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Medical Writing



Medical Communication

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EUROPEAN MEDICAL WRITERS ASSOCIATION



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Medical Writing is the official journal of the European Medical Writers Association (EMWA). It is a quarterly journal that publishes articles on topics relevant to professional medical writers. Members of EMWA receive Medical Writing as part of their membership. For more information, contact mew@emwa.org

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Medical Writing

Medical communication writers: Who are they and what do they do?

Amy Whereat, Guest Editor

For many EMWA members, the meaning of medical communications is a bit hazy. In this issue, we have invited various medical communications specialists to explain who they are and what they do. Their articles will illustrate a few of the varied angles of this somewhat heterogeneous specialty.

What is medical communication?

Medical communications, sometimes referred to as “MedComms”, encompasses many different activities that can range from publications, to congress presentations, posters, advisory boards, satellite symposia or standalone meetings. Nevertheless, from a medical writing perspective, it is really all about producing a text that contains a few well chosen key messages, which has a specific purpose and is for a particular audience. Like regulatory writing, MedComms writing is tremendously varied in terms of medical specialty, text and readership, yet also follows certain norms and is supported by a

growing number of guidelines. MedComms writing is tremendously varied in terms of medical specialty, text and reader.

Who are medical communication writers?

MedComms writers come from diverse backgrounds, indicating that the skills required for this area are

highly transferable from either academia or industry. Most have a scientific background and are usually highly qualified. Some work for agencies, others in-house and an increasing number turn to freelancing.

MedComms writers are very flexible. They love to delve into one scientific area, pull out the essential information and then dive into another. They usually juggle several projects at the same time. Sound familiar?

What do medical writers do?

As MedComms is the interface between clinical research and promotion, the need to understand marketing and communication is paramount. For an academic group, this might mean communicating their research, increasing the profile of their research group or international renown. However, for a pharmaceutical company, marketing means ensuring that doctors and other health professionals have access to and know about the medicines and devices they have developed.

Pharmaceutical marketing is about choosing appropriate strategies to make their products available. This involves a mix of pricing (reimbursement), packaging or place (choosing where best to sell the product or device). Not all medical products are bought in a pharmacy with a prescription. Some are sold directly to hospitals, others to specialised clinics or even a supermarket. One part of the marketing mix is communication, the specific activities by which companies communicate to their clients and stakeholders about a disease area, a service or a product. Communication strategies are sometimes developed in-house but are more often developed in collaboration with an agency or a medical communications consultant. Specific activities are chosen depending on the communication objectives (what needs to be said) and the needs of the end user or prescriber (who are you talking to, where and when?).

Classical medical research communication activities include



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Medical communications, sometimes referred to as “MedComms”, encompasses many different activities that can range from publications, to congress presentations, posters, advisory boards, satellite symposia or standalone meetings.

publications, posters and international symposia. However, the pharmaceutical industry has developed other activities such as sponsored satellite symposia, advisory boards, or stand-alone meetings. These activities facilitate discussion between opinion leaders, researchers and sponsors. They also provide a forum for experts to share their ideas and build guidelines and recommendations, foster continued research or share experiences. Medical communications

writers are involved in all these activities from planning the event to writing or checking slides as well as producing brochures or even publications from these meetings. Native English writers can (and should) also work closely with non-native speakers to ensure that their voice is heard and that their knowledge does not get lost in translation.

I would like to thank all the contributors to this special edition who have shared their advice, experience and precious time. I would also like to thank our fearless editor Phil Leventhal for, firstly, raising the profile of MedComms within EMWA and, secondly, giving me the opportunity to orchestrate this edition. I’ve had the pleasure of meeting some very talented and enthusiastic people along the way. I hope this might elucidate some aspects of medical communications writing and perhaps even inspire some interest to get more involved in this exciting front in medical writing.



Kent Careers’ Fair – Entry into the Industry

On Wednesday January 20, 2016, Canterbury Christ Church University Life Sciences students were given the opportunity to discover potential career opportunities in life sciences at a fair organised by their department. We were able to network with the other presenters, who portrayed two aspects of careers within life sciences. On the one hand, pharmaceutical industry recruitment agencies and various suppliers were represented, and on the other, there were ecology organisations such as the National Trust and some local wildlife conservation trusts. I focused on presenting pharmaceutical industry careers within regulatory affairs and medical writing. It is always a pleasure to present aspects of a job I have done for nearly 20 years to young people embarking on careers in science. Visitors were keen to ask questions and we covered many topics including pharma in the news, how benefits and risks of medicines are monitored and balanced, and what a job would include on a day-to-day basis.

Questions included how graduates first enter the industry; the advice given was to approach individual pharmaceutical companies for intern posts

and summer jobs. The Life Sciences course at the university is developing a drug development module, and it was a chance to think a little from an employer’s point of view as to which skills could best be nurtured during their time in Canterbury. It made me think that EMWA Professional Development Programme and TOPRA’s (The Organization for Professionals in Regulatory Affairs) Basics of Regulatory Affairs course both offer elements that could be incorporated into a suitable module.

It is always energising talking with young people looking forward to their careers and their enthusiasm was quite delightful, as evidenced by all my EMWA and TOPRA literature disappearing into their hands. I left hoping that the industry is ready to train these bright young minds and make the most of a new generation of life sciences students.

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EMWA News

EMWA team responds to ICMJE requirements on sharing clinical trial data

In January 2016, the International Committee of Medical Journal Editors (ICMJE) proposed requirements on sharing clinical trial data, in Darren Taichman's editorial, *Annals of Internal Medicine*.¹ The ICMJE stated its belief "... that there is an ethical obligation to responsibly share data generated by interventional clinical trials because participants have put themselves at risk. In a growing consensus, many funders around the world – foundations, government agencies, and industry – now mandate data sharing". The editorial outlined ICMJE's proposed requirements to help meet this obligation, and encouraged feedback on the proposed requirements at www.icmje.org by 18 April 2016.

In May 2016, comments on the ICMJE's proposal were provided directly to the corresponding author, Dr Taichman, by an EMWA team that included members of the EMWA Regulatory Public Disclosure Special Interest Group (Christopher Marshallsay and Tracy Farrow) and the Budapest Working Group, developer of CORE (Clarity and Openness in Reporting: E3-based) Reference (Art Gertel, Sam Hamilton, and Tracy Farrow). Dr Taichman confirmed that 'EMWA's thoughtful comments ... will be shared with the ICMJE group.' EMWA's comments are available at: http://www.emwa.org/Documents/EMWA_comments-ICMJE_proposals-09may16.pdf.

Further EMWA contributions to the discussion on this topic can be seen at Retraction Watch² and on the LinkedIn pages for EMWA³ and The Publication Plan.⁴



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Templates for clinical study protocols: Where are we?

In contrast to clinical study reports, hardly any formal guidance for document structure has been available for clinical study protocols (CSPs). The resulting lack of consistency

across CSPs presents challenges, especially in times of the ever-increasing complexity of clinical trials. This situation is set to change, with two authoritative initiatives releasing in parallel one CSP template each.

SECTION EDITOR



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Early in 2016, TransCelerate BioPharma launched its "common protocol template",¹ which provides a heading structure and common text expected to be used across CSPs. This initialcore template is accompanied by a set of text libraries for specific areas (e.g. diabetes, asthma). TransCelerate views its common protocol template as a foundational element in the longer-term movement towards an electronic protocol. As stated on TransCelerate's web site, recommendations for modifications in future releases of the common protocol template can be submitted at any time and will be reviewed on a routine basis.

Members of the Budapest Working Group (Tracy Farrow, Art Gertel, Walther Seiler, and Sam Hamilton) have already submitted preliminary comments.

Only a few weeks later, on 18 March 2016, the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) jointly released their own draft CSP template for public comment.² The template contains instructional and sample text; its heading structure differs from TransCelerate's common protocol template. The open comment period for this draft version closed on 17 April 2016.

This parallelism of two major initiatives on the same complex topic was unexpected. Yet, any medical writer interested in the challenging subject of CSP structure should keep an eye on both initiatives.

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President's Message

Dear EMWA Members,

Our Munich 2016 Spring conference was a great success that showcased a mature association leading on important topical issues. EMWA's outward-looking perspective developed over the past couple of years is the focus of my final President's Message.

EMWA has set new standards with the publication of the CORE Reference (Clarity and Openness in Reporting: E3-based) – the outcome of a 2-year enterprise. This open-access resource to support authoring of

clinical study reports for interventional studies can be downloaded from: <http://www.core-reference.org>. In addition, EMWA's involvement in 2016 with external protocol template initiatives has come about because we are now a recognised and respected industry player.

Two Special Interest Groups (SIGs) – the Pharmacovigilance (PV) SIG and Regulatory Public Disclosure (RPD) SIG – allow experienced members to engage in important 'conversations' in developing areas with external industry counterparts and regulators. Stay updated through the dedicated EMWA web pages.

The Expert Seminar Series (ESS) provides experienced and senior professionals with an in-depth perspective on cutting-edge topics. ESS has the effect of returning experienced members to conferences and thereby encouraging cross-fertilisation of ideas that benefit all members.

EMWA's influence and reach are increasing as a direct result of these, and other, initiatives. Your voluntary efforts have contributed to the success that we all share.

In Munich, I stepped down as President and handed over to Alison Rapley. Welcome to the new Executive Committee members, Abraham Shevak, Vice President and Marian Hodges, Education Officer. Good luck to the new EC and you, as together you shape the EMWA of the future.

Finally, "thank you for having me", to all of you, and especially to my wonderful and highly professional EC colleagues who have supported, challenged and accepted this (sometimes) outspoken Yorkshire woman with smiling good grace and the gift of friendship.

Best wishes,

Sam Hamilton

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Dear EMWA Members,

Firstly, I would like to thank Sam and the rest of the EC for sharing their experience and ideas with me over the last 12 months, and for making my job as Vice President both enjoyable and productive.

The last few years have seen the development of a number of new initiatives for EMWA including, the ESS programme, the development of two new SIGs, the development and publication of the CORE Reference by the Budapest Working Group (BWG) and further development of the webinar programme with a monthly programme of live webinars.

In order to ensure initiatives such as these are sustainable and continue to develop, one of our main aims this year will be the streamlining of the behind the scenes infrastructure of the organisation. This will make life easier for the EC, Head Office and all our volunteers. We have already begun with the development of a document repository available to all EC members via the website, and the development of standard formats and templates to increase efficiency.

We are already planning for the next conference in Brussels in November, and for the 2017 conference in Birmingham to include a symposium on Public Disclosure and a full ESS programme.

All of this involves a lot of work behind the scenes, something that I have been made very aware of during my term as Vice President. We are a voluntary organisation and need you to get involved. The more volunteers we have the less pressure there is on existing volunteers.

Finally, I send my best wishes to our new EC members, Abraham Shevak and Marian Hodges. I look forward to working with both new and longstanding EC members and our many volunteers over the coming 12 months to ensure our organisation continues to prosper.

Best wishes

Alison

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Suggested reading in recent issues of *European Science Editing*

Among the highlights of the November 2015 issue of *European Science Editing* (ESE) is an essay on whether interpretation of research ethics is universal. Writing from an Iranian perspective, Behrooz Astaneh describes how cultural norms and inadequate financial means are used by some to justify practices that we in the West would consider unethical, such as guest authorship and the fiddling of results.¹ He also speculates that the burden of international sanctions might encourage Iranian researchers to rationalise unethical behaviour as ethical.

Elsewhere, Duncan Nicholas highlights how scientists have been slow to embrace social media, before going on to explore how social media can be harnessed to facilitate research, communicate research findings to the public, and scrutinise published research.² He also looks at the potential use of alternative new metrics to assess both the spread of research findings on the internet and the active contributions of researchers to this dissemination.

ESE kicked off 2016 with an important piece on how to deal with major mistakes in scientific papers.³ Hannah Cagney of the *Lancet* and her colleagues argue that simple retraction is too punitive, and an erratum inadequate, for papers that contain serious errors but are otherwise valuable. Instead, they propose a system of “retraction and republication”, whereby the original version is retracted and a corrected version published in its stead. Annotated copies of both versions with the errors highlighted are maintained in an online appendix.

In the same issue of *ESE*, Michèle Nuijten tries to solve the problem of statistical errors in the literature.⁴ Her solutions include encouraging journal editors to use software such as “statcheck” (the author’s own creation) to scan papers for errors. She also advocates increased data sharing. This is a hot topic: the ICMJE (International Committee of Medical Journal Editors) recently proposed mandatory sharing of de-identified patient data within 6 months of publication.⁵ Nuijten’s third suggestion – preregistration of clinical trials in an online registry – is already an ICMJE requirement.⁶

Finally, editor-proofreader Paul Beverley advises on creating stylesheets to maintain stylistic consistency in Word documents and



ensure adherence to house style.⁷ He presents his own macros for checking hyphenation, spelling, punctuation, and capitalisation (among other things).

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Medical affairs writing: A key role to relay medical information to everyone

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Abstract

Medical Affairs is a link between the scientific and marketing units of a pharmaceutical company. Medical writers in this field are responsible for writing varied document types from regulatory reports to scientific publications, and marketing supports. Sources of medical information include scientific literature, pharmaceutical company internal data, and regulatory guidelines. For each of these documents, the final reader is different. Consequently, the key message and writing style should be identified and adapted accordingly. The medical writer has a responsibility to ensure that the right medical information is relayed to the target reader.

Introduction

The scope of the term 'medical affairs' varies between pharmaceutical companies nevertheless, it is a delicate role that balances scientific and clinical research information with communication activities for sales and marketing needs. From the scientific side, medical affairs means highlighting the right data in the right context required for prescribers to correctly use the product. And, from the marketing side, it means enforcing regulatory requirements that sometimes constrain more attractive



wording for advertising.

Pharmaceutical companies have a responsibility to sell high-quality, effective, and safe products for treating illness or relieving patients from pain or symptoms. However, they need to clearly communicate accurate information about their products to their customers (practitioners and patients). Medical information is also provided by health authorities and general public media. Medical writers are well placed to ensure that this information is communicated appropriately and ethically.

What type of documents are written?

Depending on the size and structure of the company, essentially any document linked to drug development may be required to be

“Medical information comes from everywhere”

written at medical affairs, from preclinical to post-marketing documents as well as, communication brochures and conference or sales materials. An example of documents is listed in Table 1.

What are the sources of medical information provided for patients/practitioners?

Medical affairs writers are involved in creating content for a variety of channels. Increasingly, internet sources, scientific internet databases (e.g. Pubmed/Medline or TOXNET) have become the first entry point for practitioners to obtain a better knowledge of a therapeutic area. Health authority websites provide more specific treatment guidelines and recommendations based on robust meta-analyses practices in



the therapeutic area. Moreover, professional societies give additional details on the current practice established with literature, practitioner’s perception of real life, and surveys. Patient websites delivered by clinics or by pharmaceutical companies also deliver comprehensive information for patients. Lastly, practitioner and patient forums can provide anecdotal information to highlight a misunderstanding, miscommunication or lack of medical information.

What are the sources of medical information for medical writers?

Medical affairs writers have a plethora of different source types to use in creating medical information. Information concerning efficacy and safety come from the clinical development programme, such as

Reader Document	Health Authority	Key Opinion Leader	Scientist	Practitioner	Patients & General Public
Marketing Authorisation dossiers, study protocols and reports, oral defence, safety reports	X				
SmPC, package insert/ leaflet	X				X
Specialised/ generalised articles		X	X	X	X
Abstract, poster, oral presentation for congress, conference brochures, information meetings		X	X	X	
Advert support (sales guides, website, journal, television)	X	X	X	X	X

Abbreviations: SmPC, Summary of product characteristics.

Table 1. Examples of documents and their target readers.

clinical study reports, publications, and other research data. However, many studies now also collect other types of data, such as from patients concerning their opinion about the efficacy or safety, their adherence to the intervention, or changes in their quality of life. Quality of life questionnaires provide valuable data on how a product affects the patient’s daily life, a non-negligible aspect that goes beyond clinical efficacy. This type of data is useful for writing patient materials. Specific populations (e.g. elderly or hypertensive patients) will be concerned by clinical data such as efficacy of a drug in their population but are also particularly interested in the adverse events or risk-benefit profile. Other (often forgotten) sources include preclinical studies, post-marketing pharmacovigilance data, and sometimes marketing research data. Preclinical studies, such as *in vitro* or *in vivo* models, can provide evidence about mechanisms of actions that lead to product efficacy or safety. Moreover, images from *in vitro* studies can illustrate certain concepts. For example, a drastic increase in immunofluorescent cell number due to an effective

drug is more meaningful for people than a schematic graph. Pharmacovigilance can highlight adverse reactions or susceptible sub-populations, often leading to post-marketing surveys.

Post-marketing data obtained from practitioners or patients may reveal information about the product that did not surface during clinical development. Post-marketing studies can also be useful for evaluating the impact of an identified risk, a new indication or a new technique to complement scientific data on the product. Market research data can help position the product regarding its use in the therapeutic arsenal available to practitioners and patients. It is essential that practitioners have a good knowledge of product characteristics when prescribing new products. However, patients also need to be adequately

informed about managing side effects to ensure they continue to adhere to the treatment. Questionnaires regarding patient satisfaction and the commercial experience due to the direct contact with the clients are essential for understanding the product market. Medical affairs writers

“Medical writers require interdisciplinary skills in order to fully understand data sources and to highlight the key medical information”

“Medical writers have a key role for adding value to product and pharmaceutical company perception”

need to take these different sources into account and weigh their level of evidence carefully with the key communication messages.

How do medical writers transmit the medical information?

Who is the target reader and what is the key message?

Like any document, before writing, the first question to ask is “Who is the final reader of this document?” Some examples can be found in Table 1. The writing style and vocabulary should be adapted to the reader to be meaningful. When writing for patients for example, many technical and scientific terms are inappropriate. For example, the term “headache” is preferred to “cephalgia” for patients or practitioners whereas “cephalgia” may be preferred in a specialised published article. The second question one should ask oneself is: “What is the key message is to be communicated?” The clearer your message the better the readers will understand. To ensure that the message comes across clearly, particularly for non-native speakers of English, simple sentence structure is paramount. The vocabulary can be adapted to the reader where specific medical terms can be replaced with common terms for a given text. Involving the medical affairs writer should be critical in the process of key message development as they provide the link between the data and the communication objectives. The medical affairs writer adapt their writing style to transparently convey the scientific content and to best present the marketing tone and the company image.

How to write and what help do you have?

Each document is written in a particular style. Regulatory dossiers are written in simple direct informative style, whereas scientific articles tell a story about the research performed. Sometimes specific sentences or key words are recommended. For example, standard statements need to be followed, such as, “X is contraindicated in children aged x to y <years, months> <or any other relevant subsets e.g. weight,

pubertal age, gender> <in the indication ... > (cross-reference to section 4.3).”¹ Guidelines for writing the Common Technical Document (e.g. safety part) or Clinical Evaluation can be found on the ICH or European Commission websites.^{2,3} For publications, instructions for authors are available on journal websites, and several guidelines are available such as GPP, CONSORT, STROBE, and ICMJE.⁴⁻⁹ The EASE guidelines provide some useful tips for non-native speakers of English. Lastly, to improve readability, medical affairs writers can apply many of the plain English language techniques such as simple sentence structures, to their documents.¹⁰ Concise language, specific tone adapted to the audience, clarity in wording and presentation are the main components for relaying your key message and answering your readers’ expectations.

Conclusion

Medical affairs plays a key role in effective communication of medical information to various target readers guaranteeing the scientific value. Moreover, the appropriate, unbiased scientific and clinical published data is a bonus for the good image of pharmaceutical companies.

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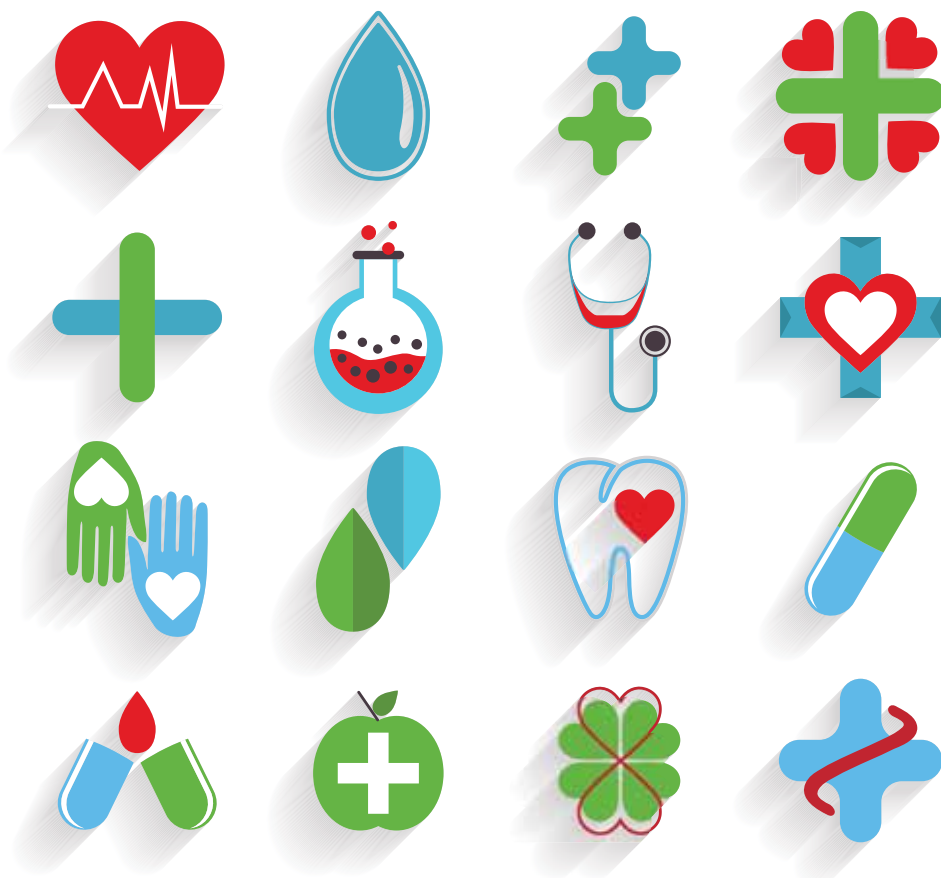
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Author information

Before starting out as a freelancer in 2015, Marie-Odile FAURE, PhD was Head of Medical Affairs in a pharmaceutical company. She provides expertise and writes scientific and medical documents.

Top ten questions about careers in MedComms



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Abstract

NetworkPharma has been running a series of careers events and workshops aimed at entry-level jobs in MedComms, and publish a careers guide, *From Academic to Medical Writer*, which is updated annually in March. In this article, Peter Llewellyn from NetworkPharma, and Annick Moon, author of the careers guide, answer some of the most prevalent questions asked by entry-level candidates at the workshops they have attended over the past decade. The areas covered focus on jobs in MedComms, particularly medical writing in the UK.

Introduction

For almost a decade, NetworkPharma has been running a series of careers events and workshops aimed at entry-level jobs in MedComms, with a focus on medical writing. Events held in Oxford, Manchester, and London, have provided scientists with the opportunity to learn more about writing and other careers in MedComms and to meet industry experts. Details of all events, past and future are freely accessible at www.FirstMedCommsJob.com

Careers events and the MedComms community

The portfolio of events in collaboration between NetworkPharma and the Oxford Medical Sciences Division of the University of Oxford are now an embedded feature of the careers calendar, and are open to Oxford University students and staff, as well as students from other universities, and people working in relevant industries. The annual Lunchtime MedComms session in January kicks off the year with presentations from industry experts and exhibitions from agencies. The careers guide, *From Academic to Medical Writer*, is updated annually in March, and in response to the success of the previous Careers Insights workshop, from May 2016, a new one-day event will be held to provide the opportunity for attendees to discuss MedComms face-to-face with prospective employers.

In this article, Peter and Annick answer some of the most prevalent questions asked by entry-level candidates at the workshops they have attended over the years.

Ask Peter

1. What is MedComms and what do the agencies actually do?

This is where all the conversations start and it's more or less impossible to answer unambiguously! If you line up several MedComms specialists and ask that question you can get very different answers. This is one reason we prioritise the 'meet the

agencies' sessions at our careers events. Anyone wanting to pursue a career in MedComms should understand the wide range of services that are encompassed and that agencies can have very different approaches and cultures.

In essence, we say; 'Medical communications provides consultancy services to the pharmaceutical industry to help raise awareness of medicines.' We then go on to describe how, under this over-arching description, the MedComms agencies specifically have their roots in medical education, and traditionally produce the more highly technical scientific materials such as journal manuscripts for peer review, learning resources, slide kits, and posters and presentations for conferences. Much of this work, by definition, involves working closely with external experts. In principle it seems easy to draw a line between MedComms and the more marketing-led agencies such as branding and PR at one end and the more arms-length, accredited continuing medical education (CME) providers at the other. In practice, though, the edges are often blurred and many MedComms agencies are a part of broader communications groups that enable them to work beyond those edges anyway.

For many though, the absolute truism is that in MedComms the accuracy and robustness of the data is paramount and it is a business community that is heavily dominated these days by post-graduate level writers who are well equipped to understand, interpret and communicate the science appropriately to the intended audience. Increasingly the work is led within client companies by medical affairs teams rather than marketing teams, and it's a feature of the MedComms community that most individuals are working at an international level, usually commissioned by head offices of the global pharma companies.



2. So, what should I consider when looking for an entry-level writing job in MedComms?

It's unlikely, though not entirely unknown, that an entry-level writer will work from home from the start. Most agencies will expect their new staff to be based in the office initially at least, learning their craft. So aside

from practicalities like where those work opportunities are based, the key message is that a trainee writer's job descriptions may sound similar from different agencies but the day-to-day work experiences can be quite different. So, one way or another, gain insight into as many different agencies as possible, and try to identify what best suits you, before taking the first job.

You'll find agencies that are small, independent and privately owned, where the Directors sit across a desk from you and where it's case of all hands on deck when any deadlines are to be met, which is a lot of the time. Other agencies are bigger and more formally structured with cross-functional teams operating on long established programmes quite independently of each other. Some agencies have developed particular specialisms perhaps in therapy areas such as oncology, or in terms of their outputs, for instance publication planning, events management or digital type work. Some will pride themselves on being 'full service agencies'. In some agencies the writers do much more client-facing work than in others where account managers will take that role.

