointless of these which costs all of us considerable wasted time and nerves for no benefit whatever - defining abbreviations at 'first use'.

If you think about this for even a moment, it must be obvious that this rule only makes sense if you read a document from the first page. If for whatever reason you don't start at the first page, you run the risk of missing that all-important 'first use' and therefore being unable to find out what an abbreviation actually means. Most competent medical writers have long since taken up the very sensible habit of including a list of abbreviations at the start of any document to ensure that no matter where you are or start reading in a document, you always know how to quickly find the meaning of any abbreviation without long and frustrating searching through the text for the 'first use'. But despite this much more sensible alternative, most of us still spend a ridiculous amount of QC and editing time searching for and defining every abbreviation at 'first use'.

Do we do this because we are all masochists? Actually, I believe that this is simply an old-fashioned habit that we all seem reluctant to abandon, despite its obvious lack of any utility. Here is a suggestion that could save all of us endless writing and QC time searching for a 'first use' which will undoubtedly change with the comments in the next review cycle. Any client or author who still asks for this should simply be directed to the list of abbreviations at the start of every document and informed that, in fact, we are still following the rule, it just so happens that 'first use' is the same for every abbreviation - it is the list of abbreviations!

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Answers to Medical Writing Jumble #9:
EVENT, UNMEAS, SUGAR, and EFFECT.
'As a lot of the funding in the Life Sciences
department was going to neurobiology, the bota-
nist was turning GREEN with ENVY.'