A good question to ask a prospective employer is, what training opportunities are on offer? In many cases most training will be done on-the-job led by your more experienced colleagues. In some agencies there are formal training programmes and induction periods, in others less so. Some will encourage you to attend external courses such as those offered by EMWA, others will be less

inclined. It is less a matter of size and age, and more of culture. No one approach is better than another overall, but certainly may be so for any one individual. So again, aim to find the best fit for you.

3. Do agencies offer paid internships, work experience or shadowing opportunities?

It's a personal soapbox of mine that more MedComms agencies could offer more such opportunities. In reality, though, most don't. Most will say the reality is that their employees are too busy with deadlines constantly looming and that it's not fair on either the existing staff or on the individuals looking for genuine work experience to subject them to that added pressure. Having said which, some agencies are now introducing more formalised paid internship programmes, which can then lead to a full-time job, and we do what we can to highlight these via the information service at www.FirstMedCommsJob.com

There's no harm in approaching the agencies directly but it can be difficult to find the right person to contact and the right time to do so when they are so busy. Networking one way or another via careers events and your own contacts can be a valuable way to find those opportunities.

As a general point, I'd say this is a very competitive business to enter and any opportunities you can find to demonstrate your writing skills and aptitudes are worth grasping enthusiastically. So you might offer to help your colleagues with their presentations and papers, or volunteer to help with a specialist publication. These days there are plenty of opportunities to contribute to online resources and, for instance, to blog about your own interests.

The posts don't have to be directly related to medical science let alone your own fields of interest. Be aware, though, that even social media posts can and will be spotted and then scrutinised for grammatical errors and typos!



4. What are the entry requirements for a medical writer in MedComms?

You'll meet many successful writers in MedComms who don't have a PhD or other post-graduate qualification, but they tend to be the ones who joined MedComms a while ago. Today it's fair to say there is an emphasis on employing entry-level writers with at least a PhD and maybe post-doc experience. It's even fair to say there is a drift overall towards employing that same level of staff in account management roles, though there the backgrounds are much more varied.

If you don't have the post-graduate qualifications, you will probably need some good experience, maybe in publishing or the pharmaceutical industry.

On the positive side, for those of you with a PhD, this is a business area that welcomes your experience. Above and beyond the scientific and technical expertise and analytical skills you bring, you will also have valuable transferable skills from your experience of writing, presentations, project management and team working.

One key message, though, is that MedComms, like any agency business thrives on people and their people skills and the chemistry between people. You'll never be working alone; you will be working in teams and for clients on a potentially wide range of varied projects. The skill of the interviewer is seeing beyond the obvious skills and qualifications on paper. Your aim is to get the interviewer to take notice of your unique offering.

5. What are the longer-term career opportunities for a medical writer in MedComms?

It's not so long ago that MedComms was regarded as an invisible business and you'll meet many writers who say they simply stumbled into it. That has changed, much more information is available and people joining now can see quite formalised career pathways stretching ahead if they want them. It also offers lots of flexibility, though, once you have entered and, of course,



offers some people the opportunity to gain some very valuable skills they can then go on to offer as freelancers, for instance. But within the agency community now, typically a new medical writer will join in a trainee capacity, maybe as an associate medical writer, and continue and progress within writing departments to reach principal writer and editorial team leader positions. Others will move to roles that are less about writing and more about managing and directing accounts, for example. In many companies there is also opportunity to move within the bigger communications group to allied services or to move countries. It is, after all, a growing, global business.

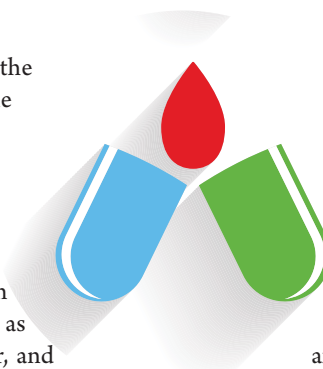
A key message is to remember that once you get that entry-level role, the rest is down to you. There is no real barrier to what you want to do or what you can achieve. My advice is always aim to get as much experience as possible, and put the effort in, and you'll find this a great business to be in if you like science but maybe aren't so keen on the lab work. The opportunities are boundless and the rewards likewise, financial and intellectual.

Ask Annick

6. What can I expect in the writing test?

You need to impress the agency with your CV and covering email, and maybe in person at a careers event, before you'll be sent a writing test. Then to make it to interview for a writing job, whether as a trainee or a senior writer, usually, you need to do a writing test. If you're a newbie, to get this far, you've probably done your research into MedComms agencies so you should be familiar with the types of writing you'll be expected to produce.

What agencies are usually looking for in the writing test is whether you can take scientific information



about an illness you probably know nothing about and communicate it to a specified audience. MedComms agencies usually want people with a strong scientific background, the ability to follow a brief, and excellent language skills. The aim of the writing test is to assess your analytical skills and your aptitude for writing.

The standard of writing among successful candidates is high so you need to check everything you send to the agency carefully. An initial writing test brief is often designed to take about 1–6 hours, although it varies widely, and as a general rule, add on a few hours to the time they suggest it should take you. If you get to interview, be honest about how long the test took. It won't be a negative if it was much longer than specified; they'll likely just be interested to know. Don't be tempted to ask a mate in the industry to proof-read your writing test because if you get the job, depending upon how bad your writing is, they'll uncover your scam.

7. Can I get examples of writing tests?

Practicing your medical writing before applying for your first writer job is difficult, and for many newbies, the first time they do any proper medical writing is the writing test. This was my experience, so whenever I'm asked this question, I describe the two writing tests that I've done.

The first writing test I did was after I'd been working in my first medical communications job as an editorial project manager and I applied for an entry-level medical writer job at another agency. I was sent about fifteen abstracts about hypnotics in insomnia and asked to review them. The review took me twice as long as specified and I got an interview. They gave me feedback on the test at the interview, which was horrifying: spelling mistakes, random commas, and other crimes against writing, which ordinarily, so I was told, would have been an instant fail. However, instead of summarising one abstract after another as

apparently most of the other candidates had done (and what I would have done if I'd thought of it), I read the material and then presented the information by subcategory, added an introduction, discussion, conclusion, and title. They liked how I'd approached the brief, and I was given the job, with the caveat that I had a lot of training to do. This large MedComms agency then sent me on several training courses and I got lots of writing experience.

After nearly two years in the industry, I applied for my next medical writer job. For the writing test, I was sent information about administering parenteral antibiotics in a home-setting. They wanted a 1200-word article aimed at nurses. I bought a couple of nursing magazines and journals and read the articles in them. Then I wrote an article in the same style using the background materials they'd sent me. I gave it to a writer-mate to proof-read and she hardly found anything. I got the job.

To summarise:

1. Read the brief and list the items to be covered;
2. Go through the background materials provided and match up the info with each point in the brief;
3. Read other articles aimed at your audience and then pitch your article in the same way.

8. Will I get feedback on my writing test?

If you get an interview, they'll probably give you feedback on your writing test and discuss areas they think you'll have to work at to improve your writing. If you don't get an interview, it's unlikely that the agency will be willing to comment on your test. It may be frustrating if you've spent ages writing an article and then you get rejected with no feedback, but keep trying. If you are asked to complete a writing test several times, yet never get offered an interview, you may want to consider applying for other entry-level agency jobs, and then once you're in, explore the options of becoming a writer.



9. Can I work from home as a medical writer?

It would be usual for a trainee writer to be office-based although the arrangements for home workers at MedComms agencies differ. If the home-working policy at the agency isn't mentioned in the job description, then it may be worth discussing at the interview.

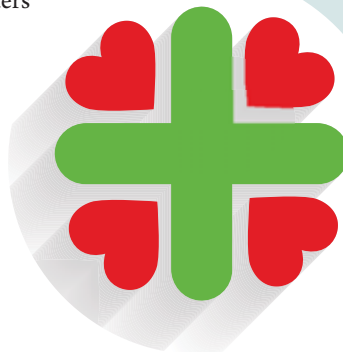
But remember that agency life is fast-paced and you'll be expected to attend client meetings and conferences, which involves a lot of travelling. As a new writer at a MedComms agency, it helps to be within reach of a major airport.

If working from home is attractive to you, then medical writing is a good career option. In general, you need a few years' experience before becoming a principal writer and moving to your luxury garden office in an area with good schools.

10. How do I get into freelance medical writing?

I get asked this by all sorts of people who are keen to jump into freelance writing. My reply is usually that medical writing is a profession, so ideally you need to have an extensive medical writing portfolio before embarking on a freelance enterprise. If freelancing is your long-term ambition, then keep it quiet to start with, i.e. don't mention at the interview. It costs a lot to train a writer, so agencies tend to try and hang on to them, meaning that the opportunities in MedComms may make you re-think your freelance plans once you get established. It's a tough choice:

1. Lead a team of writers from an office;
2. Sit alone in your pants writing fabulous articles.



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Conflicts of Interest and Disclaimers

Peter runs numerous events and publishes a range of information services for individuals working in and around the MedComms business, funded by the community of MedComms agencies. Annick provides freelance consultancy services to the MedComms industry.

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Dr Annick Moon is Director of Moon Medical Communications Ltd and has provided communications consultancy and writing services to the pharmaceutical industry for over 15 years.

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Staying ahead of the game in the changing arena of ethical medical communications – Viewpoint of a freelance medical writer

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Abstract

Laws, regulations, pharmaceutical industry codes of practice, and other guidelines play an important role in ethical medical communications. When working on medical education programmes and materials, a professional medical writer must not only consider audience, timelines, and potential content to fulfil client briefs, but also ensure alignment with the appropriate regulations. For medical writers who are freelance, staying informed of evolving laws/codes of practice is essential but may feel like a challenge. However, in an era where information is accessible 24/7, staying ahead of the game is not an impossible task.

Laws, regulations, and guidelines in med comms – A daunting prospect?

Laws and regulations that guide interactions between the pharmaceutical industry and healthcare professionals (HCPs) play a significant role in medical communications. On the surface, these wordy, complex documents and lists of ‘rules’ may appear somewhat daunting to a professional medical writer or, for that matter, any medical communications specialist. However, their importance in this field cannot be understated – one minor deviation or slip from ethical guidance could result in significant ramifications for the pharmaceutical company and the HCP concerned, potentially damaging reputations and, in

turn, public confidence in the healthcare industry.

This article will examine the landscape of ethical medical communications from the personal perspective of an independent (freelance) professional medical writer. In particular, this piece will provide a general overview of typical regulations and guidelines available, and examine which of these may be considered when developing medical education materials, such as items for meetings, publications, and so forth. Finally, the question of how to stay informed of evolving laws and regulations will be addressed.

Healthcare compliance – Where to start?

Numerous laws, regulations, and codes of practice are in place that help to govern ethical, transparent, and appropriate interactions between the pharmaceutical industry and HCPs (Box 1). These include international, regional, and national association codes of practice relating to the promotion and marketing of medicines, such as those from the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA).^{1,2} These codes of practice encompass all methods of medicine promotion, including oral and written promotional activities, journal advertising, use of internet/electronic communications, and video recordings. Ultimately, their aim is to ensure that any information available to HCPs is accurate, fair, and objective, thus helping support prescribing independence and in turn benefiting patient care. Furthermore, pharmaceutical codes of practice extend beyond the realm of regulating promotion of medicines to guide interactions with HCPs/medical institutions, covering items such as fees for services and disclosure of fees/transfers of value, entertainment, hospitality, and gifts.^{1–5} As well as industry codes, there are laws that embrace the pharmaceutical sector to prevent bribery, such as the UK Bribery Act 2010 and the US Foreign Corrupt Practices Act (2012),^{6,7}

both of which have a global reach (Box 1).⁸ Pharmaceutical companies may also have their own internal standard operating procedures and codes of conduct that enforce international/regional/national codes of practice and applicable laws/regulations.

Box 1. Key pharmaceutical laws and regulations on promotion of medicines and HCP interactions*

- International Federation of Pharmaceutical Manufacturers and Associations Code of Pharmaceutical Marketing Practices¹ (<http://www.ifpma.org>)
- European Federation of Pharmaceutical Industries and Associations Codes of Practice on the Promotion of Medicines² (<http://transparency.efpia.eu>)
- Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interaction with Healthcare Professionals⁴ (<http://www.phrma.org>)
- Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry⁵ (<http://www.abpi.org.uk>)
- Other European country-specific codes of practice (available from: <http://transparency.efpia.eu/codes-of-conduct/countries>)
- UK Bribery Act 2010⁶ (<http://www.legislation.gov.uk/ukpga/2010/23/contents>)
- US Foreign Corrupt Practices Act⁷ (<http://www.justice.gov/criminal-fraud/foreign-corrupt-practices-act>)

*This is not an exhaustive list and serves to provide examples only.

The laws and codes of practice touched upon here serve as a brief snapshot of the types of guidelines that exist, and highlight how tightly pharmaceutical-HCP relationships are regulated, as well as the scrutiny under which the industry operates. As

stipulated in codes of practice,^{1,2} pharmaceutical companies must ensure that agencies/other parties operating on their behalf are aware of and comply with industry regulations. For their part, medical communication companies have compliance divisions/compliance programmes aimed at equipping all accountable personnel with the knowledge and tools required to make sure that HCP-directed activities are implemented in accordance with professional and ethical standards.

Which guidelines sit at the top of a professional writer's list?

While anti-bribery laws, disclosure codes, and similar such guidelines are important in the context of pharmaceutical-HCP interactions, the most *relevant* regulations for a writer to consider will depend on the area of medical communications in which the materials to be developed sit. There are, broadly speaking, three key areas of medical communications:

- Promotional activities and materials, e.g. sales aids, product launch meetings, advertisements/advertorials
- Educational/scientific, e.g. scientific meeting content and materials, slide decks, disease area websites, associated literature
- Scientific/clinical publications, e.g. posters, abstracts, clinical trial publications, review articles

As a general rule, typical medical writing projects 'fit' into one of these categories, although compartmentalising some projects is not always an easy task and a degree of overlap may exist.

By and large, when starting out on a writing assignment, certain questions immediately spring to mind such as 'What is the project?', 'Who is the intended audience?', 'What will the content focus on?', and 'What are the timelines/When is the first draft required?' (Figure 1). However, as medical writers, regardless of the number of years' experience accumulated, do we immediately turn to pharmaceutical-HCP interaction codes of practice and relevant laws? Whatever the answer, it

is always worth reminding ourselves of key guidance because codes of practice and other regulations are constantly evolving and, ultimately, they help determine permissible content and dictate other requirements, such as authorship criteria and inclusion of disclaimers or abbreviated prescribing information.

The following is a brief discussion of guidelines with respect to promotional communications, medical meetings, and publications. In no way is this meant to be an in-depth discussion of the do's and don'ts stipulated in the various laws, guidelines, and codes of practice. For additional information and clarification on guideline requirements and ethical communications, the reader is advised to consult the appropriate websites and documentation, as cited below.

Promotional communications

In the context of the pharmaceutical industry, promotion is any activity that a pharma company has involvement in to help encourage the sale/supply of its products.² In this regard, a medical writer may work on a variety of medical communications deemed promotional, including journal advertorials, website content, and exhibition booth panels/materials. For these types of activity, it is appropriate for pharma to follow national industry association codes of practice for the promotion of medicines (see Box 1), not only for the country in which the company is located, but also those of the country where the promotional activity is planned to take place.² The EFPIA website (<http://transparency.efpia.eu/codes-of-conduct>) contains links to national codes of practice for member associations based in Europe. A key element of all promotional materials is that content should be accurate, fair, balanced, objective, complete, up-to-date, capable of substantiation by approved labelling or scientific evidence, and consistent with the product licence.^{1,2,4,5}

Medical meetings and associated content/materials

Meetings are often a core component of medical communications and therefore may

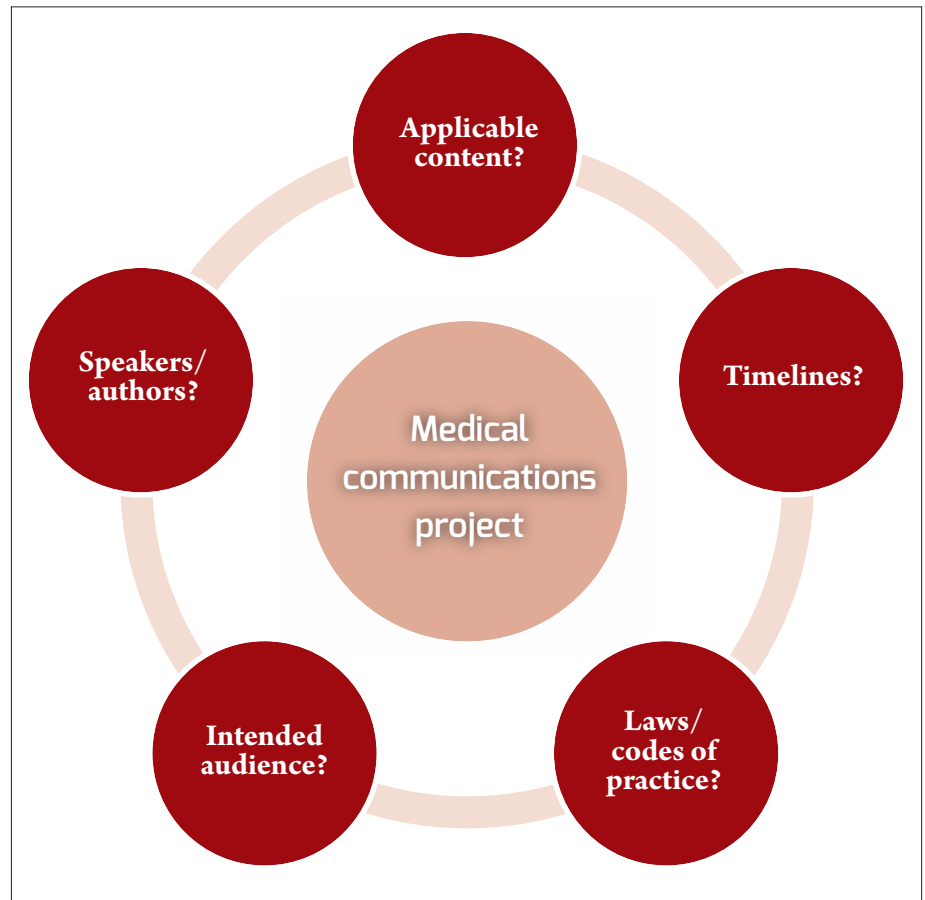


Figure 1. Questions for consideration when starting a medical communications project: Perspectives of a professional medical writer.

be central to a medical writer's daily responsibilities. Medical writers become involved in many different types of meetings (promotional, scientific, professional) supported by pharmaceutical companies, including but not limited to standalone meetings, product launch meetings, advisory boards, satellite symposia/congresses, and speaker training forums. Since most meetings will involve interactions with HCPs, complying with the appropriate national/regional guidance is necessary as there is potential for breaching rules that apply not only to meeting content/distribution of materials and associated activities, but also to speaker selection, meeting venue, speaker honoraria, and hospitality.² The industry association codes of practice include sections (clauses/articles) that focus on pharma-supported meetings, associated activities, and hospitality.^{1,2,4,5} As stated in the IFPMA Code of Practice, the purpose of any meeting organised by a pharmaceutical company and

directed towards HCPs should be to provide scientific or educational information with content that is relevant to the audience.¹

Publications

Publications and publication planning is likely to be another key aspect of a professional medical writer's role. There are numerous publication-specific guidelines on best publication practices and ethical standards, including the International Committee of Medical Journal Editors (ICMJE) Recommendations, which represent a cornerstone of authorship criteria,⁹ and the Good Publication Practice 3 (GPP3) guidelines on communicating research results sponsored/supported by the pharmaceutical industry.¹⁰ Additionally, various reporting guidelines exist for different study types, such as CONSORT for randomised studies,¹¹ STROBE for observational studies,¹² and PRISMA for systematic reviews/meta-analyses.¹³

Publication ethics is a hot topic at

present, particularly in light of publication of the GPP3 guidelines, sponsored by the International Society for Medical Publication Professionals (ISMPP), in 2015.¹⁰ Key aspects that were updated in GPP3 include (but are not limited to) guidance on authorship; author payment and reimbursement; the role of the professional medical writer; and data sharing. Interestingly, the benefits surrounding use of professional medical writers in assisting authors to prepare publications has received further attention,^{14,15} most recently following publication of a cross-sectional study that demonstrated improved clinical trial reporting and higher quality of written English in those publications with declared medical writing support.¹⁵

Guidelines and staying informed

It is usual when working in medical communications to be guided by the pharmaceutical company's internal standard operating procedures and recommendations from 'client' contacts. Furthermore, as freelance medical writers are often tasked to work on specific aspects of materials – sometimes mid-project – it may not always be necessary to consult guidelines. Nevertheless, there remains an obligation for professional medical writers to stay up-to-date with changing pharmaceutical-HCP codes of practice and relevant laws/regulations. When one considers the additional responsibilities of an independent writer in terms of business ownership it can be difficult to stay informed on such matters, but keeping abreast of evolving guidelines need not be challenging:

- During quiet times (which may be few and far between), check out websites such as the IFPMA and EFPIA.^{1,2} It is normally easy to see at a glance if there are updates. Naturally, you can also refer to these websites when working on specific projects at the start of a task/as needed.

As stated in the IFPMA Code of Practice, the purpose of any meeting organised by a pharmaceutical company and directed towards HCPs should be to provide scientific or educational information with content that is relevant to the audience.

- Consult the EQUATOR (Enhancing the Quality and Transparency of health Research) network website (www.equator-network.org) for information related to publication ethics.
- Refer to medical writing/publication association websites such as EMWA (<http://www.emwa.org/>) and ISMPP (<http://www.ismpp.org/>). Additionally, these and similar associations offer webinars, publications, bulletins, and annual meetings that support ongoing education initiatives in areas covering ethical medical communications, thereby keeping their members up-to-date on relevant laws/regulations.
- LinkedIn is a valuable source of up-to-the-minute information. Being a member of relevant LinkedIn groups, such as EMWA, ISMPP, The Publication Plan, and MedComms Networking, makes it easy to stay informed of what's new in the field of medical communications and the pharmaceutical industry.

There are likely to be other ways in which freelance medical writers stay informed of current laws, regulations, and guidelines on pharmaceutical-HCP interactions, ethical medical communications, and publications. For example, it may be necessary when working with some clients to undertake informal 'on-the-job' compliance training before an assignment commences, particularly if the freelance writer has been contracted to assist throughout the life of a project. While this is likely atypical, inclusion of compliance training as part of a project can be a valuable exercise. It would be interesting to conduct a survey among freelancers to ascertain (1) how important it is to remain informed of codes of practice/regulations and (2) what other sources of information are of value in this regard.

Conclusion

Good publication practice as well as guidelines, regulations, and codes of practice governing pharmaceutical-HCP interactions and promotion of medicines are central to professional and ethical medical communications. Such is their importance that it is essential for all those working in the medical communications sector to stay informed of evolving guidance. For the freelance/independent professional medical writer, a number of routes are available for keeping up-to-date, including membership of professional writing/publication associations and LinkedIn professional groups.

Conflicts of Interest and Disclaimers

The views expressed in this article are those of the author and should not be construed as anything more than personal opinion. The latest available codes of practice and other guidelines cited herein have been consulted. While this article discusses some codes of practice and guidelines, the reader is advised to consult relevant websites for further understanding, information, and clarification.

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A PhD and medical writing: A good match

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Abstract

The transition out of academia can involve a good deal of change. For PhDs who enjoy writing, a career in medical communications is a viable option. The field of medical writing is broad, encompassing everything from regulatory affairs, to writing and editing manuscripts, to medical education and promotion. Despite numerous novel experiences offered by medical writing, several skills typically acquired during the course of a PhD programme align nicely with the new

requirements and responsibilities. From the perspective of a medical communications agency, PhDs form an important bridge between the need for deep and thorough biomedical knowledge and the daily responsibilities of writing, editing, educating and promoting. Should one choose to apply these skills to medical writing, the result can be an interesting and enjoyable work for the PhD, and a benefit to the employing agency.

writing at a much greater frequency than once every 5-7 years. From assisting in the preparation of manuscripts for pharmaceutical-funded research to writing lengthy summaries of clinical trial results for physicians, medical writers produce documents which are at least as lengthy as an average PhD dissertation.

2. The ability to examine large amounts of data and think critically. A PhD candidate has to read and synthesise large amounts of scientific literature and to explain primary points and conclusions. Instead of focusing on the narrow speciality of a dissertation subject, however, a medical writer will often touch on numerous subjects in the course of preparing an educational module or promotional material. While not always going as deeply into a subject as during the dissertation research, acquiring a moderate level of familiarity in multiple subjects is often required. For example, a medical writer may have to write promotional material for an oncology product. In so doing, he or she would not only consult the publications detailing clinical trial results, but also those of the main competitors. Additional literature on diagnostics and the history of treatment are also necessary to put this new treatment in context. Summaries of product characteristics for approved products also contain a wealth of detailed information for comparing different treatments and explaining approved uses. Finally, clinical guidelines are additional resources to convey the opinions of

Introduction

As opportunities in academia become fewer and far between, an increasing majority of PhD recipients select careers in other areas.^{1,2} Hopefully, the multitude of skills acquired in the five or more years needed to obtain the PhD degree will be put to good use afterwards. While many pursue a career in research and development in the pharmaceutical industry and others leave biomedical research altogether, a suitable career path that capitalises on the skills obtained during PhD training is medical writing.

Medical writing spans multiple areas, from regulatory affairs to manuscript writing and editing, to medical education and promotion.³ Such jobs can be done in pharmaceutical or biotech companies, government agencies, or with healthcare communications agencies.

The following summarises the author's experience in transitioning from postdoctoral research to a career in medical writing, written with the intention of highlighting certain skills acquired in a PhD programme that transition well to medical writing.

Skills acquired during a PhD

PhDs often make successful medical writers. Among the reasons for this are the parallels between medical writing and the intense research experience in a typical PhD programme, which are not always easy to discern. These are:

1. The amount of writing involved in a PhD programme and medical writing. Most dissertations in biomedical fields are between 100 and 200 pages.⁴ This lengthy bit of writing is great training for a career in medical writing, which often requires similar volumes of technical

experts on appropriate treatment use. All these may be needed simply to promote a new medication. The structured and logical thinking involved in processing such data are important skills for a medical writer.

3. Finding creative ways to solve problems. Often, a PhD candidate will have to answer research questions by seeking novel ways of experimentation or analysis. By applying new assays or techniques from other fields, or even inventing completely new procedures, a PhD has ideally practised finding solutions from multiple sources. In meeting clients' demands to look for the most compelling way to position and discuss a product, a medical writer often has to utilise methods and information from sources outside the 'hard sciences' (see point 3 in the next section).
4. Communication skills. A definite prerequisite in medical writing is the ability to communicate with others, which has likely been honed during PhD training. For example, PhDs are often asked to submit research proposals, which are evaluated by non-experts. The competence to turn expert knowledge into understandable communications is quite valuable in medical writing where materials have to be prepared for a wide range of recipients including other leading experts, general physicians, nurses and other healthcare professionals, and even the general population. Tailoring the information to each group is something at which a PhD can excel.
5. Ability to liaison with experts. Medical communications often require the input of academic leaders and there are few other people in a typical agency who can speak their language. A PhD should have plenty of experience in drawing out the knowledge of an academic researcher and can assist both in eliciting the expert's information and in making the expert feel more comfortable in a 'marketing' environment. Consider an advisory board composed of a dozen academic researchers discussing the role a pharmaceutical company's new

product plays in the clinical care of the condition for which they are experts. Even capturing the contents of such a discussion requires a high level of competence in the subject. Medical writers in this situation are key in preparing notes, assembling references, and even formulating presentations.

Therefore, PhDs are well-positioned to apply the skills gained in conducting research and writing dissertations to medical communications, no matter their speciality.

New skills to gain

Although not every facet of medical writing is commonly experienced in a typical PhD programme, versatile candidates can broadly adapt their skills and greatly enhance their overall competence.

Areas such as promotion in particular, take on a completely different flavour. Instead of the dry, fact and data-based presentations following the 'Introduction, Methods, Results, Discussion' format, promotional materials come in many different formats, styles, and tones. It may at times be difficult to change the tone from simple data presentation to outright promotion. However, medical writing provides a new set of experiences and new skills have to be acquired:

1. As PhD candidates have had multiple opportunities to promote their own work, especially after acquiring exciting results, similar enthusiasm can be passed on when promoting a product. If a writer is convinced of a given product's value and the patient's need for such medication, it is not difficult to convey the data and evidence supporting its use in a promotional way.
2. The makeup of a healthcare communications agency presents an opportunity to further enhance communication skills. In a research environment, one usually takes basic knowledge for granted, as this is a prerequisite for entering a PhD programme. Not so in a healthcare communications agency. Among interns, account managers, and creative designers, one realises that this knowledge is no

longer universal. Thus, medical writers will have to explain highly specialised knowledge to an account manager, a designer, or even a client. In so doing, they can not only demonstrate their expertise but also practise putting complex biomedical facts into easily understandable language.

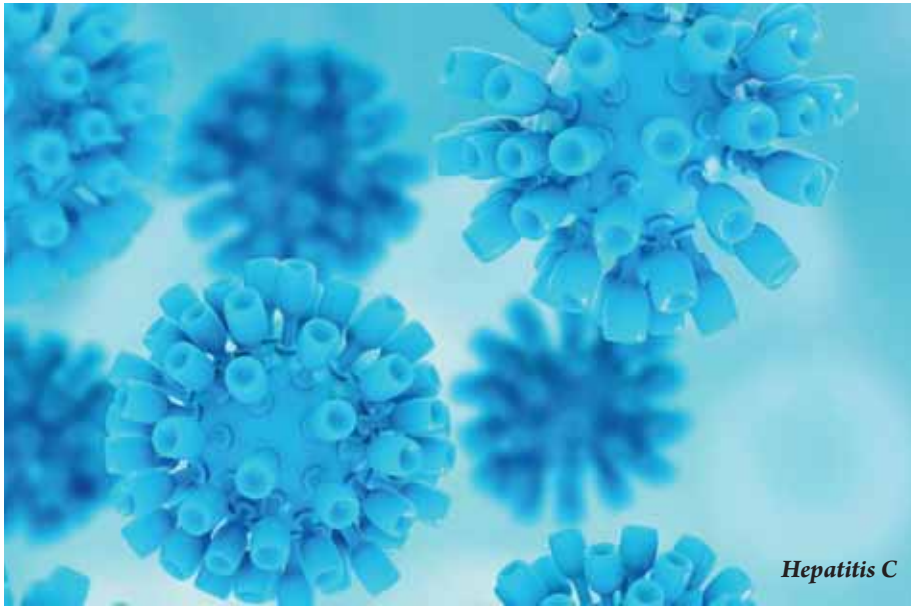
3. A PhD writer has to acquire new ways of handling information drawn from sources other than the natural sciences. In research, problems are commonly solved through formulating hypotheses and testing them. However, not all problems in medical communications are amenable to hypothesis testing and experimentation and solutions can often come from other sources, including market research and behavioural economics. Medical writers have to learn to apply these solutions and will have to blend their competence in the 'hard sciences' in presenting information. The opinions gleaned from qualitative market research may not always lend themselves to statistically significant results, but they still provide valuable insights into how customers will respond, and a medical writer can tailor communications accordingly.

Although a PhD has a lot of easily transferrable skills, medical writing may also require picking up new skills and may force a new PhD to learn new things. However, the versatility acquired in the multiple years it took to get a PhD will allow a smooth adaptation to new challenges.

Although not every facet of medical writing is commonly experienced in a typical PhD programme, versatile candidates can broadly adapt their skills and greatly enhance their overall competence.

Considerations for a career in medical writing

For the aspiring medical writer, with or without a PhD, the following points are



meant to highlight attributes suggesting a good fit in this interesting career.

- If you enjoy research, but are also interested in other aspects of biomedical science (e.g., grant writing, publishing, reviewing manuscripts), medical writing may be a good outlet for your skills; but if you can't stand being away from the bench and think everything that takes you away from your experiments is a waste of time, the variety of projects in medical writing might put you off.
- If you are always on the lookout for opportunities to talk about your research, such as in conferences and meetings, medical communications would give you a wider platform both to generate and to present your ideas; but if you hesitate to discuss your research, particularly to non-experts, the need for constant communication for multiple levels of expertise might be overwhelming.
- If you are interested in everything and enjoy learning about subjects not directly related to your research topic, the varied areas of expertise you'll need to acquire as a medical writer would keep you interested and engaged; but if you focus only on your topic of research and avoid exposure to other fields, the rapidly changing needs of medical communications might be a bit frustrating.

The value of a medical writing career

Most people involved in biomedical research would say they do what they do for the benefit of others, amongst other reasons.

From basic research to clinical trials and drug development, the ultimate goal is to produce something that improves human health. It may be hard to conceive of the role of medical communications in such endeavours, but an important role exists.

An example: a patient with hepatitis C has just heard that an effective new oral drug had been released to treat her condition in less time and with greater chance of success than any of the other marketed options. Unfortunately, her doctor told her that the drug had not been indicated for the genotype of the virus with which she was infected. The doctor was under the impression that this new drug was approved for the most common genotype (genotype 1), but the patient had genotype 2. Disappointed, this patient planned to start a longer course of more burdensome and less effective injectable therapy.

Her doctor, however, was completely mistaken. Genotype 2 was actually the easiest genotype to treat with this new therapy and had the highest chance of success. The blame for this error should not rest on the doctor alone, but on those responsible for communicating the attributes of this new drug, both the pharmaceutical company which produced and sold it and the medical writers who promoted it.

In this case, fortunately, the patient was in touch with a medical writer working on hepatitis C, who quickly recognised that the doctor might have made a mistake. Having been provided with some simple and clear information from the European Medicines Agency on the approved indication for this

new drug, the patient returned to her doctor and was successfully treated.

So medical writing has an important role to play in putting the proper therapies into the hands and bodies of the patients who need them. And for those who have been on the basic research side of things in a PhD programme, it can be eye-opening to realise that biomedical research has multiple steps, all of which are important. The skills and experiences obtained doing such research are of great value in a career in medical writing.

Conflicts of Interest and Disclaimers

The author is employed by Ogilvy CommonHealth, a healthcare communications agency.

The views expressed in this article are the author's and do not necessarily represent those of his employer.

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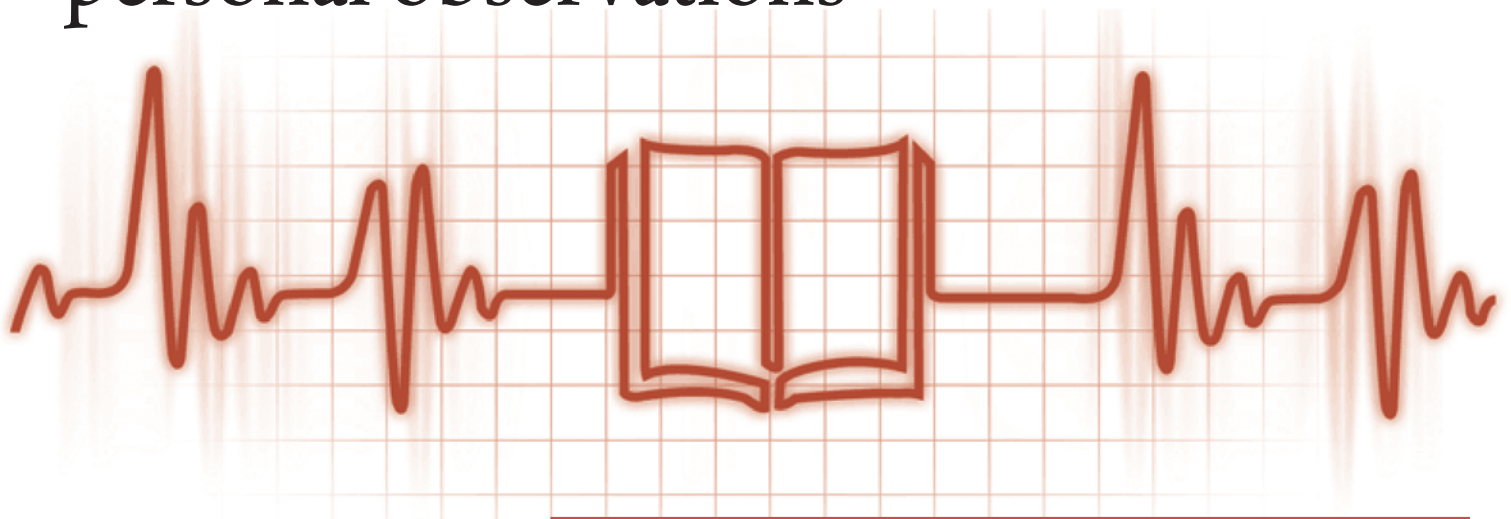
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Writing for pharmaceutical or medical device companies:

A survey of entry requirements, career paths, quality of life, and personal observations



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Abstract

The spectrum of medical writing activities across the pharmaceutical and device industries is vast. We conducted a limited survey of medical writers predominantly working in industry or for agencies to learn of their personal and professional experiences. Our results showed that writers entering the medical communications world came from diverse backgrounds and had a variety of reasons for choosing this career path. Most had a scientific background and were highly qualified. Though at times stressful and involving long hours, medical writing was generally a satisfying and well-rewarded career choice. Several individual responses suggested a lack of appreciation and poor cooperation on the part of some clients and/or authors. Quality of life differed little between pharmaceutical and device employees. While many skills are transferable, those wishing to change focus from pharmaceuticals to medical devices or vice versa may face challenges. Respondents offered a range of advice for new recruits.

Introduction

The need for medical writing continues to grow, influenced in part by increasing regulations and governmental scrutiny of pharmaceutical and device companies. Activity is currently high in China and other parts of Asia in response to the volume of research in these areas. In order to restrict headcounts many companies now outsource writing to agencies and freelancers, resulting in a multibillion dollar medical commun-

ications sector.¹ Those involved in developing publications, presentations, and regulatory documents are often highly qualified, with a background in research, medicine, or education. Projects requiring their inputs span the whole field of medicine from medicinal products to medical devices, with a small but increasing overlap between some of these areas. A recent study showed that the use of professional writers was associated with more complete reporting of clinical trial results and a higher quality of

written English, demonstrating the value of medical writers in raising the standard of clinical trial reporting.²

The features of medical devices that differentiate them from drugs may shape the kind of activities a medical writer is required to support. Medical devices span a spectrum of complexity from tongue depressors through implantable pacemakers to in vitro diagnostic devices (IVDs) found in doctors' surgeries or large laboratories. Research study designs and data endpoints differ between pharmaceuticals and devices. For pharmaceuticals, clinical studies focus on proving safety and efficacy relative to the intended purpose of the therapeutic agent. In contrast, endpoints for medical device trials are as diverse as the devices themselves. For example, therapeutic devices must prove safety and efficacy; measurement devices must prove precision and validity; and diagnostic devices must prove sensitivity and specificity.³ Importantly, device performance outcomes and safety are often highly dependent upon the experience and skill of the user. Also, while devices are subjected to continuous and rapid innovation resulting in a short product life cycle,

pharmaceuticals undergo continuous, slower innovation and hence have a longer product life cycle.⁴

Another area of contrast is legislation. The pharmaceutical industry is heavily regulated, in the USA by the Food and Drug Administration (FDA) and in Europe by the European Medicines Agency (EMA), as well as by each individual country's competent authority, such as the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK. The legislation applied to medical devices, compliance with which is also the responsibility of the national competent authorities, is currently less demanding but is likely to increase appreciably in response to calls for greater safety monitoring.⁵ These differences are reflected in the lead time from development to market: an average of 13.9 years for drugs in the USA and UK,⁶ compared with an estimated 3 to 7 years for medical devices.⁷

Anecdotal evidence suggests that writers entering the medical communications world generally travel down one of two paths: pharmaceuticals or devices, with limited crossover between these two areas. How did they get there, what is life really like, how

easy is it to change fields, and what advice would they offer to aspiring juniors? The aim of this study was to answer these questions and provide a comparison of the two industries for new writers or those contemplating a change in direction.

Methodology

An anonymised and multifactorial survey was developed using SurveyMonkey®. It was tested amongst a group of senior writers and managers working in pharmaceuticals or in medical devices and subsequently revised. The design of the survey included multiple choice questions, Likert scales, and free text options. Where appropriate, respondents were encouraged to tick more than one answer. A covering letter and electronic link were sent to contacts known to the co-authors from the pharmaceutical and medical devices world in the USA or Europe. Contacts were invited to forward it to their colleagues (industry, agency, and freelance), with the aim of receiving 50 completed surveys. The survey was made live on 8th March 2016 and closed on 14th March 2016. Results are presented in terms of absolute numbers, percentages, means, and individual quotes. In some sections we focus on comparing the responses from industry and agencies; 'Freelancers/consultants' are here excluded because their working conditions are likely to be much different from those in established companies.

No patients were involved and ethical committee approval was not sought. There was no compulsion or inducement to complete the survey and respondents were allowed to leave questions unanswered.

Results

The survey was cascaded to an estimated 200 contacts. 112 responses were received (response rate ~56%), with most respondents completing the survey and adding valuable text comments.

Overview of respondents

Approximately two thirds of respondents worked in Europe and one third worked in the USA. Of those answering the relevant question (n=108), 68% worked principally

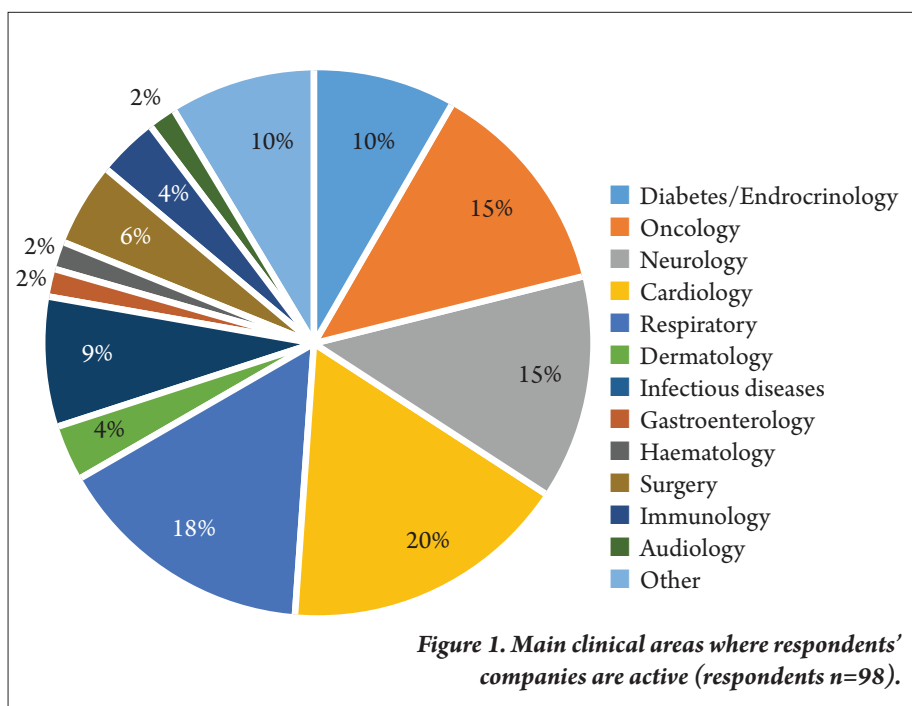


Figure 1. Main clinical areas where respondents' companies are active (respondents n=98).

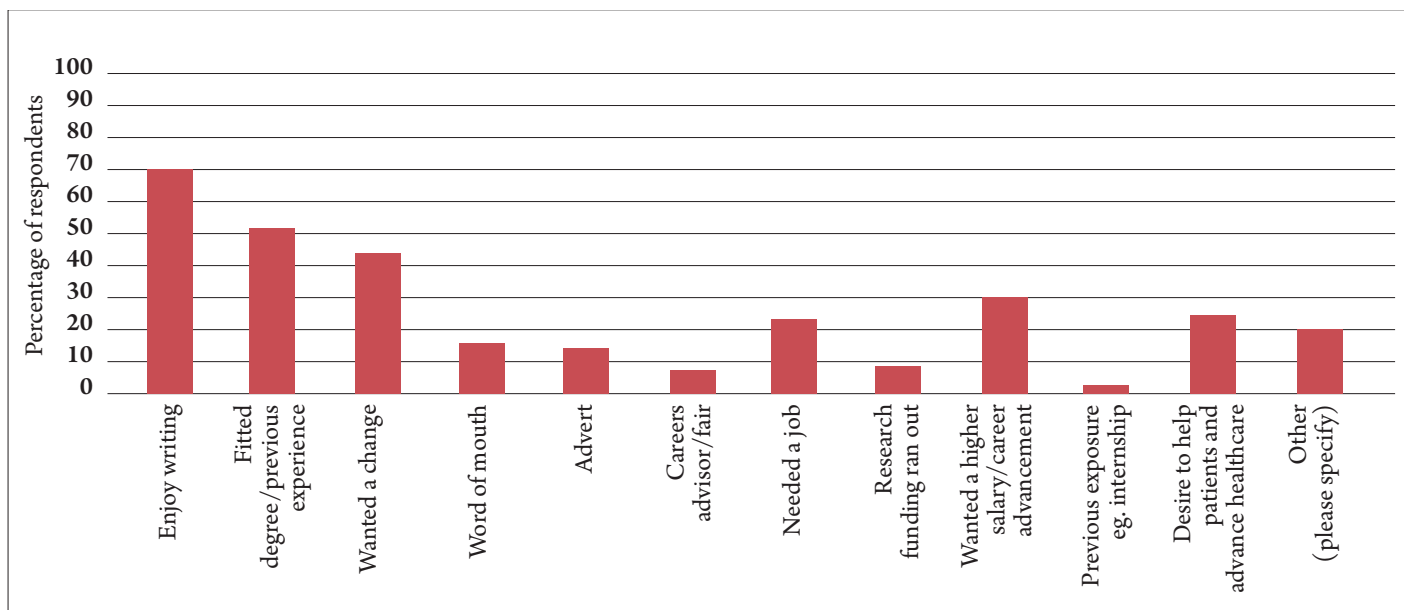


Figure 2. What made you originally consider medical writing as a career? (respondents n=110, multiple responses were encouraged).

in pharmaceutical writing, 28% in medical devices, and 5% as freelancers/consultants. Some provided their company name, indicating a spread of industry and agencies. There was much diversity in the therapeutic areas where the respondents' organisations were active (Figure 1). Respondents displayed an impressive range of degrees (110 respondents, multiple answers requested): 69% had a PhD or equivalent, 24% a Master's, and 53% a Bachelor's degree. At least two respondents were medically qualified.

Job titles varied widely: of those responding (n=109), 36% occupied managerial/directorial posts or higher, 37% senior writing positions, and 20% writing roles. The majority of the 112 respondents had occupied their post for 5 years or less (<1 year 21%, 1-2 years 24%, 3-5-years 28%), while 16% had occupied their post for 5-10-years and 11% for longer than 10 years.

Career path

The top answers to the question 'What made you originally consider medical writing as a career?' (n=110) were 'Enjoy writing' (70%), 'Fitted degree/previous experience' (52%), and 'Wanted a change' (45%) (Figure 2). A minority of respondents (20%) offered additional reasons, 'flexibility' and 'work/life balance' being the most common. Notably, 25% had a 'Desire to help patients and advance healthcare'.

What had our survey group been doing prior to starting their current posts? As evidenced by the 88 respondents who

provided free text answers, medical writers came from a diversity of backgrounds. Many were postdoctoral researchers from academia or had worked as laboratory technicians, researchers, or scientists in industry before following a common career path equivalent to 'Medical Writer, senior medical writer, senior programme manager, editorial team lead, VP medical and scientific services'. Some had a pharmaceutical, medical, or editorial ('Journal Editor') background. Others came from teaching ('English language teacher'), copyediting, translation, or medical marketing. Some had started their writing career in industry and others in clinical research organisations or agencies, with some movement between these three.

How did respondents obtain their current post (n=107)? About a third (33%) replied to an advertisement, while 'Internal advancement' (21%) and 'Invited to apply' (20%) occurred in around one fifth of cases. Recruiters were responsible for 14% of placements. Amongst 'Other' answers it is interesting that several respondents had been encouraged to apply through friends, or had contacted their company directly.

Entry requirements

What are the usual entry requirements for a career in medical writing? The majority of respondents (n=102) considered a science degree to be a necessity (90%); indeed some companies may stipulate the need for a PhD and/or experience of working in a medical/bioscience area (54%). Conversely

some respondents commented: 'Doesn't always need a science degree. I've known people with arts degrees make successful medical writers' and 'A PhD isn't really necessary for junior level positions.' Among other desirable attributes are 'Able to understand/interpret complex data, interpersonal skills, communication skills, computer proficiency, statistical knowledge' and 'An interest in medical writing.' Candidates are also often required to pass a writing test as part of the interview process (74%).

Activities, guidelines, and clinical areas

In the following sections we focus on the responses from respondents in industry and agencies and exclude the responses from the five participants who described themselves as freelancers/consultants.

There appears to be broad overlap in the types of medical writing documents and daily responsibilities of respondents working in pharmaceuticals and devices (Figure 3). The medical communication industry and regulatory guidelines followed by employees of medical device and pharmaceutical companies were also similar and included GPP3 and ICMJE, CONSORT/STROBE/PRISMA (as appropriate), plus all applicable regulatory guidelines. Several pharmaceutical respondents mentioned ICH, ABPI (Association of the British Pharmaceutical Industry), and FDA guidelines, while STARD (Standards for Reporting of Diagnostic Accuracy) and MedDev (European standards) appear in the answers



Figure 3. Word cloud representation of free text responses depicting the activities reported by pharmaceutical and device writers.

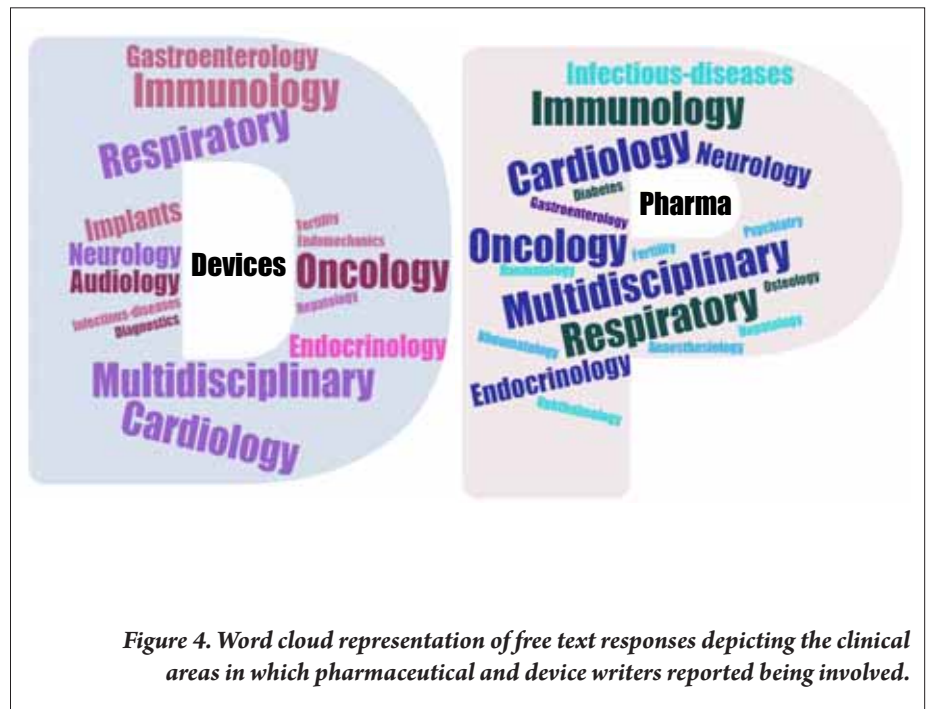


Figure 4. Word cloud representation of free text responses depicting the clinical areas in which pharmaceutical and device writers reported being involved.

given by device writers. However, there are differences in the clinical areas of activity which pharmaceutical and device writers reported being involved in (Figure 4).

Location and training

The majority of respondents (n=97) were solely office-based (pharmaceutical vs device, 54% vs 57%). It was rare for staff to work solely from home (10% vs 8%). Around a third (36% vs 35%) attended the office occasionally or regularly. The usual structure was to work in a small team in one office (19% vs 39%) or in a small team across more than one location (30% vs 36%). Pharmaceutical respondents were more likely than device respondents to work in large offices with multiple locations (39% vs 14%). Most respondents had at least daily interaction with colleagues, with those in the pharmaceutical world (70%) more likely than those in devices (50%) to have contact several times each day.

Opportunities for training and profes-

sional development (90 respondents) were generally available, although 39% of pharmaceutical and 22% of device respondents were not attending any courses at the time of completing the questionnaire.

Working hours

Out of 96 respondents, only five (5%) worked <30 hours/week. The majority reported working either 30-40 hours (pharmaceutical vs device, 50% vs 14%) or >40-50 hours (34% vs 68%); some reported working >50 hours per week (9% vs 11%). Paid holidays (excluding weekends and public holidays) were generally in either the range of 15-20 days (pharmaceutical vs device, 22% vs 43%) and >20-30 days (64% vs 36%) per year. Holidays were generally less in the USA, where 44% of respondents received 15-20 days; 75% of European staff were entitled to 25-30 days.

Career prospects, salary, and benefits

The 89 respondents gave a mixed picture.

For some, it was only possible to move up 1-2 levels before reaching a ceiling (pharmaceutical vs device, 17% vs 35%), while for others progression meant a change in role e.g. from writer to manager (35% vs 43%). Many respondents, however, selected the option ‘Progression up to senior level is possible but takes time’ (56% vs 43%). One respondent reported that it ‘depends on who you know’.

Salaries varied widely (Table 1). In response to the question ‘What do you expect to earn this year before tax and deductions?’ it can be seen that the mean (analysable) figures amongst US pharmaceutical and device respondents are broadly similar. Those working in medical devices in Europe may be better remunerated than their pharmaceutical counterparts, although numbers of respondents were small. At today’s exchange rate (March 2016) UK salaries were approximately half those in the USA.

Employees frequently received benefits

	USA	Switzerland	UK	EU excluding UK
Pharmaceutical	\$111k (n=14) (\$75k-199k)	CHF 167k (n=2) (CHF 165k-170k)	£40k (n=32) (£24k-95k)	€42k (n=4) (€24k-60k)
Devices	\$108k (n=17) (\$82k-250k)	CHF 129k (n=1)	£50k (n=1)	€62k (n=6) (€36k-130k)

Table 1. The mean (range) salary (to the nearest thousand, k) that respondents expected to earn this year before tax and deductions.

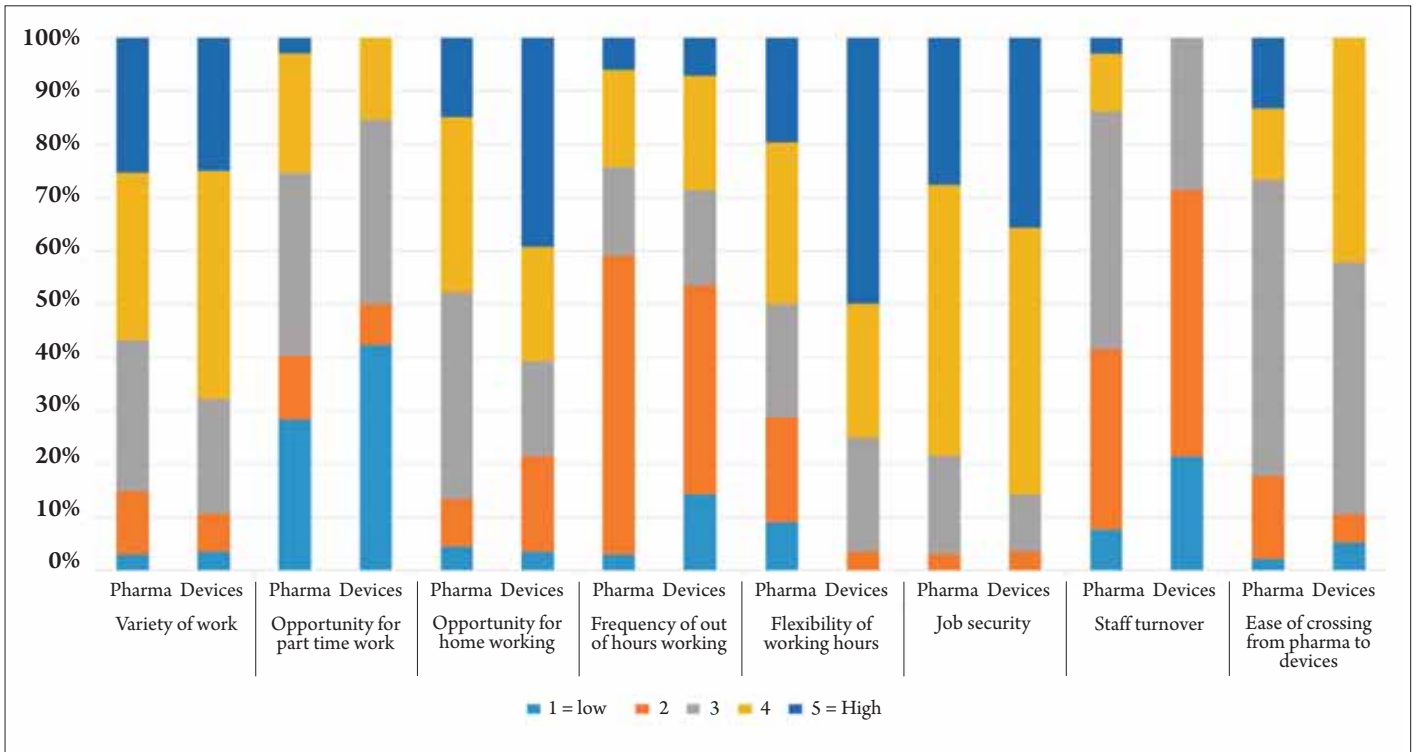


Figure 5. Employment characteristics of pharmaceutical versus device respondents (Likert scale). Number of respondents: pharmaceutical 64-67, device 26-28.

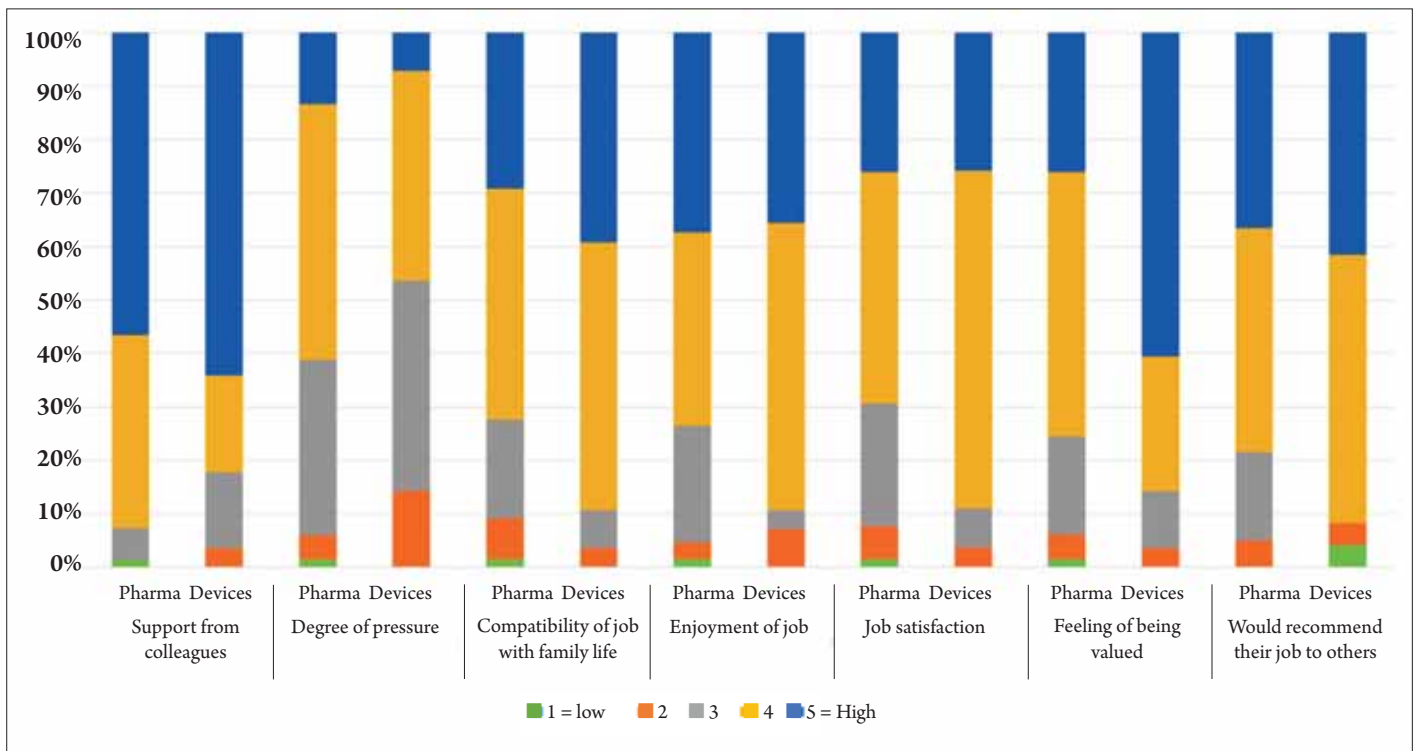


Figure 6. Factors relating to job satisfaction and quality of life for pharmaceutical versus device respondents (Likert scale). Number of respondents: pharmaceutical 64-67, device 26-28.

(94 respondents), typically health insurance (pharmaceutical vs device, 63% vs 82%) and pension or retirement plans (92% vs 68%); less frequently they received childcare/nursery placement (14% vs 32%), canteen/food vouchers (8% vs 32%), and gym membership (27% vs 54%). A few respondents mentioned other benefits: a bonus/profit share scheme, life insurance, a bicycle or travel assistance, a relocation package, and free fruit and soda. The distribution of benefits was broadly similar between Europe and the USA, although 95% of writers in the USA had health insurance and 58% gym membership (Europe 55% and 15%, respectively).

Quality of life in current role

Figures 5 and 6 provide a summary of a number of factors which may be important to the quality of life of a medical writer. Most responses to the 15 Likert scale questions about quality of life showed a positive picture with broad agreement between pharmaceutical and medical device writers, although those working in medical devices showed slightly higher ratings (4 or 5 on the Likert scale) for 'Variety of work', 'Opportunity for home working', 'Flexibility of working hours', and 'Job security' (Figure 5). Staff turnover was higher among pharmaceutical staff. Two negative aspects in both pharmaceuticals and devices were the requirement for some out-of-hours working and limited opportunity for part time employment.

As shown in Figure 6, while staff in pharmaceuticals may receive greater support from colleagues, working in the devices world was possibly associated with less pressure, greater compatibility with family life, more enjoyment/job satisfaction, and a feeling of being valued. A greater proportion of device writers considered that their job brought patient benefit (87% vs 67%, 87 responses).

Overall, the majority of respondents (n=84) would recommend their job to others (pharmaceutical vs device, 78% vs 92%).

What is bad about being a medical writer?

A total of 44 pharmaceutical respondents and 21 from devices provided free text answers. A recurring theme amongst pharmaceutical writers was unappreciative and disorganised clients and authors who failed to respect the qualifications and experience of the writer. One respondent described their job as 'Repetitive', another as 'Boring'. Other negative comments included: 'Pressure and expectation to work extra hours can put pressure on home life', 'Multiple people demanding things at the same time', 'Long hours' ('have had to work 50-hours/week for 6 months before now'), and 'Insufficient resources'.

Some clearly missed academia and felt that they were not receiving the benefits that their peers at a similar level may enjoy. Other frustrations were the peaks and troughs in workload, tight deadlines, lack of resources, sudden alterations in priorities, and changes in management. Some mentioned too much paperwork, tiresome travelling, and endless rounds of reviews and comments. It was generally not possible to link such comments to organisation type (i.e. industry or agency), although some clearly originated from agencies, such as this respondent reporting an area of frustration: 'Losing staff to other agencies with better pay.'

The range of responses from device writers was similar, although not always negative: two respondents claimed that their job had no bad points.

Out of 65 pharmaceutical respondents, seven (11%) claimed to have experienced discrimination, compared to six (21%) of the 28 device writer respondents. In response to the question 'Have you ever faced any ethical dilemmas?' 20 of 58 pharmaceutical writers (34%) reported that this had been an issue, compared to seven of 18 device writers (39%). Generally these issues were around compliance and authorship and appear to have been successfully resolved. One respondent wrote: 'This may have been the case 15 years ago but not now.'

The following quote provides a picture of what life as medical writer can be like: 'Working internationally can bring up cultural differences and exposure to misogyny. Writers are sometimes not valued

as subject matter experts or valuable contributors; constantly handling criticisms and balancing different opinions is inherent to the document review process and can sometimes turn negative.' Another quote illustrates that writers may not enjoy all aspects of their job: 'I enjoy the data, teaching others, and working with doctors and regulatory agencies, but I detest putting pen to paper.'

And what would you change?

There were fewer responses from employees in devices (16) compared with pharmaceuticals (49) but the aspects of their jobs respondents would like to change were similar across both groups. Seven pharmaceutical and two device respondents would not change anything, while a pharmaceutical respondent would change 'Everything'. Themes around company organisation included additional resources, reduced workload, less bureaucracy, fewer meetings, greater variety of work, more opportunity to write, longer holidays, better salaries, opportunities for career advancement, better training for recruits, and ability to work part time or from home.

With regard to the job itself, some respondents would like improved interaction between scientists/authors and writers, more recognition of the value of publications, and a greater opportunity to become an author.

Writing for pharmaceuticals vs devices

Does writing differ between pharmaceuticals and medical devices, which do respondents prefer, and can writers easily move between the two? The limited number of respondents who had moved from one area to the other (n=26) or who currently work across both (n=8) expressed varied opinions (Figure 5). Nonetheless, demonstrating efficacy, safety, and affordability was important for both pharmaceuticals and devices. Other similarities were in authorship requirements, rules around honoraria, and 'Bizarre journal reviewer comments.'

There are, however, a number of differences which may complicate the life of a medical writer changing between

pharmaceuticals and devices (Table 2). For some, the unfamiliar regulations and types of analyses for pharmaceuticals versus devices were problematic, particularly in the early stages of clinical development. One respondent wrote: ‘I moved from devices to pharmaceuticals and did not find it challenging at all’. Another agreed, adding that having a focus on publications rather than regulatory writing and possessing Investigational Device Exemption (IDE) experience made the transition to New Drug Application/Investigational New Drug (NDA/IND) writing relatively easy. Of their experiences in transferring the other way, one respondent wrote: ‘I moved from pharmaceutical to devices and found devices to be a far more comfortable environment where the employees are respected significantly more.’

With regards to whether publishing strategies differed between pharmaceuticals and devices, opinions were divided: 11 respondents thought strategies were similar and nine thought that they were different (two were unsure). Moreover, there was no clear difference between those preferring to work in either branch (‘Pharmaceutical’ 6, ‘Devices’ 4, ‘No preference’ 5).

And finally, what advice would you give to a new writer or your younger self?

A total of 62 respondents offered advice covering a range of issues. This advice is summarised in Table 3. Among the most frequently offered advice was to gain wide experience, join the profession early, and realise that there is more to the job than just writing.

Discussion

Medical writers now comprise a sizable proportion of the scientific community. It is therefore surprising that little is formally known about their career path, working conditions, and current activity. Our survey, though selective and representing a limited number of respondents, provides some insight for potential new recruits or those considering a change in direction.

A job in medical communications seems for many to be a fulfilling career choice. It

Pharma

- Codes of practice and regulatory requirements differ and tend to limit medicinal products more than devices
- Slow development cycle
- Multiple studies involving large patient numbers
- Push for publications and congress activities across the product lifespan
- Different audiences and communication needs
- Differences in therapeutic areas and associated language
- Study designs, outcomes, goals, and messaging tend to be predictable and consistent
- More direct-to-patient communication
- Medical writers: less experience and shorter learning curve?

Devices

- Faster development and commercialisation
- Frequent product updates, e.g. laboratory software
- Regulatory requirements differ and depend on class of device, may be less stringent
- Less emphasis on publishing and more on commercial activities, e.g. building client relationships and educating physicians and payers
- Need to consider the outcomes from the perspective of the user as well as the device
- Emphasis on accuracy and precision, ergonomics, patient preferences
- Limited publications and fewer patients per study
- Publications and congress presentations are generally focused around regulatory approval and product launch, then tend to taper off
- Operator variability and training are big factors in device performance, so learning curves are often explored in publications
- Limited publications around diagnostics

Table 2. A comparison of issues facing medical writers engaged in pharma or device activities.

also brings benefit in terms of raising the quality of clinical trial reporting.² The types of activity and range of clinical areas requiring writing input are vast. Salaries, job security, and working conditions are generally good and seem reasonably compatible with family life. Some may miss academia, although there is plenty of intellectual stimulation in helping to bring a new cancer drug or hip prosthesis to market. Downsides include a degree of pressure and out-of-hours working, with some respondents raising a number of ‘moans and groans’. One suspects that complaints about unappreciative clients, limited resources, excessive meetings, and paperwork can be heard across many industries.

There is no formal route of entry into our profession. While many possess a scientific background, have worked in laboratories, and come with impressive degrees, a minority have followed less conventional paths such as teaching and marketing. The biggest hurdle is probably getting the first job; once you have experience then qualifications tend to matter less. Amongst the most frequent pieces of advice offered by respondents is to start early in medical writing, get lots of experience across multi-

ple areas, and build personal relationships.

Our hypothesis was that variations in development and markets between pharmaceuticals and medical devices would result in a different experience for many medical writers. Based on our limited findings, this is not the case: quality of life appears to differ little between pharmaceuticals and devices, with positive responses coming from both sides. A possible reason may be the increasing need to follow guidelines and regulatory edicts in pharmaceutical and device writing, which is causing any previous distinction between the two to blur. However, taking the data as a whole, one is left with an impression that the devices world may still just have the edge, possibly due to the supportive nature of their smaller teams compared to the more frenetic activities around bringing a new drug to the global market. Changing from pharmaceutical to device writing, or vice versa, is possible but is likely to necessitate time and effort to become familiar with new regulations, language, and approaches.

This has been very much an exploratory exercise; inevitably it has limitations in covering a large amount of ground, and several respondents found the survey too

Themes	Advice (edited)
Gain Experience	<ul style="list-style-type: none"> ● Gain wide experience across different types of writing/documents, regulations, standards and guidelines. These are readily adaptable if you are willing to commit the initial effort ● Start early - write for student magazine/internships etc ● Read, read, read. Learn about many therapeutic areas as possible ● Get practice prior to having deadlines or expectations set for you ● Work overseas and travel ● Speak up if you want to get involved or have relevant experience ● Get regulatory writing experience, the jobs are abundant ● Keep an up-to-date portfolio of your work
Acquire Skills and Participate in Training	<ul style="list-style-type: none"> ● The job is not all about writing, you also need good project management and client skills ● Begin working on presentation skills early. This is essential to being effective in your role and for career advancement ● Good communication is crucial, not scientific knowledge. Manage through influence not through authority. Learn how to resolve conflicts ● Improve your business skills
Timing	<ul style="list-style-type: none"> ● Move companies after first year to gain industry perspective ● If you want a writing career, start earlier (e.g. right after a PhD). Advancement in the lab does not bring a higher position or better financial reward
Qualifications	<ul style="list-style-type: none"> ● Get a health-related Master's Degree e.g. MPH, but experience trumps degrees (generally) ● You don't need to do a post-doc ● If you don't enjoy writing and the science perhaps you should do something else
Develop Personal Attributes and Qualities	<ul style="list-style-type: none"> ● Be enthusiastic and proactive, volunteer, don't be afraid to go with your good ideas and to innovate ● Be more confident to push back (where appropriate). Don't be afraid of clients/authors but try to build a partnership with them and they will value your input. Don't let people take advantage ● Ask questions. Be curious ● Stay calm, don't panic, take a breath and then deal with the problem. Try not to get too stressed if something goes wrong – most things are fixable. Don't worry about small stuff ● Don't be afraid to seek help from colleagues. Most like to be asked ● Don't be scared of comments – they're part of the job. Develop a thick skin and don't take clients personally ● Don't deliver rubbish work because you are under pressure. If more time is needed to complete a project accurately and well then say so ● Be rigorous with some flexibility. Always put science first ● Learn to be comfortable with uncertainty and ambiguity, it will not always be possible to lay out every step/action in black and white ● Don't work overly-long hours, it becomes expected and is very difficult to get out of. Don't read emails after hours ● Be more aggressive about authorship/recognition ● Focus on what you enjoy most (for me this is the writing) ● Be open to where the job may take you – be willing to change with the job and career
Network	<ul style="list-style-type: none"> ● Join a network of people in a similar role ● To help stay on top of the science, get involved in societies, e.g. ISMPP, AMWA, etc
Other	<ul style="list-style-type: none"> ● This is a one-way road. If you love it make the most of it, if you hate it get out quick! ● There are good opportunities in medical and scientific writing but finding the good ones takes time. ● Find somewhere where the people are happy – it's the team that makes it work ● Highlight your achievements to upper management ● Have a full appreciation of the job description. Ask for more money to start ● Get into writing and away from editing quicker ● You don't have to be a manager to be fulfilled. If you enjoy writing, try to avoid getting drawn into becoming a manager ● Relationship-building is usually the key to success; focus on this when you find yourself becoming too "task-oriented" ● If you don't work for your passion/dream, you'll be working for someone else's

Table 3. Advice offered by respondents to a new recruit or younger self (edited).

long. Questions remain around the discrimination and ethical issues reported e.g. what was the issue, who was involved and what was the outcome? Moreover, we do not yet understand why there are such differences in salaries between the USA and Europe, whether simply because of differences in living costs, selection bias, or differences in the nature of the job. On this point, our results for salaries in the USA are in line with the most recent American Medical Writers Association survey,⁸ but because of the limited number of respondents may not reflect what is currently being paid to writers in continental Europe.⁹ Some of the comments hint at differences in quality of life between working in industry or for an agency, an interesting area for future research activity. Given the preliminary nature of this survey and the possibly unrepresentative sample, we did not undertake any statistical testing. However, these limitations are typical of this type of survey.¹⁰ Future replication of this study would require question validation, some shortening of the survey, and application across a much larger sample. Despite the survey's limitations, we believe the results provide some useful insights for potential new recruits to our profession and offer encouragement to those considering a change between writing for pharmaceutical products and medical devices.

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Conflicts of Interest and Disclaimers

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Medical gems

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Abstract

Every discipline employs its own secretive words – jargon that allows initiates to communicate with one another in a way that excludes others. The world of medicine is no exception. The idioms used by doctors and surgeons range from the humorous to terms which seem designed to deliberately obscure the real meaning of the word. Other phrases stand out simply due to the incongruous pairing of everyday words. This article contains some real-life examples of all these because, as you know, sometimes words have two meanings.

From business to medicine

Like a lot of you, I somehow found my way into medical writing. In my case my background is in business which, like any discipline, has its own argot to learn. I've always been impressed by words used in a certain (perhaps secretive) context. In business I was enamoured by jargon such as "Business Angels", who are people with money who fund start-up companies, or "MBWA", which means "Management by Walking Around".

The world of medicine is even richer when it comes to "special" terms. In this article I'd like to share with you some of the words and phrases I have come across as part of my daily work (mostly in trauma and orthopaedics), as well as some doozies I

have found online.

I am going to focus on accepted medical phrases, the meanings of which are not obvious at first to a layperson. I don't want to spend too much time on funny doctor slang and acronyms because the internet is already full of them. But if you like that kind of stuff, I recommend the paper by Fox *et al.*¹ which not only covers the history and cultural use of slang in medicine, but also highlights some terms apparently in use.

These include "DBI", which stands for the Dirt Bag Index. A patient's DBI is calculated as the number of tattoos multiplied by the number of missing teeth and is used to estimate the number of days without a bath! And are you already familiar with "granny dumping"? This is the practice of bringing elderly patients to emergency departments, for admission, usually before public holidays.

Decoding medical words

When I first moved into clinical research from the world of business, I kept reading reports on surgeries which contained phrases like "chronic idiopathic orofacial pain" or "treatment of idiopathic clubfoot". I was surprised to discover that idiopathic actually means "of unknown cause". This is a very useful word to describe something you don't know!

Even more interesting to me was the word "iatrogenic", which kept cropping up in reports. For example, "neurophysiologic monitoring can predict iatrogenic injury during acetabular and pelvic fracture fixation" or "treatment of iatrogenic inferior vena cava occlusion". What does iatrogenic mean?

I learned it means any adverse condition in a patient resulting from treatment by a health care professional. In other words, instead of making you better your doctor has actually made you worse!

Debridement is when a doctor surgically removes foreign matter and dead tissue from a wound in order to aid healing. Personally

Nude mice are a type of hairless laboratory mouse with a genetic mutation and are often used in cancer research because they do not reject tumour cells from other mice or other species. I do wonder if they dress for dinner like human nudists...

I think it is also a perfect term to describe the moment a nervous groom bolts from the altar on his wedding day.

One of my favourite words in English has always been serendipity, which is when you happen upon something nice that you were not actually looking for. I guess that an antonym for serendipity could be incidentaloma. The term incidentaloma is a fusion of two words and describes a tumour (-oma) which is found by coincidence (incidentally).

This normally occurs during the course of examination and imaging for other reasons.

I am not the first to say it, but there is something about the term "nude mouse" that is unforgettable. Nude mice are a type of hairless laboratory mouse with a genetic mutation and are often used in cancer research because they do not reject tumour cells from other mice or other species. I do wonder if they dress for dinner like human nudists...

Don't like nude mice? Maybe you already know about knockout mice? These are laboratory mice in which researchers have inactivated, or "knocked out", an existing gene by replacing it or disrupting it with an artificial piece of DNA. An image of the Rocky of the mouse world comes to mind whenever I hear this term.

Creep resistance might sound like a woman telling some slimy guy in a bar to go take a hike but in fact it is a term used in materials science. It means a material's ability to resist distortion when under a load over an extended period of time. This is an issue, for example, in orthopaedic and craniofacial implants.

"Hangman's Fracture" is a C2 fracture of the spine which sounds cooler than it actually is. Despite its name, this fracture was not actually often seen in post mortems of people who were judicially hanged.² Similarly disappointing to me are "occult fractures". These do not result from accidents when witches and wizards get together but rather refer to cases where there are clinical signs of fracture but no



radiographic evidence.

I love to say the words “Wobbler Syndrome” but am glad that my dog doesn’t have this disease, which is a malformation of the cervical vertebrae. It causes dogs and horses to have an unsteady (i.e. wobbly) gait.

Surgeons are different ...

While preparing this piece I asked an American trauma surgeon if there were any other words he could suggest for this article. Straightaway he said “Poor protoplasm.”

“What’s that?” I asked, somewhat naively.

“The patient’s body is a wreck”, was his droll reply. I googled it later that day. There were plenty of hits. A sentence in the first explanation I found³ read, “Like pornography, there’s no formal definition for poor protoplasm, but doctors ‘know it when they see it.’”

Later that day in a meeting, the same surgeon used a word I had never previously heard: “grantsmanship”. A red wavy line appears under this word when you type it into a Word document. (However, the same program also tells me that other words do not exist when I know with certainty that

they do). Grantsmanship is a real word which the online Merriam-Webster dictionary defines as “the art of obtaining grants”.

A Brazilian spine surgeon at this meeting who sat at the same table at lunch talked about all of the motorcycle accidents in São Paulo.

“The number of fatalities is amazing. The transplant guys love it though. Lots of brain dead donors available for transplantation surgery.”

The American surgeon turned to me and said, “There you go, there’s another one for your article, riding the donorcycle.”

“Sorry?”

“The donorcycle, i.e. the motorcycle.”

As you can see, surgeons sometimes have a different take on how to describe the world around us ...

I hope that you enjoyed this somewhat light-hearted look at selected words used in the world of medicine. Please feel free to contact me if you have any further word suggestions for a follow-up article on special medical terms.

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The request for proposal process: A brief overview for trainee medical writers

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Abstract

This article gives an overview of the request for proposal (RFP) process, which can often be challenging for those new to medical communications. Four key areas are outlined: understanding the RFP process, teamwork, the pitch process, and seeking feedback. For each area, advice and recommendations are provided with a view to helping, in particular, those who have to engage in business development activities for the first time.

Introduction

Responding to a request for proposal (RFP) is a critical function of working within medical communications, but can be a new and sometimes daunting area for trainee medical writers. Indeed, as medical communications agencies become increasingly meritocratic, trainee writers may be increasingly called upon to engage in the business development process. Whilst new to medical communications, these writers will tend to have scientific expertise and experience in relevant therapy areas, which is attractive to both their agency and pharmaceutical companies (referred to as the client, hereafter). Below, I outline some key areas which will be of particular help to trainee writers.

Understanding the RFP process

Broadly, the RFP process is a form of bidding whereby the client will invite submissions from potential vendors (e.g. medical communications agencies) relating to undertaking a piece of business. Upon submission of their proposal, agencies will then usually be called to 'pitch' for the business (readers familiar with the BBC's *Dragons' Den* take note). However, proposals can also be sent electronically (e.g. as slide decks) or be conducted over the telephone.

If you are asked by your agency to engage in the RFP process, it is likely to mean that you will have relevant experience in the therapy area in question. For example, a trainee writer asked to help submit a bid for publication planning work involving a new cardiovascular drug may have a PhD in cardiac physiology. This type of academic experience will undoubtedly help you understand the scope and background of the RFP and puts you in an excellent position to add value to your agency's response. It is important for you to read the RFP documentation and fully understand the needs of the audience. For example, it is unlikely the client will want a full explanation of the pharmacokinetics of a compound which they have themselves spent much time and money developing. Instead, companies may place higher emphasis on the creativity and innovation that partnership with your medical communications agency (*ergo* you) can offer them. In this context, 'thinking outside of the box' can sometimes be the difference between success and failure.

Teamwork

As with most lines of work, we do not work in isolation in medical communications but instead we interact with and learn from our

colleagues. In most medical communications agencies, trainee writers will be engaged with senior writers on a daily basis and this foundation of strong teamwork is critical to the RFP process. For example, it may be that senior medical writers have worked with the client in question and can advise you on what to expect; they are likely to have been involved in business development before and are valuable sources of information and education for the trainee writer. Moreover, when working on an RFP you may find yourself engaged with colleagues whom you do not work with on a daily basis, and this is a crucial opportunity to cultivate good working relationships outside your day-to-day realm. This is especially pertinent for trainee writers in larger agencies, which, for example, may have specialist creative and market research departments that are called upon during the RFP process. As a new medical writer, viewing the mechanics of how these different business functions interact to win new business can be especially illuminating.

The pitch

Trainee writers asked to take part in the pitch process for the first time will probably experience a mix of emotions, including pride and fear. It is important for you to understand your role in the pitch and to highlight anything you feel uncomfortable with immediately – it is not advantageous for either you or your agency for you to be uncomfortable in the pitch, as this will come across to the client and will be deleterious to your chances of successfully winning the business. In this context, more experienced

members of your team will be able to guide you with regard to the practicalities of undertaking a pitch and the best way of presenting your proposal. However, it is highly likely you will have been asked to participate due to your experience in the therapy area, and this should always be remembered. Indeed, clients will often see you as the therapy area ‘expert’ and a new writer’s confidence during the pitch should be bolstered by this.

Whilst the pitch should be concerned with addressing the project brief, it is also an opportunity for both you and the client to meet each other and gain a nascent understanding of how your personalities may/may not work together. In this context, it is important for trainee writers to remain relaxed and friendly, and not get bogged down in the scientific and technical information that is being presented. Indeed, trainee writers may be surprised about how much winning new business is about personality, and not necessarily level of complex scientific knowledge or technical prowess with Microsoft PowerPoint.

Seek feedback

When we are awarded business, all is well and we should rightly feel proud of our contributions. Next begins the process of actually beginning the project you have been so desperate to win, and this comes with its own set of challenges that includes cultivating a strong working relationship with the client. In cases where you and your agency have been unsuccessful, it is important not to take this too personally – although it can

be understandably disappointing when you have invested time and effort in the RFP process. For trainee writers involved in the RFP process for the first time, this will have been a fantastic learning experience; you will improve your standing in your agency and have many positives that you can take forward into your medical writing career. If possible, you should always seek feedback regarding the decision of the client – objective appraisals oftentimes being different from our own self-perceptions of performance.¹ Over time, you will notice trends in the attributes of successful vendors and this will allow extremely important insight into the procurement ethos of different clients. This feedback will help during the next RFP process that you are engaged in and, ultimately, allow you to develop and grow along your journey in the fascinating world of medical writing.

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Brevity is the soul of wit

What can you say in 140 characters? Shakespeare was right, indeed a lot. It turns out the so-called micro-blogging service Twitter is an ideal medium to share information through publicly visible links and images. Depending on who you follow your Twitter can be an incredibly individualised source of news. When looking for specific information, hashtags such as #clinicaltrials or #medcomms allow you to filter efficiently from the 65 million daily tweets in the network.

Since November 2010, the EMWA Social Media Team has been providing a selection of interesting medical writing-related news, courses and events and, of course, informing about EMWA activities such as conferences and webinars. And let us not forget that Twitter allows for plenty

of interaction between members and non-members. If you have suggestions or criticism, want us to tweet anything special or ask us a question, let us know in a message to @Official_EMWA

or to our Public Relations Officer Beatrix Doerr (pr@emwa.org).

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Winners of the Geoff Hall Scholarship Essay Competition

The Geoff Hall Scholarships (GHSs) are given in honour of a former President of EMWA. Geoff was a very special person, an extremely valued member of EMWA, and a very good friend to many EMWA members. He firmly believed that the future of EMWA lies in our new and potential members, and so it's a very fitting legacy that we have the Scholarship Awards in his memory.

The Scholarships are awarded annually on the basis of an essay competition, and the title of this year's essay was 'Are medical writers scientists?'. This resulted in quite a variety of approaches and answers, and each year we receive more and more entries, which is great news! This year's winners were Nathan D. Susnik and Trudy L. Knight.

Nathan is currently a postdoctoral research fellow, looking to become a medical writer. He has no previous medical writing experience, and his talent is obvious.

For the last 5 years, Trudy has been the Project Manager of an exciting interdisciplinary and multi-sited research project, based at the University of Birmingham. She does not have any previous medical writing experience, and she shares Nathan's talent and flair for the craft.

Nathan's and Trudy's winning essays are presented below, and we wish them the very best at the start of their very promising medical writing careers.

The scientist's hand

Scientist. Word, title, identity, prestige. Since its inception, researchers and theoreticians alike have vied over the right to be called scientist. Medical writers are no exception. Vested in the world of scientific thought, though not involved in bench work, medical writers hold in a unique position in the research community. But do medical writers have the right to call themselves scientists? The answer lies in the etymology of *scientist*, the development of the research specialist and the value of clear communication in science.

Less than 200 years ago,¹ when the word scientist was coined, scientists were men like Alexander von Humboldt, gentlemanly scholars who studied chemistry, biology, geography and physics as well as linguistics, philosophy and theology. These early scientists made their own observations, drew their own illustrations and wrote their own manuscripts, sometimes turning research into entire volumes of literature, establishing general scientific theory. With time, knowledge has expanded. Advancements in technology have given researchers new tools, increasing the rate of discovery and creating new avenues of study. Large scientific disciplines such as biology have fractioned into small disciplines, such as botany, genetics and biomedicine. Small disciplines, in turn, have further fractioned into

FOR CORRESPONDENCE



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specialties, and today's biomedical researchers build entire careers on a single molecular pathway or one cell type. The modern scientist, in other words, is a specialist. In order to achieve the same interdisciplinary discoveries as the bygone generalist, the modern scientist must work together with other specialists.

Although the way we do research has greatly changed, the definition of scientist has changed little in the past 200 years. Nevertheless, both science and language are ephemeral. New coinages enter the English language, are judged by the speaking community and either exit the vocabulary or are integrated into daily use. As time passes, words need to acquire new connotations and definitions. The term scientist still generally refers to the individual experimenter, who works alone in the laboratory gathering data. This definition fails to recognize the modern team of specialists, working together to solve scientific problems. If we view the team of specialists as a single entity, as a single scientist, then the pharmacologists, immunologists and geneticists making observations and gathering

Are medical writers scientists?

My immediate response to this question is 'yes – of course medical writers are scientists!' But are they really? I am possibly biased; like most medical writers I have been a scientist since graduating, and now embarking on medical writing, I wish to keep my scientist status. So is this desire clouding my perspective?

Let's investigate the question from different viewpoints, and start by briefly introducing medical writing. The pharmaceutical industry, clinical research organisations, government, health services and academia all depend upon medical writing as a key communication link. The range of documents is immense, and their target audiences are diverse, ranging from scientists and regulators, to medical professionals and the public. In

summary, medical writing is essential and is diverse with regards to both document type and readership. Let us dissect the term 'medical writing', and consider, what is 'writing'?

Writing is a form of communication; it requires an abundance of skills, as well as a degree of flair, to deliver a clear message. Clarity in communication is achieved by organisation of the content and careful construction of the text. The skilled writer (or 'wordsmith') considers the reader's perspective, and success lies in the wise choice of words to unobtrusively convey the message. Simplicity is the key to clarity, but it is not easy to achieve. The wordsmith is well versed in the relentless editing, culling, reviewing, rearranging, recommencing, vocalising, and checking, until

finally, the desired concise message emerges. Such honed text has an easy spontaneity, which is a joy to read, and its message is undisputable. Perfection is the result of great endeavour, as is common to all forms of art, for the work of a skilled writer is indeed an art. If writing is an art, then is medical writing also an art?

Clarity in communication is important in all writing, but is unquestionably paramount in medical writing. Both the audiences and the nature of medical documents are diverse. Consequently, the fine skills of the wordsmith are crucial, to effectively engage and clearly communicate with different readers. Thus the constructive aspect of medical writing is an art, in similarity with other types of writing. However, clarity in

data would be the scientist's eyes and ears. By extension, medical writers would embody the scientist's hand, organizing the data into clear, understandable text.

The scientist's hand practices the art of writing, but is no less important to scientific progress than any other part of the scientist's body. For instance, to accurately describe symptoms of a disease, what they saw under a microscope or a new species of bird, scientists formerly had to sketch. Today, cameras have replaced the scientist's sketchbook. A scientist, working on a complicated microscope, uses the same principles of framing and light exposure to take a pictomicrograph as a photographer in a studio would use to take a picture. We call the studio photographer an artist, but we call the pictomicrographer a scientist. This is because the pictomicrographer is a specialist, taking a picture to convey a scientific message. The same logic holds true for medical writers. While they may apply the same mechanics as fiction and other non-fiction authors, a medical writer uses scientific knowledge to accurately convey a scientific message. They are specialists in a team of researchers, solving problems through communication.

Clear communication is essential to scientific progress. Medical writers are scientific mediators, communicating between researchers and governments, the public and other researchers. Miscommunications of research to any of these audiences may have a devastating impact on the future of that research. Unclear wording may cause a government to deem an experiment unethical; an ambiguous protocol may cause disbelief of a result; an improperly explained theory may cause public fear. Good writing can speed the rate of discovery and acceptance of

scientific theory whereas poor writing can cause the rejection of a new hypothesis. Put simply: good experiments poorly explained are worthless. Had Charles Darwin written *On the Origin of Species* as a jumbled set of facts instead of an elegant manuscript with convincing arguments, the theory of evolution may have been delayed by decades. Thus, communication lies at the heart of all research.

Medical writers are the scientists' hand. They are not involved in bench work or experimental planning. Medical writers are communications specialists, not simply taking dictation, but using scientific knowledge and writing skills to solve problems. Good writing has the power to turn confusion into clarity, intelligence into brilliance and good science into great science. If the

modern definition of *scientist* is: "A person who is trained in a science and whose job involves doing scientific research or solving scientific problems,"² then medical writers have the right to claim the identity, the prestige and the title of scientist.

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2. Merriam-Webster. Dictionary & Thesaurus HD (Version 3.3.2) [Mobile Application Software]. 2015. Available from: <http://apple.com/appstore>.

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writing also depends upon organisation and delivery of the content. The content of medical writing is based on complex science, and scientists and medical professionals are among its target audience. These aspects prevent classifying medical writing, in its entirety, as an art. So, is medical writing a science?

The fruition of science depends upon communication by writing. Science and writing are entwined and cannot be separated without impeding scientific progress. Medical writing enables scientific progress by providing vital communications, both within and between teams of scientific researchers, assessors, clinical professionals and the public. The nature and form of the information communicated depends upon its purpose and target audience, but it is always based on complex science. Effective medical writing

therefore requires application of the science, in a manner appropriate for each communication. This is not a wordsmith's task. This work is fundamentally a science, and is the task of the medical writer. So are medical writers scientists?

Medical writers carry significant scientific and ethical responsibilities, for their communications are key in the advancement of global human health. They not only have biological scientific knowledge and expertise, but also understanding of its application to medicine and the relevant specialities (for example, pharmacology and pharmacokinetics). They are also adept in scientific methodologies, such as statistical analyses and epidemiological methods. Thus medical writers extrapolate and interpret data, to communicate effectively and maximise the reader's understanding. Enthusiasm is a universal

feature of medical writers, and they interact easily across the two multidisciplinary spheres of science and medicine. Clearly, the knowledge and roles of the medical writer are indicative of scientist status, and they exceed the definition of a scientist as 'a person who is studying or has expert knowledge of one or more of the natural or physical sciences' (Oxford Dictionary, 2015).

In conclusion, medical writers possess the fine skills of the wordsmith. However, it is their expert scientific knowledge, their active role in progressing science to medical advancement, the significant responsibilities they hold, and their passion for medical science which sets them apart from other writers. Medical writers are most definitely scientists!

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Abstracts from the EMWA Spring Conference Poster Session

At this year's Spring Conference, EMWA was delighted to introduce a poster session.

There was a wide variety of posters available – all relating to aspects of medical writing or of relevance to medical writers. The poster session is an excellent way for EMWA members to see the latest thinking and research in a 'snapshot', and has been introduced as an annual addition to the educational offering from EMWA. Entry to the poster session is included in the conference registration fee, so there really was no reason not to go along to see what was on offer.

In case you were unable to get to the conference, the poster abstracts are printed below.

P1 - A Common and fundamental statistical mistake in medical manuscripts

Serene Ai Kiang Ong, Tina Ying XU

Statistics has become an indispensable part of most medical studies, from the design phase to the data analysis and results reporting stage. A basic understanding of the statistical concepts commonly used for quantitative studies is imperative for the medical researchers and writers to correctly interpret the statistical analysis results

and draw study conclusions. Failure to do so may lead to distorted study findings and predispose the manuscript to rejection by journals. This poster points out a common and fundamental statistical mistake in the preparation of medical manuscripts: the lack of a clearly formulated study hypothesis. The hypothesis is a quantitative

formulation of the research question, and it dictates research methodology, sample size planning, statistical analysis and reporting. We describe how a well written hypothesis sets out the framework for the rest of the study, and how it ties together the flow of the manuscript. Hints on how to improve a hypothesis are also provided.

P2 - Journal choice: which factors do medical writers and publications managers value?

Noëlle L O'Regan, Andrew Desson, Catherine Hill, Antonia Panayi, Christopher C Winchester, Slavka Baronikova

Introduction: Medical Writers (MWs) and Publications Managers (PMs) advise authors of pharmaceutical industry-sponsored research on journals for publication. We set out to determine the factors influencing this decision-making process.

Methodology: A survey was created and distributed via: The Publication Plan website and LinkedIn group; the International Society for Medical Publication Professionals mailing list; the EMWA website; the Oxford PharmaGenesis LinkedIn group and Twitter page; and authors' contacts. Here, we compare responses from MWs and PMs (overall results

were presented elsewhere).

Results: Of 163 respondents, 53 (33%) were MWs (38 [72%] working for medical communications agencies) and 42 (26%) were PMs (29 [69%] working for pharmaceutical/biotechnology companies). The most valued factor was listing on PubMed (MWs: 98% of respondents; PMs: 91%). Short publication lead time was valued more by PMs (71%) than MWs (49%). High publication charges (MWs: 11%; PMs: 10%) and creative commons licences (MWs: 8%; PMs: 12%) were principal factors in deterring respondents from considering a journal. Wide distribution was deemed to be the greatest

benefit of digital media (MWs: 34%; PMs: 33%), while the time, effort and cost involved in producing digital media was deemed to be its greatest challenge (MWs: 52%; PMs: 38%). Compliance challenges were also recognised by 27% of PMs but just 9% of MWs.

Conclusions: Publication lead times are more likely to influence PMs' than MWs' preferences for journals. PMs are more aware of digital compliance challenges than MWs; PMs and MWs should work together to understand the opportunities afforded by digital media.

P3 - The IMRaD template for original research manuscripts

Serene Ai Kiang ONG

Original research manuscripts for medical journal submissions often follow a certain format: Introduction, Methods, Results, and Discussion (colloquially known as IMRaD). The manuscripts are also subject to a word limit, commonly 3500–4500 words. At the same time, journal manuscripts must contain sufficient detail for other researchers to verify their research; the section that constitutes the dominant reason for rejection by journals is

the Methods. Poor methodology is out of the purview of the medical writer, but journal reviewers often report as well that insufficient experimental details are provided. Thus, journal manuscripts have to be comprehensive and tightly written.

An IMRaD template for journal manuscripts can simplify the writing. This poster describes the type of content that should be provided for each section, the length of each section, and how

each section should be organised. The flow through the paper and how each section connects with the other sections are also explained. Suggestions for improving readability are given, and particular focus is given to what journal reviewers look out for. Researchers sometimes assume that the key to writing a good research manuscript is a good command of language, but it is really about understanding the manuscript structure.

P4 - Accuracy of cited claims in the medical literature by specialty: a meta-analysis

Scott A. Mogull

Introduction: Accurately summarising previous research findings is essential in scientific communication. This meta-analysis compares studies evaluating the accuracy of cited claims, or quotations, in medicine.

Methodology: This analysis compares 15 studies identified from keyword searches of PubMed/MEDLINE (61 results) and Google Scholar (959 results). Studies were selected for those evaluating medical specialities and having a random selection of quotations that were evaluated by experts. For each speciality, the

average rate of misquotation was compared to the normalised average rate across all fields using a z ratio and $P > 0.05$ and 0.01 .

Results: Across medical fields, the average rate of quotation errors normalised to the total number of claims is 21.6% (840/3880). The reported error rate by speciality ranges from 6.8% (10/147) in Psychiatry to 38.2% (152/398) in Orthopaedics. In the rare case of studies reporting the same speciality, different studies reported error rates that varied considerably. For example, a 2010 study of the Orthopaedic

literature reports a 38.2% (152/398) error rate for a 2007–2008 sample whereas a subsequent study reports 17.9% (26/153) for a 2009 sample.

Conclusion: Although error rates of quotations are presented by field, the high variability of results between and within specialities may be partially due to differences of sampling and different evaluation of claims by experts. Thus, this average of the error rate (21.1%) from multiple studies might be a better overall estimate of the misquotation in medicine than any individual study.

P5 - Know your audience: transparency in congress attendance reports

Ricardo Milho, Sirisha Bulusu, Julia Bárdos and Danielle Machin

Objective: Good Publication Practice guidelines (GPP3) discourage redundant publication.¹ Industry-sponsored abstracts are often re-submitted to multiple congresses, based on the assumption that audiences are different. Here, we evaluated the information disclosed by biomedical congresses in delegate attendance reports, to examine whether it is possible to know in advance the typical audience of a particular congress.

Research Design and Methods: Congresses in eight disease areas were screened using the Conference Authority™ database (Sylogent);

the largest five congresses in each disease area were selected for analysis. The latest published attendance reports were identified by online search (August 2015), and the information disclosed by each report was classified according to nine information categories (detailed in Table footnote).

Results: 22/40 (55%) of the congresses screened provided attendance reports (Table). Congresses in oncology (5/5), cardiology (3/5), rheumatology (3/5) and neurology (2/5) published the most informative reports (mean number of information categories

provided: between 4.0 and 6.0).

Conclusions: The extent of delegate information disclosed varied with congress size, region and disease area. Congresses with ≥ 15000 delegates, those hosted in the USA or in oncology provided the most transparent delegate attendance reports.

References:

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Ann Intern Med 2015;163(6):461–4.

P6 - Awareness, attitudes, and perceptions of Croatian-based orthopaedic and trauma surgeons towards scientific manuscripts, publishing internationally and medical writing. Results of an online questionnaire

Diarmuid De Faoite, Bore Bakota, Mario Staresinic, Mario Kopljar, Ivan Cvjetko, Ivan Dobric

Introduction: The objective of this survey was to identify the importance placed by Croatian-based surgeons on writing scientific manuscripts and publishing them internationally, as well as their awareness of and attitudes toward medical writing.

Methodology: A link to an online survey was sent to 327 Croatian-based orthopaedic and trauma surgeons. The electronic questionnaire consisted of rating scales, multiple choice questions and free text reply boxes. A total of 61 surgeons based in Croatia replied to the survey, yielding a response rate of 19% (61/327).

Results: The survey results indicate that surgeons in Croatia are active in both research and the writing of manuscripts. There is also a high level of interest among them to publish internationally in English to further their careers. While 68% (38/56) of respondents initially claimed to know about medical writing, further questioning on the subject revealed a reduced level of familiarity with the concept. Only 19% (11/58) of respondents had ever engaged the services of a medical writer and they were generally satisfied with the work done across the three areas of language, editing

and scientific knowledge.

Conclusion: Medical writers are advised to increase awareness of their services among Croatian-based orthopaedic and trauma surgeons who may well have a need for their expertise.

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News from the EMA

More information can be found on the Agency's website: www.ema.europa.eu.

The articles included in this section are a selection from the European Medicines Agency's news and press release archive for November 2015 to March 2016.

European Medicines Agency guidance on methods to be used in the design and conduct of post-authorisation efficacy studies

November 6, 2015 – The European Medicines Agency (EMA) has released a draft scientific guideline that outlines how post-authorisation efficacy studies (PAES) should be designed by companies to support regulatory decision making in the European Union (EU). In addition, a guidance that describes the regulatory aspects for the fulfilment of imposed PAES is also published.

These studies are conducted within the authorised indication after a medicine has been granted a marketing authorisation, to collect data on aspects of its benefits that can only be or need to be explored once the medicine is marketed. In particular, PAES can address questions related to the benefits of a medicine stemming from the way it is used in everyday medical practice, including in specific populations, in relation to its use with other medicines or over time, and when there are changes in the understanding of a disease or the medicine's mechanism of action. The knowledge generated by these studies complements the information about the medicine's benefits that was assessed during its approval process.

These studies can be imposed by regulators

or may be carried out voluntarily by companies. The situations where a PAES can be required by medicines regulatory authorities in the EU were specified by the European Commission in April 2014. Prior to that date, regulators could request these types of studies in certain cases such as in the context of conditional marketing authorisations, authorisations under exceptional circumstances, paediatric use or referral procedures.

PAES can now be required for medicines with a standard marketing authorisation:

- At the time a marketing authorisation is granted, if new data indicate that the benefits of the medicine should be further studied.

The results of these studies should translate into better labelling and better use of medicines by patients and prescribers in clinical practice.

The draft scientific guideline applies to imposed and voluntary PAES. It has been developed in collaboration with the EU Member States and other interested parties and was released for a three-month public consultation. At the time of writing this article, additional regulatory and procedural guidance was planned for release together with the scientific guidance to clarify aspects in relation to the imposition of PAES, including the submission of study protocols by companies and their assessment by

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EMA, the assessment of the study results, and the possible regulatory outcomes following the conduct of an imposed PAES.



Launch of PRIME – Paving the way for promising medicines for patients

March 7, 2016 – The EMA launched its new PRIME (PRiority MEDicines) scheme to strengthen support to medicines that target an unmet medical need. The scheme focuses on medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients with no treatment options. These medicines are considered priority medicines within the EU.

Through PRIME, EMA offers early, proactive and enhanced support to medicine developers.

PRIME builds on the existing regulatory framework and available tools such as scientific advice and accelerated assessment. By engaging with medicine developers early, PRIME aims to strengthen clinical trial designs to facilitate the generation of high quality data for the evaluation of an application for marketing authorisation. Early dialogue and scientific advice also ensure that patients participate in trials that are likely to provide the necessary data for an application for marketing authorisation, and help to make best use of limited resources.

To be accepted for PRIME, a medicine has to show its potential to benefit patients with unmet medical needs based on early clinical data. Once

a candidate medicine has been selected for PRIME, the Agency:

- Appoints a rapporteur from EMA's Committee for Medicinal Products for Human Use (CHMP) or from the Committee on Advanced Therapies (CAT) in the case of an advanced therapy, to provide continuous support and help to build knowledge ahead of a marketing authorisation application.
- Organises a kick-off meeting with the CHMP/CAT rapporteur and a multi-disciplinary group of experts from relevant EMA scientific committees and working parties, and provides guidance on the overall development plan and regulatory strategy.

Increasing access to reports on adverse reactions to medicines

December 18, 2015 – The EMA will give increased access to reports on suspected adverse reactions to medicines authorised in the EU, while guaranteeing that personal data will be fully protected. This is the outcome of a revision of EudraVigilance Access policy, which was adopted by EMA's Management Board at its December 2015 meeting. The adoption followed a broad public consultation generating close to 400 comments which have been taken into account in the final policy.

EudraVigilance is the European database of all suspected adverse reactions reported with medicines authorised in the European Economic Area (EEA). Managed by EMA on behalf of the EU medicines regulatory network, EudraVigilance receives over one million adverse drug reaction (ADR) reports per year.



The large datasets included in the database provide the backbone for the continuous safety monitoring of medicines in the EU.

The Agency has made data from EudraVigilance publically available since 2011. At the time, EMA defined levels of access to information on ADR reports for medicines in EudraVigilance per stakeholder group: for European regulators, for healthcare professionals, consumers and patients, for marketing authorisation holders and for academia. Information from EudraVigilance on centrally authorised products and substances commonly used in medicines is available through a dedicated public website.

The revised policy takes into account the changes to the system of safety monitoring of medicines introduced by the pharmacovigilance legislation, such as new transparency provisions, the introduction of direct patient reporting across all EU Member States and a simplification of the reporting of adverse reaction reports for pharmaceutical companies.

Key changes include:

- The public will have access to more information, including line listings of the side effect reports and summary presentations for individual adverse reaction reports received in EudraVigilance. While ensuring that patients and those who have sent in reports of suspected side effects are not identifiable, this access represents a significant increase in transparency for the users of medicines.
- Academia will be able to get extended access to data sets upon request in support of their research activities.
- The Uppsala Monitoring Centre (UMC) of the World Health Organization (WHO) will

be added as a new stakeholder group who will be provided with individual case safety reports (ICSRs) originating from within the EEA.

- Medicines regulatory authorities in countries outside the EEA will be provided with data, in line with the WHO dataset, upon request.
- Marketing authorisation holders of medicines authorised in the EU will be given enhanced access to reports related to their medicines in support of their signal detection and other pharmacovigilance obligations.

These changes will come into effect in the third quarter of 2017 in parallel with EMA implementing a series of technical improvements to the EudraVigilance system.

Data transfer agreement with WHO

To allow the transfer of data on suspected adverse reactions occurring in the EEA, EMA and the WHO concluded an agreement earlier this month. The data will be transferred electronically to WHO's UMC on a daily basis. The start of this data transfer in 2017 will follow the introduction of the new reporting rules within the EEA which take effect after a successful audit of the improved EudraVigilance system.

The transferred reports on suspected adverse reactions occurring in the EEA will contribute to VigiBase, the WHO Global Individual Case Safety Report database, on behalf of the WHO Programme on International Drug Monitoring. Better global knowledge on the safety of medicines will also help to promote the safe use of medicines for the benefit of patients worldwide.

- Assigns a dedicated EMA contact point.
- Provides scientific advice at key development milestones, involving additional stakeholders such as health technology assessment bodies to facilitate patients' quicker access to the new medicine.
- Confirms potential for accelerated assessment at the time of an application for marketing authorisation.

While PRIME is open to all companies on the basis of preliminary clinical evidence, micro-, small- and medium-sized enterprises (SMEs) and applicants from the academic sector can apply earlier on the basis of compelling non-clinical data and tolerability data from initial clinical trials. They may

also request fee waivers for scientific advice. Since SMEs and academia often lack experience with the regulatory framework, they can benefit in particular from earlier scientific and regulatory advice.

Strengthened regulatory toolkit for medicines addressing unmet needs

EMA has released guidance documents on PRIME as well as a comprehensive overview of the EU early access regulatory tools (accelerated assessment, conditional marketing authorisation and compassionate use). Revised guidelines on the implementation of accelerated assessment and conditional marketing authorisation have also been published. All these tools are reserved for

medicines addressing major public health needs. Although PRIME is specifically designed to promote accelerated assessment, it will also help to make best use of other EU early access tools and initiatives, which can be combined whenever a medicine fulfils the respective criteria.

PRIME was developed in consultation with the Agency's scientific committees, the European Commission and its expert group on Safe and Timely Access to Medicines for Patients (STAMP) as well as the European medicines regulatory network. The main principles of PRIME were released for a two-month public consultation in 2015 and the comments received were taken into account in the final version.

Handling competing interests: revised rules for Management Board members

January 14, 2016 – The EMA has published its revised policy on handling competing interests for members of its Management Board. The revised policy was adopted at the December 2015 Board meeting. The revision aligns EMA's Management Board policy with the Agency's policy on handling declarations of interests for scientific committee members and experts which underwent a major overhaul.

In order to ensure that its scientific experts, staff and Management Board do not have any financial or other interests in the pharmaceutical industry that could affect their impartiality, EMA, over recent years, has continuously reviewed and fine-tuned its policies taking into account experience obtained. The Management Board takes strategic decisions and oversees [sic] corporate activities of the Agency, such as setting EMA's budget and approving its annual work programme. It does not give recommendations on marketing authorisations of medicines.

The Agency will apply a 'risk-based' approach, to determine the level of involvement in activities of the Management Board for a Board member with a declared interest. This approach is based on four factors:

- The nature of the declared interest
- The timeframe during which the interest occurred
- The type of Management Board activity and the likely impact of the Board's decision on the pharmaceutical, or other industry
- The type of action requested by the Management Board, e.g., whether a decision such as approval or endorsement has to be taken by the Board or not.

The new policy will enter into force on 1 May 2016.

Breach of trust procedure

The current "breach of trust" procedure on declarations of interests for Management Board members has also been revised and was approved by the Board in December 2015. Changes are aligned with those introduced in 2015 for the breach of trust procedure for the scientific committee members and experts. The breach of trust procedure was developed in 2012 to deal with cases of incorrect or incomplete declarations of interests of Board members. The revised breach of trust procedure came into effect on 1 January 2016.



EMA sets up task force on Zika virus

February 8, 2016 – The EMA has established a task force of European experts with specialised knowledge in vaccines, infectious diseases and other relevant expertise to contribute to the global response to the threat of the Zika virus infection. This group will be available to give advice on any scientific and regulatory matters for the research and development of medicines or vaccines against the virus.

The EMA task force was established following the declaration by the WHO on 1 February 2016 that the Zika virus outbreak is a Public Health Emergency of International Concern. There are currently no anti-Zika virus vaccines or medicines that are approved or undergoing clinical studies. The Agency is encouraging medicine developers to contact EMA if they have any promising projects in this area. EMA will also

proactively reach out to companies already planning to work on investigational vaccines and offer scientific and regulatory advice. EMA will review any new information as soon as it becomes available to support the response to this widening public health crisis.

During a health emergency such as the Zika virus outbreak, EMA works closely with European bodies, including the European Commission and the European Centre for Disease

Prevention and Control (ECDC) and with international partners such as WHO and other international regulators from affected countries.

Existing mechanisms available to support medicines' developers

There are already a number of existing mechanisms and tools which can be used to help speed up the research and development of medicines and vaccines in the context of an emerging viral disease such as Zika. Companies may seek scientific advice from EMA on the appropriate tests and studies required in the development of their products. Early and regular interaction with the Agency can significantly speed up the development of medicines. The European Article 58 procedure also provides an opportunity to give a scientific opinion on treatments intended primarily for use in non-EU countries, while collaborating closely with WHO and experts from those countries.



Consultation on revised guideline on medicines to treat Alzheimer's disease

February 1, 2016 – The EMA has released a revised guideline on medicines for the treatment of Alzheimer's disease and other types of dementias for a six-month public consultation. Stakeholders are invited to send their comments by 31 July 2016 to: cnswpsecretariat@ema.europa.eu using the template provided.

According to the WHO, 35.6 million people have dementia worldwide and this number is expected to double by 2030. Recent progress in understanding the pathophysiology of Alzheimer's disease suggests that the biological changes associated with the disease start to occur as early as 10 to 20 years prior to the emergence of clinical symptoms. Experimental medicines should therefore be evaluated in earlier disease stages as certain treatments may be more effective at that stage than later in the illness.

EMA considers dementia as a key public health priority and follows a multi-stakeholder approach to facilitate research and development of more effective medicines. The revised guideline takes into account comments received at EMA's workshop on the clinical investigation

of medicines for the treatment of Alzheimer's disease in November 2014. This workshop brought together a wide range of stakeholders, including patient representatives, regulators, pharmaceutical industry and independent experts. The aim of the workshop was to ensure that during the revision of its guideline, EMA would be able to consider the most up-to-date scientific developments in understanding and treating Alzheimer's disease and views from experts in the field. The revised guideline also builds on EMA scientific advice provided for a number of specific development plans for Alzheimer's disease in recent years, as well as the qualification of several biomarkers for the selection of patients in clinical trials.

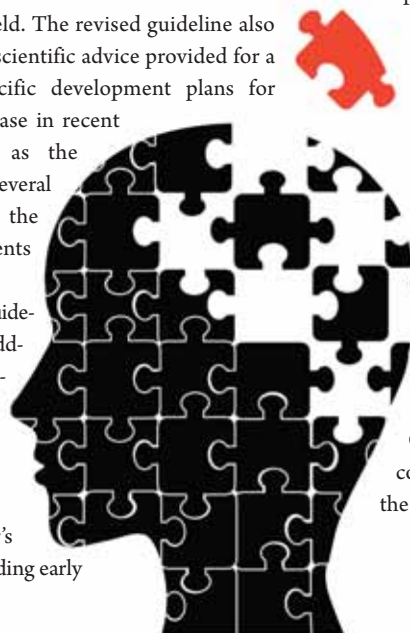
The revised guideline specifically addresses the following:

- The impact of new diagnostic criteria for Alzheimer's disease, including early

and even asymptomatic disease stages, on clinical trial design.

- The choice of parameters to measure trial outcomes and the need for distinct assessment tools for the different disease stages in Alzheimer's (different signs and symptoms, differences in changes over time, severity).
- The potential use of biomarkers and their temporal relationship with the different phases of Alzheimer's disease at different stages of medicine development (mechanism of action, use as diagnostic test, enrichment of study populations, stratification of subgroups, safety and efficacy markers, etc.).
- The design of long-term efficacy and safety studies.

Comments received during the consultation will be taken into account in the finalisation of the guideline.



Guidance for the publication of clinical data

March 3, 2016 – The EMA has published detailed guidance for pharmaceutical companies on the requirements to comply with its policy on the publication of clinical data. EMA's pioneering policy entered into force on 1 January 2015 and applies to clinical reports contained in all marketing authorisation applications submitted on or after this date. The first reports are currently foreseen to be publicly available in September 2016.

The guidance consists of four chapters:

- The first chapter is an overarching introduction with information on the scope and definitions used throughout the text.
- The second chapter details procedural aspects on the submission of clinical reports including the concrete processes.
- The third chapter gives guidance to companies on how to anonymise clinical reports for

the purpose of publication. EMA recognises that a number of methods are available to make sure the data is presented in a form that does not allow re-identifying individuals who have participated in clinical trials. Therefore the guidance does not single out one specific anonymisation method yet gives recommendations to companies on how to best balance data utility for researchers with a minimal risk of re-identification. Companies will need to provide a report explaining their approach to the anonymisation of the data, which will be reviewed and published by EMA.

- The fourth chapter focuses on the identification and redaction of commercially confidential information (CCI) in clinical reports submitted to EMA for the purpose of publication. The guidance makes clear that the vast majority of the information contained in clinical reports is not considered CCI. However, in the limited circumstances in

which clinical reports might contain CCI, companies will need to submit to EMA for review a table justifying why such data has been redacted. The guidance clarifies which type of data EMA would typically refuse as being CCI and how the redaction of such data will be handled.

This detailed set of guidance has been finalised following an extensive consultation with all stakeholders concerned throughout 2015.

To further ensure that companies are well prepared for the proactive publication of clinical data, EMA will now start reaching out to companies which are concerned by the first wave of publication, i.e. those for which the decision making process has been finalised since the policy entered into force. In addition, EMA will organise a webinar in the second quarter of 2016 to allow companies to ask any outstanding practical questions. This webinar will be live broadcast and will be available for future reference on the EMA website.

Journal Watch

Journal Watch is based on the French-language blog Rédaction Médicale et Scientifique, available at <http://www.redactionmedicale.fr>.



Real world data have their reporting guidelines: The RECORD statement

In pricing and reimbursement dossiers, real world data (RWD) are commonly used to complete information from randomised trials. The RWD are routinely collected without specific or a priori research questions developed prior to utilisation for research. Data sources are registries, primary care databases, administrative data, etc. The REporting of studies Conducted using Observational Routinely collected health Data (RECORD) statement was created to assist authors to write papers. RECORD is an extension of the STROBE (STrengthening the Reporting of OBServational studies in Epidemiology) statement, and it has its own website (<http://www.record-statement.org>). It is a result of a collaborative process that involved more than 100 international stakeholders comprising researchers, journal editors and

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consumers of data. The RECORD checklist has 22 items that are described with illustrative examples by Benchimol *et al.* in an article in *PLoS Medicine*.

Reference: Benchimol EI, Smeeth L, Guttman A, Harron K, Moher D, Petersen I, *et al.* The REporting of studies Conducted using Observational Routinely collected health Data (RECORD) Statement. *PLoS Med* 12(10): e1001885.

Scoping reviews: There is a need for a guideline to standardise methods and reporting

A team of Canadian epidemiologists analysed 494 scoping reviews that were disseminated between 1999 and 2014. Scoping reviews are used to identify knowledge gaps, set research agendas and identify implications for decision-making, and their number has steadily increased since 2012. The conduct and reporting of scoping reviews is inconsistent in the literature. Scoping reviews can be seen as a hypothesis-generating exercise, while systematic reviews can be hypothesis-testing. A mean of 118 studies (range 1 to 2600) were included in the 494 scoping reviews. Assessment of scoping reviews was done with the Joanna Briggs Institute methodology guidance: 13% of scoping reviews reported the use of a protocol, 36% used two reviewers for data sharing, 43% used a pre-defined charting form. No guidelines for reporting scoping reviews or studies that assessed the quality of scoping review reporting were identified.

Reference: Tricco AC, Lillie E, Zarin W, O'Brien K, Colquhoun H, Kastner M, *et al.* A scoping review on the conduct and reporting of scoping reviews. *BMC Med Res Methodol*. 2016;16:15

Marketing purposes influence study design for 20% of randomised clinical trials publications in the highest impact general medical journals

Under the leadership of Virginia Barbour, six investigators independently reviewed 194 randomised clinical trials (RCTs) published in 2011 in six journals (*Annals Intern Med*, *BMJ*, *JAMA*, *Lancet*, *NEJM*, *PLoS Medicine*). The investigators defined six indicators of marketing-influenced trials and characterised the reviewed trials as YES/MAYBE/NO suspected marketing trials: 41 trials (21%) were categorised YES, 14 (7%) as MAYBE, and 139 (72%) as NO. All YES and MAYBE trials were funded by the manufacturer compared to 37% of NO

trials ($p < 0.001$). There was no significant difference between groups in the median number of participants screened ($p = 0.49$), but the median number of centres recruiting participants was higher for YES compared with NO trials (171 vs. 13, $p < 0.001$). YES trials were often better reported in terms of blinding, safety outcomes and adverse events than NO trials. YES trials more frequently included speculation that might encourage clinicians to use the intervention outside of the study population compared to NO trials (59% vs. 37%, $p = 0.03$). Two journals (*NEJM* and

Lancet) published 77% (150/194) of the trials. The consensus was that about a fifth of the drug trials published in the highest impact medical journals in 2011 had features that were suggestive of being designed for marketing purposes.

Reference: Barbour V, Burch D, Godlee F, Heneghan C, Lehman R, Perera R, *et al.* Characterisation of trials where marketing purposes have been influential in study design: a descriptive study. *Trials*. 2016;17:31.

Only 29% of completed clinical trials conducted by the faculty at major academic centres were published within two years of completion

Researchers from Yale School of Medicine analysed 4347 interventional trials across 51 US academic centres registered on ClinicalTrials.gov with a primary completion date between October 2007 and September 2010. Among the trials, 1005 (23%) enrolled more than 100 patients, 1216 (28%) were double blind, and 2169 (50%) were phase II to phase IV. Of the 4347 trials, 2458 (56.5%) had been published as of July 2014. The time (months) from primary completion date to publication varied significantly, with 1245 (28.6%) having been published within two years and 952 (21.9%) more than 24 months after the primary completion date. Only 13% (547/4347) reported results on ClinicalTrials.gov. Academic medical centres showed noticeable variation and poor performance in the dissemination of clinical trials results.

Reference: Chen R, Desai NR, Ross JS, Zhang W, Chau KH, Wayda B, *et al*. Publication and reporting of clinical trial results: cross sectional analysis across academic medical centres. *BMJ*. 2016;352:i637.



Randomised clinical trials published in high impact medical journals are less likely than observational studies to be the subject of a journal press release

Researchers from Auckland (NZ) tested whether the design of a clinical study determines the extent of its media coverage, because the latter influences public health beliefs. They compared two study designs: RCTs (n =85) and observational studies (n =86). Observational research is conducted more frequently than RCTs, and can generate hypotheses but not reliably test them. The investigators searched publications in seven high impact journals (*Annals Intern Med*, *BMJ*, *JAMA*, *JAMA intern Med*, *Lancet*, *NEJM*, *PLoS Medicine*) in 2013. They used www.eurakalert.org to collate editorials and press releases that accompanied the publications. They also used *Factiva*, the top 10 USA and UK newspapers, and the top 10 English language news agencies. They observed that

editorials in high impact journals were more commonly written for RCTs than observational research. Journal press releases, which influence the content of news stories, were more common for observational studies than RCTs (50% vs 17%, $P < 0.001$). The conclusion was that study design of clinical studies published in high impact medical journals is not associated with the likelihood or amount of ensuing news coverage.

Reference: Wang MTM, Bolland MJ, Gamble G, Grey A. Media coverage, journal press releases and editorials associated with randomized and observational studies in high-impact medical journals: a cohort study. *PLoS One* 2015;10(12):e0145294



Too many results are irreproducible: strategies to improve reproducibility must be implemented

The report of a meeting held in London with a panel of 80 experts was published at the end of 2015 by the Academy of Medical Sciences, the Biotechnology and Biological Sciences Research Council, the Medical Research Council and the Wellcome Trust. This meeting discussed poor research practices, as described by R Horton in the *Lancet*: “*The case against science is straightforward: much of the scientific literature, perhaps half, may simply be untrue. Afflicted by studies with small sample sizes, tiny effects, invalid exploratory analyses, and flagrant conflicts of interest, together*

with an obsession for pursuing fashionable trends of dubious importance, science has taken a turn towards darkness.” This 80 pages report described six issues: data dredging, omitting null results, unpowered study, errors, underspecified methods, weak experimental design; and seven possible strategies to improve reproducibility: open data, pre-registration, collaboration, automation, open methods, post-publication review, and reporting guidelines. A poster is proposed to researchers with the seven strategies using logos representing the six issues.

Reference:

1. Horton R. Offline: What is medicine's S sigma? *Lancet*. 385(9976):1380
2. Reproducibility and reliability of biomedical research: improving research practice. Symposium report: 2015 [cited 2016 Mar 7]. Available from: <http://www.acmedsci.ac.uk/policy/policy-projects/reproducibility-and-reliability-of-biomedical-research/>

In the Bookstores



Getting Research Published. An A to Z of Publication Strategy (Third Edition)

Elizabeth Wager
CRC Press; 2015
ISBN 9781785231384
£29.95. 188 pages.

Dr Elizabeth Wager has been a freelance publications consultant and trainer since 2001, having previously worked within the publishing and pharmaceutical industries. She is a current and previous member of a number of committees that safeguard biomedical publication ethics, and has authored and co-authored a number of papers and industry-standard books on good publication practice and peer review. I have heard her speak on publication strategy on a number of occasions and, just like her presentations, *Getting Research Published* (now in its third edition) is packed full of good advice and sprinkled with humour. This makes it very easy to read and digest.

This book is designed to be relevant to readers with differing levels of experience and expertise in the management and writing of journal publications and abstracts, whether they are based in pharmaceutical companies, medical communications agencies, or academia. It consists of two parts: the first, which contains five chapters, provides an overview of publication strategy, and the second is organised (as the title suggests) as an A–Z list of useful topics in medical publications planning and practice.

This new edition has been revised to contain recommendations from the most recent edition of the Good Publication Practice guidelines (GPP3)¹ and the latest publications guidance from the International Committee of Medical Journal Editors (ICMJE),² which were both published in 2015.

The first chapter of *Getting Research Published* provides step-by-step suggestions for timely publication of an individual paper with the minimum of pain and stress for the participants. Wager emphasises the need first to establish a writing group for the paper and then agree the roles and responsibilities of its members at the start of the process. She also recommends early discussions to agree the target audience for, and aims and content of, the paper. Finally, there is a reminder that the responsibilities of the writing group don't end when its members sign off the

final draft – they still have to complete the submission package (e.g. copyright transfer forms, declarations of authorship, and statements on competing interests), revise the manuscript if required, and, finally, check the proofs.

In chapters 2 and 3, Wager goes on to propose a strategy for establishing a publication plan for a multicentre study and makes suggestions for gauging how long the process might take. Such studies are likely to provide opportunities for multiple publications that highlight different aspects of the study's findings, or country-specific data. It is important that each of these publications comes into the public domain in a timely manner – particularly if the study is a phase 3 clinical trial – but without jeopardising other planned publications. Wager explains how, by assembling a well-chosen team early in the study, its members can use their expectations of the types of data that will be produced in the study, and the timetable for their delivery, to start to assemble a list of appropriate scientific meetings with abstract submission deadlines close to the expected date for database lock, and to sketch out how the actual dates of the meetings might influence submissions to journals. Of course, study dates change and Wager stresses the importance of getting the team together regularly, either in person or on the phone, to ensure that the publication plan reflects those changes.

Chapter 4 is devoted to the advantages and disadvantages of involving professional medical writers in a publication. This chapter is firmly underpinned by the ICMJE and GPP guidelines and the need to make sure that all authors are happy to have a medical writer on board; be clear about what the medical writer is going to do (and not do); and understand how the target journal views the work of the medical writer and how it should be acknowledged.

In chapter 5, the author uses a fictional tale of ambitious pharma executives, greedy agencies, disinterested academics, and unapproachable statisticians to illustrate how the absence of a publication strategy can prevent the outcomes of pharmaceutical research reaching the eyes of doctors whose patients might benefit from them.

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It's an unusual way to make a point, but as the alternative would be akin to a lecture, I think that it works well.

Part 2 of *Getting Research Published* – the author's dictionary of medical publishing – covers around 250 topics in 145 pages. The list of terms is comprehensive and even covers a number of areas that I didn't know I didn't know about. This part of the book is intended both to provide more detailed information about specific topics covered in the first part of the book and for people to consult if they have a particular problem or question. It is a fantastic resource for people who have had little or no exposure to the medical publishing industry and for others like me, who worked in the industry some time ago and need to catch up on more recent developments.

In short, this is a must-have book for writers, editors and account managers in medical communications agencies and in the publications departments of research institutions and pharmaceutical and medical device companies. I also recommend it to my fellow freelance writers as an easy way to ensure that you are 'on the same page' as the companies that you are working with when it comes to disseminating medical research findings.

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1. Battisti WP, Wager E, Balzer L, Bridges D, Cairns A, Carswell CI, *et al.* Good publication practice for communicating company-sponsored medical research: GPP3. *Ann Intern Med.* 2015;163(6):461–1.
2. International Committee of Medical Journal Editors. Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals. 2015 [cited 2016 Mar 14]. Available from: <http://www.icmje.org/recommendations/>.

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The Webscout

Medical Communications

'Medical Communications' is an unspecific term. Sometimes it is used only to describe publications, medical education, and public relations; sometimes it also includes regulatory writing and advertising.

Our colleagues from the American Medical Writers Association offer a technical definition at www.amwa.org/about_med_communications. 'Medical communications is a general term for the development and production of materials that deal specifically with medicine or healthcare. Medical communicators write, edit, or develop materials about medicine and health.' Hence, this definition closely links to medical writing, as many people working in this business are medical writers.

According to the careers guide *From academic to medical writer* by Annick Moon, the objective of medical communications is 'to educate and inform stakeholders such as doctors, patients, nurses and hospital managers about innovations and perspectives in healthcare'. A Google search displays countless companies offering medical communications services and there is a need for qualified medical communicators. For anyone currently thinking about starting a career in medical communications, Annick Moon's guide gives some advice on how to achieve this, with a focus on the role of a medical writer: <http://medcommsnetworking.com/careersguide.pdf>.

The term 'health communications' – which describes a subcategory of medical communications – is usually used when it comes to promoting health information to the general public, e.g. during public health campaigns (http://en.wikipedia.org/wiki/Health_communication).

The so-called 'Pink Book' was published by the US Department of Health & Human Services as a planning guide for health communication programs. It leads you through the planning process step-by-step, from strategy and message development to implementation and impact assessment. It also explains how health communicators can make use of a wide range of methods, including public relations, advertising, and media advocacy. The e-book is available from www.cancer.gov/publications/health-communication/pink-book.pdf.

Social media can also be integrated into public health campaigns. The Centers for Disease Control and Prevention has issued *The Health*

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Communicator's Social Media Toolkit. The main advantage of using social media is that it is interactive. It helps you understand your audience better. Depending on your audience, the channels of communication might differ. As an example given in this toolkit, Facebook had been considered a good tool for a mother-centred program as it has a large population of young women with children, is free, and requires minimal technical expertise. You can download the complete toolkit from www.cdc.gov/healthcommunication/ToolsTemplates/SocialMediaToolkit_BM.pdf.

Finally, let's have a side glance at physician-to-patient communication, which is also covered by the term medical communications. Effective communication between patient and doctor is considered essential to efficient health care. An article on the impact of ineffective clinician-patient communication summarises that it is linked to an increased malpractice risk, non-adherence, and poor health outcomes. According

to the article's authors, addressing communication skill deficits is of the utmost importance: <http://healthcarecomm.org/about-us/impact-of-communication-in-healthcare/>.

TEDMED, the health and medicine edition of the TED conferences (a global community to share ideas and passions), invited experts to a virtual round table on this topic in 2013. They discussed initiatives to improve physician-to-patient communication, from education to technical applications. The recording can be found at <http://www.tedmed.com/greatchallenges/liveevent/277484>

The basic methods to ensure effective communication during a patient interview, including the principles of open questions, empathy, and summarising, are illustrated in the following video: <https://www.youtube.com/watch?v=13m6d95yJd8>.

Did you like this Webscout article? Do you have any questions or suggestions? Please feel free to get in touch and share your thoughts.

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Regulatory Matters

The growing need for drug safety documents



SECTION EDITOR



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When I first started in regulatory writing (over a decade ago now, how time flies when you're a medical writer), the types of document that I would be involved in were typically clinical study reports, investigator brochures, maybe protocols, and then later clinical summaries and overviews. Posts advertising for regulatory writers would usually mention these documents, which were also the focus of the EMWA training programme. My impression was that the pharmaceutical companies did not give as much importance to drug safety documents as to other types of document. These documents seemed more like

compilations of notifications of adverse drug reactions rather than documents that attempted to synthesise and analyse information.

Increasing prominence of drug safety documents

A greater focus on drug safety, both during drug development and post approval, has however led to a change in how these documents are perceived and increased documentation requirements. Drug safety documents are now becoming increasingly important to companies and regulators, and a quick glance at the current EMWA Professional Development Programme Brochure shows that workshops are available for the three main types: Periodic Benefit Risk Assessment Reports (PBRERs), Development Safety Update Reports (DSURs), and Risk Management Plans (RMPs).

Differences between drug safety documents and other regulatory documents

In terms of general processes, there are differences between these drug safety documents and other regulatory documents (which, from my perspective, I will call traditional regulatory document types, for want of a better term). One obvious difference is that in the case of PBRERs and DSURs, these are documents that are updated periodically, whereas other traditional regulatory documents are usually written on an as needed basis (except for investigator brochures and protocols I suppose). This periodic nature means that resource planning is more predictable although the timetables for submitting drug safety documents can be quite complex (see later discussion). RMPs are not needed according to

a periodic schedule, but they are still living documents that are frequently updated. To assist with the updating process, drug safety documents generally have a very modular structure.

Another difference is that drug safety documents will often attempt to integrate information from multiple sources within 'the real world' (e.g. spontaneous reports of adverse drug reactions from health care providers and literature reports) to a greater extent than traditional regulatory documents, which generally use clean data collected with well controlled procedures (for example, a case report form). The large number of sources coupled with their greater heterogeneity can be a challenge when writing and compiling drug safety documents.

Development Safety Update Reports

On submission of the marketing authorisation application, the safety of a drug will be exhaustively assessed by the reviewers. If safety issues are detected, this will be too late to prevent exposure of patients to the risk. The health authorities therefore continually monitor the safety of drugs in development. In the past, each International Conference on Harmonisation (ICH) region had its own requirements for providing updated safety information. As part of the drive towards common standard documents, the DSUR was introduced. (Note that a DSUR needs to be submitted for drugs that have already been approved if clinical development for a different indication, for example, is still ongoing). ICH Topic E2F provides detailed guidance on the structure and content of a DSUR (http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E2F/Step4/E2F_Step_4.pdf).

Periodic Benefit-Risk Evaluation Reports

The number of patients exposed to a given drug during drug development may be too small to reliably detect small (but important) safety signals and patient populations are often limited to 'ideal populations'. Once on the market, not only are many more patients exposed, but patients are also treated who would not have been included in clinical trials. This 'real world data' provides important additional information on the use of the drug in clinical practice.

The main purpose of the PBRER, according to the ICH guideline E2C (R2) (available from

https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E2C/E2C_R2_Step4.pdf), is therefore to

“present a comprehensive, concise, and critical analysis of new or emerging information on the risks of the medicinal product, and on its benefit in approved indications, to enable an appraisal of the product’s overall benefit-risk profile.”

The PBRER replaced the Periodic Safety Update Report (PSUR), itself an attempt by ICH to harmonise the format for safety reporting. The PSUR focussed, as the name implies, on drug safety. There was increasing recognition, though, that the safety of a product should be interpreted in the context of its benefit. Clearly, the threshold for acceptable safety risks is higher in an oncology product than in cough mixture. The PBRER, as its name (Periodic Benefit-Risk Evaluation Report) implies and as reflected by the mission statement above, attempts to put safety issues into context. In many ways, the benefit-risk section of the PBRER bears many similarities to the benefit-risk sections of a clinical overview.

Overlap between DSUR and PBRER and submission schedule

There will be a period in which a drug has been approved for a given indication but is still under development for another indication or, for example, while studies included in the Paediatric Investigation Plan are being conducted. Often, this period will extend for many years. During this time, both DSURs and PBRERs will be required. As there will be much overlap between the two documents (in fact, the modular nature of the two types of report means that some sections may be identical), it makes sense to develop and submit the two documents in parallel. This also eases the burden on the health authority reviewers. Working out the schedule to make this work is not always easy. The submission dates for PBRERs are generally gated on the first approval of the drug (International Birth Date or IBD) whereas DSURs are gated on first authorisation for the conduct of a clinical trial (Development International Birth Date or DIBD). Furthermore different regions may have different requirements regarding the frequency with which a document needs to be submitted.

Risk Management Plans

Unlike PBRERs and DSURs, RMPs do not follow a periodic schedule. An RMP must be submitted with an initial Marketing Authorisation Application and it is then updated following certain triggers, for example, the availability of new information that may have an impact on the benefit-risk profile. They may also be updated when an important pharmacovigilance milestone is reached (for example, when the results of a Post-Authorisation Safety Study [PASS] become available). In addition, the European Medicines Agency or a national health authority can request an update if these bodies consider it necessary. The upshot is that the timing of RMP updates is unpredictable, and there may be situations when an update needs to be submitted at short notice.

Typically, an RMP includes information on the safety profile, approach to risk minimization, plans for studies to generate further safety and efficacy information, risk factors for adverse events, and measurement of effectiveness of risk-minimization measures. The exact format and content is variable from one region to another, in part because, unlike PBRERs and DSURs, RMPs are not explicitly covered by ICH guidance. Companies will usually have an internal core global document that can then be adapted as necessary to the local requirements (the European Medicines Agency for example has detailed guidance on the structure of EU RMPs, see http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2012/11/WC500134650.pdf).

Potential opportunities ...

The increasing focus on pharmacovigilance and drug safety is generating a greater need for drug safety documentation. The documents discussed above need to be updated regularly (periodically in the case of PBRERs and DSURs) or in the case of an RMP, an update may be needed at short notice. As drug safety is not something that stops as soon as approval is obtained, PBRERs are still required even when clinical development of a product has finished. In some cases, the documents may be complex, and the interrelationship between these documents may need careful management. The result is a high documentation burden for pharmaceutical companies and potentially a good source of work for regulatory writers.

Lingua Franca and Beyond

Communication, communication and even medical communication ...

What is it about? Let's start with the Wikipedia definition: "Communication (from Latin *communicāre*, meaning 'to share') is the purposeful activity of information exchange between two or more participants in order to convey or receive the intended meanings through a shared system of signs and semiotic rules."¹ So it is about *sharing information on purpose*, and in this light medical communication should be perceived as any medical information shared between any parties, as long as it is done on purpose. But is it really what we, medical writers, have in mind when talking about medical communication? To check it, I went back to the archive of *Medical Writing* and even *The Write Stuff* (*Medical Writing* ancestor) and searched for a definition or explanation. It didn't take me long to come across Ryan Woodrow's article in which he tries to answer a very simple question: "So what exactly does your job involve?" Ryan is a freelance medical communication consultant. His answer is simple and short: "I help pharmaceutical companies to communicate about their drugs to doctors", but then he elaborates:

"I understand that many EMWA members are from a background of clinical and regulatory writing, and that medical communications may be somewhat of a mystery. Well, *med comms* agencies traditionally support pharmaceutical and biotechnology companies in three key areas:

1. Publication planning, including the development of clinical publications and congress presentations in close conjunction with authors and in line with Good Publication Practice.
2. Thought-leader educational programmes, including the delivery of live scientific meetings such as advisory boards, satellite symposia and standalone meetings. This includes generating all the scientific content of the meeting (from slides to programme books).
3. Production of an extensive range of other educational materials for healthcare professionals including slide kits and monographs."²

Well, *med comm* agencies definitely focus their activities on the pharmaceutical industry, but medical communication is definitely much wider and covers, in my eyes, any communication relating to medicine and biomedicine. I would say

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that it is also about medical journalism, communication to non-medical audiences, including patients, caregivers and patient advocates; and don't forget the involvement of regulatory agencies. We heard and learnt about it a lot during the fantastic EMWA Symposium in May this year.

I am sure that many of us, working in medical communication and publishing, have our own stories to share, pinpointing the risky part of it. For me the most terrifying ones relate to the accuracy of information shared, quality of published articles and overall proofreading. I will never forget, when in the very last moment just before sending my thesis for printing, when I was tired and fed up of proofreading the whole thing endless times, all of a sudden I noticed *assessmnet* printed in capital letters on my title page... I was terrified, but fortunately the printed version had *assessment*. Let's read about David Bennett's story now. David has very many years of experience working in the medical communication business and now he is going back to his early days.

I would also like to welcome Elisabeth Heseltine, who shares her thoughts in response to articles on acronyms and abbreviations published in *Medical Writing 24.4*, in December 2015. Elisabeth is a freelance scientific editor, translator and reporter-writer with great international experience. I would like to take this opportunity to thank Elisabeth for her comments and also to remind all readers that your comments and opinions relating to articles published in this section are more than welcome.

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More thoughts on acronyms and abbreviations

Acronyms and abbreviations have been defined as 'A code designed to keep out the uninitiated', i.e. 'If you don't understand this bunch of letters, you're not a member of the club.' This is counterproductive for communication, as it ostracizes readers outside the *club*. People looking for information in a domain outside their own have to look up strings of letters in a list of definitions (if there is one) back at the beginning of an article, thus constantly interrupting their reading.

Another crime committed by abbreviations and acronyms is that they remove the meaning from the phrase they represent. Perhaps the most egregious example is the now widespread use of FGM for *female genital mutilation*. Some years ago, the World Health Organization changed the term *female circumcision* to *female genital mutilation* expressly to include the word *mutilation*, to underscore the appalling nature of this practice. Reduction of the term to FGM removes that effect and again makes the term anodyne.

A further crime due to abbreviations and acronyms is that many medical terms have the same abbreviation or acronym, with consequences for patient safety.¹⁻³ The Joint Commission, an organisation that accredits health care institutions in the USA, has even issued a *don't use* list to avoid the multiple medical errors that have occurred due to misunderstanding an abbreviation or acronym. The Health Quality Council of Alberta has a website (abbreviation.hqca.ca) with the slogan 'Writing it out can save a life. Let's stop the use of abbreviations in healthcare.'

Written abbreviations were first used when the author had to chip words into stone or write with ink on scarce parchment, and continues today with text messaging on small cell phone screens. Although acronyms date back almost as far as abbreviations, their widespread use is a 20th Century linguistic phenomenon. Common examples include RADAR, LASER and AIDS. They have become such an accepted part of language that often capitalisation and punctuation have been dropped; many users do not

know what the initials originally indicated.

Abbreviations are also used orally in the clubs mentioned above, to communicate rapidly with colleagues, who use the same terms.

With the almost ubiquitous use of computers and word processing, there is no need to use abbreviations and acronyms. For the reasons listed above, they should be discouraged. The instructions to authors of nearly all scientific journals instruct authors to use abbreviations and acronyms sparingly. Useful rules of thumb are to use an abbreviation or acronym only if:

- it replaces a very long term, such as ethylenediaminetetraacetic acid (EDTA), and is used more than once;
- it is used more than 10 times in an article or publication; and
- it replaces more than one word (shortening diabetes to DB is not helpful).

Spelling out abbreviations and acronyms adds only a few words to a manuscript, especially if an attempt is made to cut out other verbiage. Abbreviations and acronyms do not help the reader to understand a text. They detract from communication.



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Simpler times?

I have attained a near ripe age and worked in or around the medical publication industry all my working life – there is no incompatibility between the two. During this wonderful experience, publication technology has been transformed, but even when simpler methods to communicate science prevailed, I managed to conjure my fair share of mistakes and cause myself embarrassment with ease.

As the exit door on my career comes into clear view I sense that there is nothing to lose by revealing all. I begin by sharing one occasion to get the cathartic process underway.

But first, for younger readers (probably those still at school in the mid-1980s), I need to give a short history of print production in 'my day'. If you fall into this age category, you may find it hard to imagine the practical problems that pre-dated desktop publishing (is that a term even in use now?). There was a time when the design studio's major output was the 'boards'. 'Boards' refers to large white sheets of card, typically A2 in size. Onto these boards

were placed photographic prints (bromides) on which were printed the type. Bromides were cut and pasted into the precise position the text was designed to appear on the printed page. (Sadly, there were graphic artists who would do this all day long.) Over the board would be a semi-transparent sheet indicating the position of photographs or giving other guidance. Once approved, the stack of boards for a book or a chapter would be gratefully received by the printer. The next thing the publisher saw would be printed proofs, and the rest is no doubt familiar to all.

My first project in medical publishing was a great book (now in its 8th edition) – *Immunology* (Roitt *et al*). Completing the boards for the first chapter to be proofed was an exciting day early in my publishing career. For our company, it was a highly significant and ground-breaking book – so many of the high quality graphics that make modern science textbooks effective and pleasurable to read derive from *Immunology*. The upfront investment in the title was correspondingly high. As a consequence, our Director, the great science publishing innovator, Vitek Tracz, supervised every aspect of the project personally.

The day the first boards were due to be sent to the printer (needless to say we were squeezing the deadline), Vitek insisted on reviewing the final boards with me. What could go wrong? The studio colleagues had checked them, as had I several times – only a sufferer of obsessive-compulsive disorder could have been more thorough. Vitek slowly scrutinised each board, and as he carefully turned each one my relief grew to the point I could feel a satisfied smile forming. As Vitek studied the final board I felt like a sprinter about to chest the finishing tape, only for it to be dragged away from me, as my boss asked his first and only devastating question – 'and where is the final page'? The double-page spread before us sadly was not the end of the chapter. Panic is responsible for some of our most stupid acts. In my case, this drove me instinctively to turn the board over in search of the missing page. Whether it was meant by way of mentoring or an expression of his disappointment in me, the only comment Vitek could muster was: 'it doesn't work like that'.

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Gained in Translation

SECTION EDITOR



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Editorial

We may pose many questions about translation, but the most frequent in the specific literature is “why translation matters?” In my opinion, however, the question should be rephrased as, “For whom is translation important?” The

answer might seem obvious, but if so, why are translators and interpreters underused in medical settings?

The following article, written by Audrey Laur, a lawyer and accredited translator specialised in medical law and international law, lists a number

of reasons for and issues related to the underuse of translation services. The article also describes necessary measures to make healthcare more culturally and linguistically accessible.

Enjoy!

Laura C Collada Ali

The underuse of qualified interpreters and translators in medical settings

Language barriers in healthcare settings can have a serious impact on both patients and medical providers. Language barriers are not restricted to migrants who cannot speak the official language of their host country – they also include people with hearing impairments, ethnic minorities, illiterate nationals, medical tourists, and tourists who get sick while on holidays. Although international studies have highlighted the benefits of professional interpreting and translating services (T&I) and the risks caused for not using them,¹⁻³ qualified interpreters and translators remain underused. These professionals are indeed key actors who ensure that patients can access and receive appropriate care, and they help prevent medical professionals from breaching their ethical and legal responsibilities.

Populations subject to language barriers

A recent census showed that nearly 863,000 UK residents are not proficient in English⁴ and that 50,000 were deaf,⁵ and in the US, 25.3 million have limited English proficiency⁶ and 30 million are deaf or are hearing-impaired.⁷ These language barriers compromise patients’ accessibility and quality of care by interfering with their ability to book medical appointments, explain symptoms and medical history to medical staff, understand their diagnosis, read documents, and provide informed consent.^{8,9} These people are also subject to increased risk of medical errors, emergency room visits, and unnecessary laboratory tests, and they have poorer compliance with medication instructions, and are more often dissatisfied with their medical care.

Restrictions in T&I services

T&I services are often employed to help people with hearing impairments or linguistic diffic-

ulties. Health facilities spend millions of British pounds on T&I services each year. In 2012, the National Health Service of the UK spent £23.3 million on T&I services of which £3 million was spent on translation,¹⁰ and annually each UK hospital spent between £60,000¹¹ and £1 million.¹² Investment in T&I services by the Swedish national health service was €45 million (£31 million).¹³ Globally, there is an increasing need for professional T&I services,^{9,10,12} but these services remain underused and are even facing budget cuts.

Recent studies have shown that only 30% of hospitals in California use professional interpreters,¹⁴ and a British survey reported that only six qualified interpreters were included in 1008 consultations surveyed.¹² Also, according to a British report, 40% of hospitals do not employ translators and 8% do not translate any of their documents.¹⁰ Similarly, a US report revealed a frequent failure to translate key medical documents such as informed consent forms.¹⁵ In the UK 100 languages are spoken,¹⁰ but translations are made in only 5 to 25 languages.¹⁵ Similar results have been found in the USA.¹⁶

Financial resources

T&I services may be underused for many reasons. In addition to the on-going lack of awareness of some medical practitioners regarding T&I services,² a main factor is financial resources. Healthcare centres restrict the use of T&I services because of the upfront fees they have to pay.^{9,12} Such financial costs can become a real burden and deterrent when hospitals run on a restricted budget.² Therefore, they seek alternatives. For example, instead of translating all documents in every language, healthcare providers restrict the number of medical documents to translate (e.g., discharge forms)

and languages. Alternatively, they offer translation services only upon request,¹⁰ or opt for verbal communication to avoid administrative complications and concerns about literacy. Hospitals have even been recommended to refer to bilingual staff instead of professional translators,¹⁶ or to use free translation software to save money when translating website content.¹⁰

Over-reliance on ad hoc interpreters

There is an over-reliance on ad hoc interpreters, who are mainly family members and bilingual staff. Ad hoc interpreters are used in 70% of medical consultations where translation is needed in the UK¹² and 80% in Australia.¹⁴ Medical practitioners believe that ad hoc interpreting is an easy, time-saving, and free solution that avoids increasing their workload.^{1,2} Healthcare professionals also consider that using such untrained interpreters create a more trusted atmosphere, especially for patients from some religious or small communities.¹⁵ Although untrue, they often believe that using lip-reading, hand gestures, or hand-written notes are convenient ways of communicating with patients, such as deaf individuals.^{2,12} However, some deaf people do not lip-read or understand written documents. The same goes for people with limited English proficiency: some might be illiterate, and some hand gestures can be misunderstood because they have different meanings in different cultures.

Lack of appropriate equipment

Other reasons reported for not using professional interpreters were a lack of appropriate equipment such as telephone and videoconferencing devices in specific rooms.² However, some doctors working in medical facilities, which do have such technologies, report that discussions with



qualified interpreters over the phone were too awkward and complex to be useful.¹⁷

Health care professionals' perceptions of T&I services

A recent report by the British Broadcasting Company confirmed that healthcare professionals are unwilling to use T&I services.¹⁸ Most doctors interviewed believed that patients should book professional interpreters and bear the costs of their services themselves. They also consider that migrants should make an effort to speak English and providing them with T&I services will not encourage them to learn English. Lastly, they think that public funding should concentrate on financing medical staff, materials and medicines rather than on T&I services. Overall, these findings show doctors' misunderstanding of how important qualified interpreters and translators are.

Ethical and legal consequences

Codes of professional conduct in all countries insist that medical practitioners should respect and be sensitive to cultural, social, ethnic, and other differences or disabilities when communicating with patients. Despite this, some healthcare practitioners recognise that patients with limited English proficiency are treated differently than other patients.^{1, 19} For example,

patients may not be provided with translated documents such as informed consent or discharge forms. This violates article³ of the Convention on Human Rights and Biomedicine, which is the ethical and international right to equal treatment and access to care, as well as the patient's informed consent. A lack of translated materials such as information brochures can also affect preventive measures, putting people at risk. Furthermore, confidentiality may be compromised by using ad hoc interpreters instead of professional interpreters: qualified interpreters are independent, impartial, understand medical terminology, and are bound to respect patients' confidential information, whereas untrained interpreters are more likely to misuse the information they learn for their own advantage, for example related to insurance policies, legal proceedings, or wills. Untrained or ad hoc interpreters may also change the message, add to it, or omit information delivered by the medical practitioner for personal or cultural reasons.¹ For example, HIV infection, infertility, child or sexual abuse, domestic violence, or abortion are viewed differently in some ethnic minorities or religions, which can lead to improper changes in messages. Meanwhile, family members may be uncomfortable and distressed by translating sensitive topics, for example to children, so messages may not be transmitted accurately.² Untrained

interpreters and translators may also not be able to correctly transmit medical terminology and equivalences, which can lead to medical errors, some potentially fatal. For example, an ad hoc interpreter might be unable to explain a rectal bleeding diagnosis and treatment, might mix up words in the same language such as "humoral" and "humeral", might confuse words from two different languages, or might not understand that the same word might have different meanings in different medical specialties.

In the US legislation, language services are described in Title VI of the Civil Rights Act (Hill-Burton Act).²⁰ Although the UK does not have a broad legislation on language services, medical professionals can be held responsible for negligence or malpractice if they fail to provide T&I services when needed. Healthcare practitioners can be considered negligent for failing to obtain patient's informed consent while knowing that the patient needed a professional interpreter or translator to do so. It is also their responsibility to ensure that patients understand the information provided via a professional interpreter or a translated document. In one case, a doctor was found responsible for sterilising a low-English proficiency patient without her consent,²¹ and in another case, the doctor was found liable for providing an illiterate patient with a translated consent form that she was unable to read, even in

her native language.²² In a third case, a healthcare professional was considered liable and had to pay damages for delaying the diagnosis of a child with Kawasaki's disease because the family, who had low-English proficiency, were not provided with a professional interpreter.¹⁵

Although there is no legislation on language services in the UK, the Equality Act 2010 forbids discrimination based on race, age, gender, religion, and disability. Such legislation can be used against any medical professional who treats patients with disability differently. In fact, under this legislation, deaf individuals have successfully sued medical facilities for failing to provide them with professional sign language services.^{23, 24}

Recommendations and conclusions

Many solutions have been proposed to bridge the gap between the availability and needs for T&I services:

- Provide hospitals with more workshops on ethics and how to use T&I services.²
- Ensure accurate translation of important documents such as informed consents, discharge forms, or psychometric tests.²⁵ If the patient is illiterate or does not understand a document, a professional interpreter should be appointed to help them.¹⁵
- Ensure that the language used in translations is culturally sensitive, accessible, and written in plain language.
- Supplement translation with other approaches, such as combining pictures with short dialogues (writing and sign language) in information brochures or combining voice over, subtitles, sign language, and pictures for preventive health campaigns.
- Simplify booking of interpreters, especially for emergencies. Bilingual staff or family members should be the last resort if a translator is not available for the specific language.
- Invest in technologies and have fully equipped rooms in medical facilities, such as operating rooms, to facilitate communication with interpreters.²
- Consider employing on-site interpreters in hospitals for the most foreign languages encountered.

T&I services increase patients' satisfaction, ensure compliance with medication and medical appointments, and reduce unnecessary laboratory tests and misdiagnoses. More importantly, T&I services can avoid litigation related to language issues. T&I services should not be considered a burden but rather as an effective way of both improving patient care and avoiding litigation costs.

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Medical Writing Teaching

Teaching manuscript writing in Africa

SECTION EDITOR



Claire Gudex

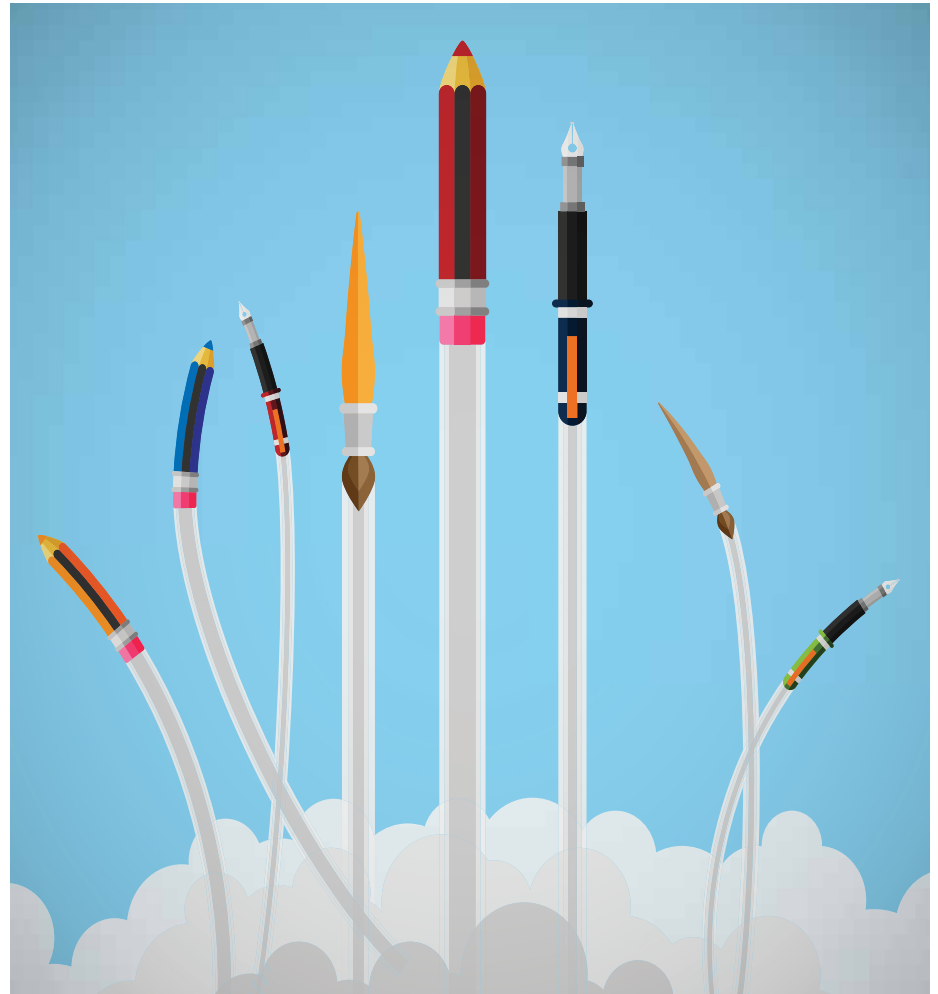
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I'm glad to have the opportunity to contribute to this new regular feature in MEW – 'Teaching medical writing'. Why write about teaching in Africa? Well, Claire Gudex – who will manage the section – thought my experience with teaching in Zimbabwe and Tanzania could be of interest to our readers, and I hope (think) she's right.

In 2006, Professor (now Emeritus) Babill Stray-Pedersen – expert on women's health - engaged me to help write applications for funding of the African research-and-capacity-building programme 'Better Health for the African Mother and Child' (BHAMC).¹ BHAMC was formed in 2000 as a collaboration between the University of Zimbabwe (UZ); Tumaini University and Kilimanjaro Christian Medical Centre (KCMC) in Tanzania; and the University of Oslo (UiO) in Norway.

Professor Stray-Pedersen and I kept in touch, and in 2013 she asked me to give a manuscript writing course at the Letten House Research Center (LHRC), established in Harare, Zimbabwe, in 2010 to cater for students engaged in the BHAMC programme. The scientific programmes running at LHRC are a collaboration between UZ and UiO. The sixth PhD candidate from UZ, supervised by Babill Stray-Pedersen, defended her thesis successfully at UiO on 18th December 2015, with the second opponent and the dean from the medical faculty of UZ present. Patience Kuono's dissertation was filmed and was followed real-time at LHRC by more people than were present in Oslo.

The manuscript writing course that I gave in Harare in October 2013² was the first 2-day course I gave on that topic – but I had given six 1-day courses to 6-700 PhD candidates at UiO the same year. To avoid carrying too much paper on that very long (8,769 km) journey from Oslo to Harare, we had planned to print the course material at the LHRC. However, the printer was incredibly slow and the printing quality was not great, so that was not such a good idea.



Otherwise, the technical equipment needed to give a course at LHRC was up to standard, and the course location was beautiful. During group work, people could sit in the garden around little tables under palm and avocado trees – looking at a purple jacaranda – in temperatures around 25°C. The unpredictable government-supplied electricity in Zimbabwe could have been a problem, but LHRC has a generator in the garden that we had to use on the second course day – when the other source of electricity failed.

Before the course, the participants sent me some material from articles they were working on, i.e. knowledge gaps, purpose statements and result presentations to be discussed during exercises. The plan was to start the course at 9 o'clock, but few people came before an hour

later. I soon realised that it would be difficult to follow the agenda and planned timelines, and that circumstances rather than plan would have to be decisive for what to do; as it always should be, but in this case I had to be more flexible than I was used to. About 12 people attended the course. Because HIV is such a huge problem in Zimbabwe, most of the manuscripts the participants were working on concerned different aspects of HIV. It was sad reading, and I would say that the main difference – that I experienced – between teaching manuscript writing to academic researchers in Africa and Europe, concerns the type of research questions that studies can be powered to answer, and the words used in the participant texts to be discussed.

The terms used to describe demographic

characteristics expressed the severe situation for the children of Zimbabwe; e.g. stunting (low height-for-age – a measure of chronic undernutrition), wasting (low weight-for-height – a measure of acute undernutrition) and mid-upper-arm circumference which identifies undernourished children at high risk of dying. The Zimbabwe Demographic Health Survey 2010/2011³ showed that 32% of under-five children were stunted, 3% were wasted and 10% were underweight. When I read numbers like that I wondered if there might be some decimal mistakes – it was unfathomable. Follow-up of mother-child pairs in the BHAMC cohort was complicated by the large-scale Zimbabwean government campaign ‘Operation Murambatsvina’ (Operation drive out rubbish)⁴ that started in 2005 to forcibly clear slum areas across the country. Many participants in the BHAMC cohort were moved to places without addresses, thus hindering further follow-up. Also, many mothers and children died in the follow-up period, which reduced the sample size substantially.

One and a half years after my teaching experiences in Zimbabwe, I gave a manuscript writing course in Moshi, Kilimanjaro region, Tanzania, at the Lutheran Uhuru hotel. It was a nice location (apart from the wrinkled sheet [instead of a screen] and poor lighting) at the foot of the Kilimanjaro mountain – ‘a shy mountain that tends to hide in the clouds’ (I didn’t see it), according to Dr. Sia E. Msuya who was the local organiser of the course. Dr. Msuya got her PhD at UiO in 2014 and is currently the Director of Institute of Public Health, Kilimanjaro Christian Medical University College, Moshi. Participants at the writing course in Moshi were also involved in the BHAMC programme, so the studies they were doing were in some respects similar to those in Zimbabwe.

Forty-one publications have come out of BHAMC. They are published in a variety of African and international journals, PLoS One included, and address topics such as predictors of failure to return for HIV test results, female genital cutting, cognitive development of children born to HIV-positive mothers and multidrug-resistant tuberculosis. A study from 2010, published in the Journal of the International AIDS Society, explored why the prevalence

The unpredictable government-supplied electricity in Zimbabwe could have been a problem, but LHRC has a generator in the garden that we had to use on the second course day – when the other source of electricity failed.

of HIV among pregnant women is so much higher in Zimbabwe than in Tanzania (26% vs. 7%) despite that all risk factors tested for were more common in Tanzania than Zimbabwe.⁵ It is still not clear why there is such a difference. That strange discrepancy was what triggered Professor Stray-Pedersen to engage herself in these Africa studies in the first place. The BHAMC programme has influenced policies in Tanzania, especially in the fields of nutrition and prevention of mother-to-child transmission of HIV and nutrition, and networks of researchers have been created within different research topics and between several international universities.

It has been an interesting experience to teach medical writing in Tanzania and Zimbabwe. Teaching in Africa is not much different from teaching in Europe – planning and flexibility is as important there as here. But, be prepared to be laughed at if you go out to sit in the sun and drink your warm tea during breaks.

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Profile

An interview with Juliane Chaccour

Writing in Mozambique



On her private Twitter profile, Julie (Juliane) describes herself as “freelance medical editor, mother, immunologist with an interest in tropical diseases and vaccines”. Julie works as a freelance medical writer and editor, is managing editor at Clear Science and is also our EMWA Twitter manager. From May to August 2015, she was teaching medical writing in Mozambique. Yes, for four months, you received EMWA tweets from the African bush! The panorama picture shows the view only 500m from the research centre, the second picture shows Julie at her internet desk – there are certainly worse places to work from!

We turned to Julie to learn more about this exciting experience. Her example shows the variety of opportunities in the field of medical writing – even teaching in Africa. What especially impressed me is that Julie did it all with three young kids (and a husband). While it was for sure a great experience for her kids, I do not envy the 30+ hours travel experience on their way back home to Spain!

Medical Writing (MEW): How did you get into medical writing?

Julie (JC): I first worked in research, mainly in the field of immunology and tropical diseases. When I had my first child, I needed a more flexible job and – as I always liked writing – got into medical writing. While doing the EMWA foundation certificate, I was contacted by a friend

who asked me to write a review. So I registered as a freelancer. Of course, at that time I was conscious of the need of a medical writer and editor in my immediate environment (many of my Spanish friends are clinicians or researchers). This is how I got started as an editor. The nice thing about medical writing is that the profession is fairly new and you can find your personal niche in which you can use your skills best. If you are open-minded and have a good network, you can do a lot. Learning from my Mozambique experience, I will teach a workshop at the University of Navarra in Spain in Spring 2016.

MEW: The most burning question is – how did you get the job offer in Mozambique?

JC: My husband and I have both been involved in research on tropical diseases and it was clear we wanted to go abroad again (we spent one year in Venezuela from 2008 to 2009). We picked Mozambique and decided on a “test run” for 4 months. As the Centro de Investigação em Saúde de Manhiça (CISM) is one of the field sites for the trials of the RTSS malaria vaccine, I intended to amplify my background in clinical immunology. Then a friend of ours, a local principal investigator, suggested that I teach a writing course. When I contacted my supervisor in Manhiça about it, he jumped at the opportunity and was very welcoming. With the official language being Portuguese, researchers from

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Mozambique struggle to communicate their science well in English, even though the CISM does first-class research in infectious diseases and social sciences.

MEW: What were the most challenging situations you faced? How did the situation in Mozambique differ from Europe specifically Spain where you are living now?

JC: Obviously there are differences in your everyday life; life becomes much simpler (in spite of the lack of washing machines). What we did find challenging was the corruption among traffic police or the exorbitant prices for imported food (that is, almost everything except fruit). Our daily visits to the hospital next door also opened our eyes to the human plights and showed us that neglect is not solved by simply getting the necessary resources and technical knowledge. The quiet, pleasant demeanour of the Mozambicans, the beaches and the sunny weather almost make up for all these though. A challenge of a different sort was deciding whether to eat the hippo liver we were given as a present.

MEW: You have not taught medical writing before. What did you do to prepare your course material – and what did you do to prepare yourself for living for four months on a different continent?

JC: In Spain, I mainly edit scientific manuscripts of non-native speakers, so I had plenty of material to share. The mistakes Portuguese and Spanish speakers make in English are very similar. This way, I could prepare workshops with plenty of practical examples. We started with very basic things, like how to structure a research article. What is taught in every university in Europe does not come naturally to scientists in Mozambique who have not had that privilege but really want to advance science and have great results to share. I probably learned as much as my students in those four months.

Before we embarked on our adventure, we mainly prepared the kids (they were five and three years and 10 months old) by telling them about the impending basic life and the change of routines. One thing we prepared meticulously

was our medicine cabinet and especially the antimalarials.

MEW: What advice can you give someone who would like to do something similar?

JC: If you are interested in promoting good scientific writing among a wider community, you might want to register with AuthorAid (<http://www.authoraid.info/en/>). The exchange with researchers from developing countries can be helpful to both parties. Often by answering questions you are forced to think about a topic more thoroughly.

In general, being abroad is an experience that will teach you many lessons, especially about the

lesser known disadvantages of developing countries. Make sure to go with an open heart and mind, and prepare to be surprised in many ways.

Conclusion

Julie shared her adventure with us. We can learn from her experience in many different ways. I have seen many medical writers who are not aware of their strength, only recognizing what they do not know instead of focusing on what they know. The role of a medical writer offers many opportunities, we just need to go out there and dare to do something different. If you are new to the profession and have a specific

knowledge – try creating your own niche. You then should start to prepare for a new role by building upon existing knowledge (regardless how big or small it might be) and focus on your strengths. Whether you are travelling to a different country or taking on a new job – start with an open mind, set your expectations realistically, and prepare for the unexpected.

We hope that Julie's example encourages you to dare engage in new endeavours. If she managed to take on a new job in Africa with three young kids, you will be able to achieve your dreams too!

Julie Chaccour can be contacted at jchaccour@gmail.com

Letter to the Editor

Dear Editor,

EMWA and other organisations (eg, AMWA, ISMPP) support the principles of Good Publication Practice (GPP). As a co-author of the recent GPP3 guideline¹ and leader of the professional medical writer section, I was concerned by a recent article² in the latest edition of EMWA's Medical Writing journal. In their article, Prashant Auti, Rishabh Pandey, and Vatsal Shah (SIRO Clinpharm Pvt Ltd, Thane, India) include a section in which they "...review the important steps in the drafting of a manuscript."² At best, their process description is ambiguous. At worst, their process description is clear, but any of your readers who follow it could risk noncompliance with GPP3.

As per GPP3, the writer "...must receive direction from the authors at the earliest possible stage (for example before the outline is prepared)."¹ Auti and colleagues do not stress, nor even mention, this critical first step in the process. Indeed, Auti and colleagues do not bring the author into their process until the writer has had a content outline approved by the client (see p 38), has written a shell draft that includes "...bulleted text for the introduction and discussion and text paragraphs for the methods and results section." (see p 40), and has had the shell draft approved (they don't say by who, but I fear it is not the author).² Even if this omission of early author direction and input is inadvertent, it is not acceptable. In addition, Auti and colleagues never explicitly state that it is the authors who must give final approval of the manuscript. Auti and colleagues don't even include authors in their list of "approvers".

I respectfully ask that, consistent with COPE guidelines, you ask the authors to revise the article and publish a correction.

Sincerely,

Professor Karen L. Woolley, PhD CMPP

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Author Response

Dear Editor,

We thank Dr Woolley, co-author of GPP3, for providing her insights on our manuscript.

We have critically evaluated the comments from Dr. Woolley. As professional medical publication writers, we understand the importance of every stakeholder in the publication process and did not intend to undermine the role of authors. We have already mentioned the importance of authors throughout the manuscript. Our article proposes a project management process for publication writing projects with special emphasis on work in agencies. Our article in no way should be interpreted, analyzed or considered an extension of publication writing guidelines as it specifically focus on business aspects, process and day-to-day activities of CROs or agencies.

In Table 3 (page 41) of the manuscript, we discussed the potential risks that can arise during publication writing process and their possible resolution/action plan. In the second row from the bottom, we discussed the risk of availability of minimal data sources, which usually occurs

during pre-drafting phase (preparatory activity).

The action plan proposed for this is a kick-off meeting with the authors to get the credible data sources and to decide future directions and flow of the manuscript. This in turn highlights the importance of receiving the direction from the authors in the publication process at the earliest possible stage.

We would like to explain here that the word 'client' is used as collective term for the ease of mentioning stakeholders in the light of agency work. We have clearly mentioned in the initiation section (page 38, column 2) that the scope should be discussed in great detail with the client so that the expectations of both parties are aligned thereby indicating the early involvement of stakeholders including authors.

Also, Dr. Wooley mentioned that we did not include authors in the final approval of the manuscript. We would like to clarify that certain stakeholders (researchers, statistics head, and the clinical team head) mentioned in the final approval of manuscript (page 40, column 2) are indeed potential authors.

Since a few terms like authors, researchers, clients and approvers are used interchangeably from the CRO standpoint, this may have led to the confusion and misinterpretation. However, we agree with editor's suggestion to make minor changes in our paper to address Dr. Woolley's concerns.

Prashant Auti

Editor's Response

We agree with the comments from Dr. Woolley, and we appreciate the authors' response. The original pdf of the Auti et al. article on the journal website (journal.emwa.org) will be replaced by a revised version that addresses our and Dr. Woolley's concerns.

Out On Our Own

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Editorial

Welcome to the OOOO section of Medical Writing.

Whilst members who attended the freelancers' networking meetings in The Hague (November 2015) or Munich (May 2016) may have noticed the recent changing of the guard at the Freelance Business Forum, for those who did not, please allow us to introduce ourselves as Julie and Satyen, the new Freelance Advocates.

First and foremost, we would like to thank Alistair Reeves, Kathryn White, and Sam Hamilton for their past service at the helm and generously giving their time and effort for the

freelancers' cause within EMWA. It is our intention to continue in a similar vein and keep adding to the solid work that has been carried out in the past. On this note, we sincerely request your input, advice, and yes, any articles that you have penned and wish to share for the benefit of fellow members.

In this (our first) issue, we have included an editorial extra to provide you with a glimpse of the future with your new team J and S.

We are particularly delighted to include some insightful contributions from our EMWA freelancing community.

Joselita Salita, an experienced freelancer based in Bremen, Germany, writes about an integral skill for any business professional –

networking. More specifically, she gives a few pointers on certain issues that should not be ignored (but sometimes tend to be) when it comes to developing business relationships.

In addition, we present the second part of Marion Alzer's article on medical translation as a profession. Here, Marion talks about the most significant decision that we as freelancers have made at some point or other – the decision to go freelance! An important message in Marion's article is the need to carefully consider personal factors when it comes to choosing between the security of life as an employee or the unknowns of running one's own show.

Best wishes and happy reading.

A glimpse of the future with your new team – An editorial extra

Given our different backgrounds and experiences, Satyen and I bring diverse and new perspectives as Freelance Advocates. However, you will also find that we are both passionate and enthusiastic about serving you as best we can for the "freelance cause", and we hope this will be to your advantage.

I have been here before. I see freelancing as an option that allows personal choice at different stages of life and career. You don't have to put up with an employment situation in a company that really isn't working for you – I'm not saying don't try to make it work and I'm certainly not encouraging everyone to suddenly resign and throw caution to the wind, as personal responsibilities, financial commitments etc. need to be carefully considered before such a big decision is made. However, I would like to strengthen the support made available by the freelancing community. If you know freelancing is a feasible option, even if it doesn't necessarily suit you at a particular time, it puts you in a position of strength to make informed decisions about what you actually want at different stages of life and career. Maybe this could even encourage companies to be more flexible in their treatment of employees as power shifts more towards the individual.



If and when the time is right you can take the leap, or decide not to – but the choice is ultimately yours. That is how I see the future.

So, what have we got lined up for you in future editions of OOOO?

We can tell you that we are continuing to develop our relationships with other associations (IPSE and others beyond the UK) and we are already lining up a wide range of serious (and entertaining) articles about business and the practical aspects of freelance working.

We are also receiving ideas directly from you

and we want to encourage this flow, whether this is in the form of letters to the editor, recommended reading for freelancers, interview style pieces, or anything else that you feel would be of benefit to our wider community.

We want to hear your stories, your experiences of freelancing and tips you can share with us all. We like serious, and also lighter topics – keep your eyes out for freelance foraging photos.

Ultimately this is your section, and together we can work to both inform and entertain to the benefit of all. Until next time....

Julie Charlesworth

Medical translation – A dead-end job or a gateway to opportunity? Part 2

When I was a teenage student studying English as a foreign language, I used to think translating was boring; utterly boring to be precise. So, why did I follow a career as a professional translator and what made me change my mind?

Flexibility in the job search

It was while working in the Frankfurt area that I met my future husband, a native speaker of English and a medical writer. He took a position in Munich and although I also tried to secure a position as a medical translator in the area, there were no openings. However, a small clinical research organisation (CRO) that worked in German and English offered me a position. They were looking for an assistant who was familiar with clinical trial documentation, paid attention to detail and was fluent in English. In contrast to the classic employee in a large, well-established pharmaceutical company, employees of smaller companies typically perform a whole range of responsibilities. This was a dynamic and highly demanding working environment. I had to learn the ins and outs of clinical research and many new tasks quickly. During the next ten years the company grew rapidly and I did my best to balance bringing up a young family with the day-to-day demands of my career. The employment was based on both full- and part-time roles which varied: clinical research associate (CRA), phase 1 manager and quality assurance associate. Box 1 below details the variety of my responsibilities.

My responsibilities

- Co-ordinating and monitoring phase 1-3 trials
- Conducting monitor and investigator meetings
- Preparing training materials and presentations for monitors and investigators
- Providing input into study protocols, informed consent documents and case report forms
- Performing quality control of study protocols and clinical study reports
- Preparing and maintaining trial master files
- Writing, reviewing and updating standard operating procedures
- Co-authoring publications

Flexibility at work

Working for a CRO meant providing services to international clients as well as fulfilling their expectations and individual needs under

considerable time and cost constraints. Being faced with these challenges daily helped me understand both the service provider's and client's perspective. It enabled me to develop a customer-oriented approach and become fast and flexible at re-focussing on ever-changing projects and priorities.

New skills in a new business

In 2005, the experience I gained at the CRO proved to be invaluable when I took the plunge to become self-employed. At home, the head-count had increased by two and we needed more space. We had no choice but to move out of the city. The distance from home to work was too far for me to commute. As I was unable to work from home on a part-time basis I decided it was time to become my own boss. Given my previous experience, medical translation seemed the obvious career path. Translation work can be carried out remotely and projects usually have a clearly defined beginning and end. So I went back to my roots.

New challenges

The skills I had gained and the contacts I had made in previous years were all favourable for starting my own business. My former employers were also my first clients. Little investment was required because I already had a desk, a PC, software programmes and dictionaries. What I totally underestimated, however, was how much time and effort I had to invest in business aspects such as accounting, tax issues, marketing, business development and pricing. I can recommend the following resources to those in a similar scenario: "The Entrepreneurial Linguist: The Business-School Approach to Freelance Translation" by Judy and Dagmar Jenner, and "Freelancing – Are you ready to go solo?" by our EMWA colleague Kathryn White.^{1,2}

Today, the world of translation uses sophisticated computer-assisted translation (CAT) tools and translation memories (TM). CAT tools are programmes that facilitate the translation process by splitting text into smaller segments and showing source

text and translated segments side by side. Both are then stored in a translation database called translation memory, and can be retrieved for future translations. For further information, see Emma Goldsmith's free e-book "An Introduction to Translation Memory."³ When I first worked as a translator in the early 1990s, CAT tools and TMs were in their infancy. By the time I went freelance in 2005 these tools were indispensable for anyone wanting to succeed in the translation business, and I needed to catch up.

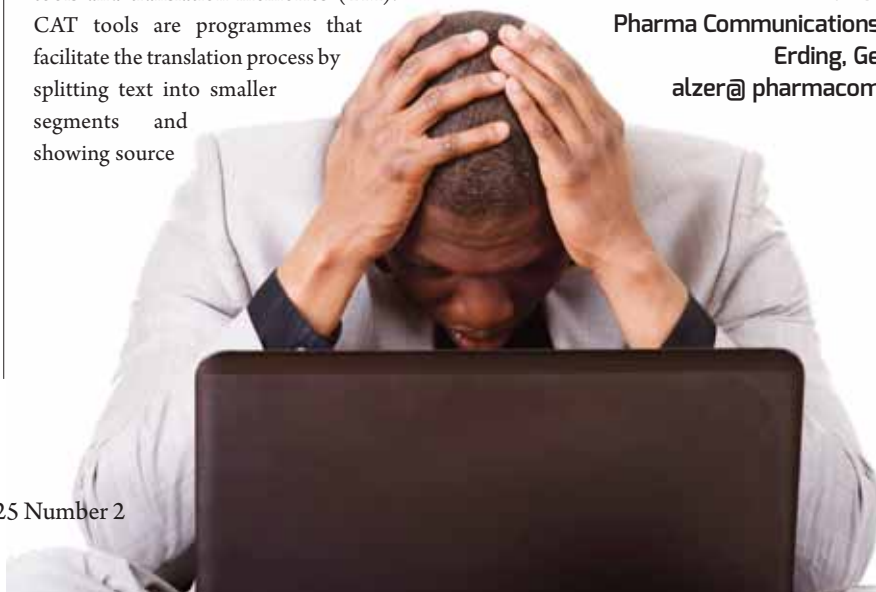
Alysia Battersby describes the importance for freelancers of getting out of the office, networking with peers, and enjoying the team spirit and exchange of information.⁴ Similarly, I joined the Federal Association of Interpreters and Translators (BDÜ) which is Germany's largest association of language professionals.⁵ The BDÜ offers professional development and networking opportunities to more than 7,500 members, the majority of whom are freelancers like me. I have personally benefited from many seminars and workshops they have offered and in the process met peers with whom I have since collaborated.

(To be continued in the next issue. Editor)

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important give you an appointment or answer your email. She said you shouldn't say who you are and what you can do, but instead say how you can help or support his/her business. In this webinar, her advice for crafting an effective email was to imply that you are offering assistance and not directly applying for a job.²

In networking events, you should also be prepared to offer help and not just expect to be helped. And this time, I mean, seriously offering your talent, whatever you can do. In a network, you help others who will help others, who in turn will perhaps help you. You don't even have to be selective (with target individuals) as you can't predict who will someday provide you with connections. Kathryn White's article on freelancing argues that marketing does not necessarily have to be hard selling;⁸ you can sell yourself just by being genuinely you.

Networking strategies via social media are also similar. In Stelzner's webinar on the use of social media to increase one's business, he gave examples of successful business people and social media personalities.⁹ One of them, Ana White, is a carpenter and successful blogger. The reason for her success is because she shares her knowledge on creating furniture through a lot of do-it-yourself instructions. Many businesses, big and small, also offer free webinars or free-for-download information in order to create a following and benefit from it.

In the medical writing business, you network to connect with medical writers and you can offer your help directly to your target, such as an established medical writer, or to an organisation like EMWA. You can consider this as a form of internship. However, you should also be cautious of being exploited. One good alternative is assisting in clubs or organisations. In this way, your activity and assistance are transparent and there will be fellow members ready to support you. For example, you could take advantage of the many volunteering opportunities in EMWA. It is the best way to hone your writing and editing skills (e.g. for the EMWA website or *Medical Writing*, EMWA's official journal), or liaising and organisational skills (helping out in organising conferences.). These skills are transferrable and much sought after in the medical writing business. Plus, you get updated and stay current on developments in regulatory writing, pharmacovigilance, etc. Also, organisations are, in general, very generous in giving recommendations which you may someday need. After all, John F. Kennedy's famous inaugural words "Ask not what your country can do for you but what you can do for your country" also holds true in this business.¹⁰

Closing remarks

Networking is an opportunity to get to know people in the business. As in life generally, it takes time to get to know another person. Getting to know someone means listening to them, finding out their interests and needs, and being prepared to fulfil these needs.

Happy networking!

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So, English speakers should do their washing only when no-one else is present (one wonders why)?

Hey ho -
it all comes
out in the wash!

Oops not quite the intended translation! 'yourself' not 'alone' – a bit like Freelancers – independent and just getting on with things – Out On Our Own but not alone!
By the way where do all those lost socks go...



Themes of forthcoming issues of **Medical Writing**



September 2016:

'Statistics'

This will include articles for medical writers on presenting and understanding basic statistics.

The issue is closed to new articles.



December 2016:

'Medical Education'

This will include articles on running advisory boards and preparing slide kits, conference presentations, and other learning resources.

The deadline for feature articles is September 12, 2016



March 2017:

'Writing Better'

This will include articles and exercises to help medical writers write better in English.

The deadline for feature articles is December 12, 2016



June 2017:

'Medical Devices'

This will include articles on the regulatory approval process for medical devices, preparing related documents, writing publications on clinical studies about medical devices, and other aspects of the medical device field relevant to medical writers.

CONTACT US



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



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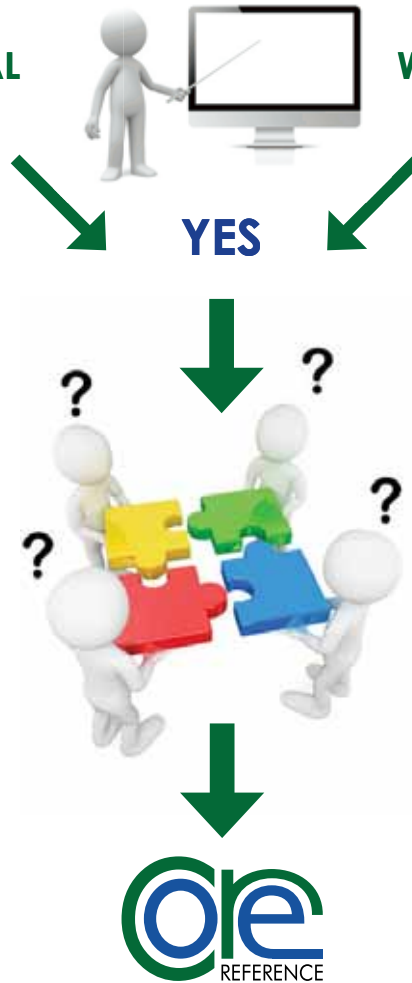
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