Volume 25 Number 4
December 2016

Medical Writing

Medical Education

EUROPEAN MEDICAL WRITERS ASSOCIATION

EUROPEAN MEDICAL WRITERS ASSOCIATION

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

Submissions:
For instructions to authors, go to the journal section of EMWA's website (www.emwa.org). All manuscripts should be submitted to mew@emwa.org.

MIX
Paper from responsible sources
FSC® C006300

Volume 25 Number 4 | December 2016

Medical Writing

Medical education implies providing education or training of unbiased scientific or medical content. However, the reality is that medical education is now more a spectrum of educational activities that span from more promotional to purely educational.

Medical education has nevertheless maintained its role as the mainstay medical communication tool. Pure medical education is considered to be at one end of the education-promotion spectrum, while detailing or advertising are at the opposite end. In the middle of the spectrum are activities by medical education providers, which are most often supported by industry, and which aim at raising awareness or the profile of a specific therapeutic area by communicating results from basic, clinical or epidemiological research. This information is disseminated during satellite symposia, stand-alone meetings, or advisory board meetings, which continue to be considered by health professionals to be of high educational value, even though the content is sometimes related to a specific product or device. Medical education providers include continuing medical education (CME) organisations, independent providers, and in some countries' universities. These providers have no or limited industry support and provide educational content under strict guidelines, independent of any promotional motive or industry control.

CONTACT

Amy Whereat
amy.whereat@speakthespeech.fr

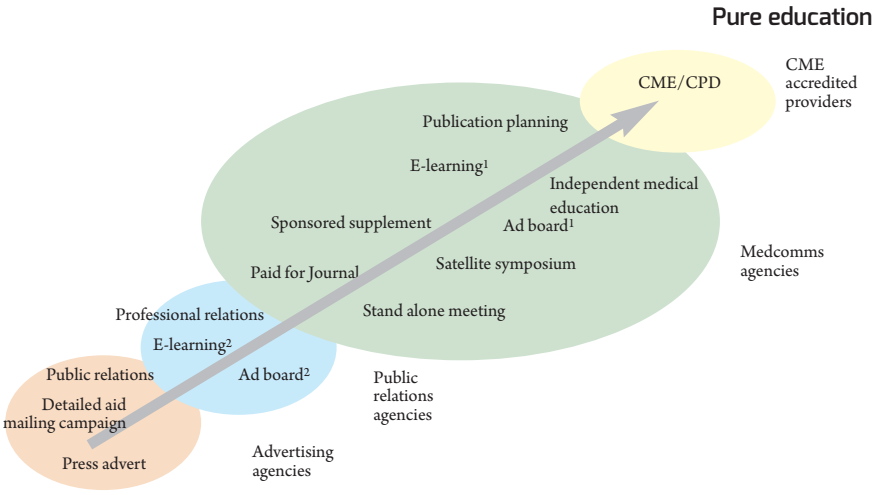


Figure: The education–promotion continuum, coined by Eugene Pozniak, represents the broad selection of activities that medical education covers. At one end of the spectrum is a pure promotional activity, press advertisement, which is fully sponsored by industry and promotes a specific product (pink bubble). At the other end lies pure continuing medical education (CME)/continuing professional development (CPD), an ideal situation where CME is provided by accredited CME providers and funding is independent of pharma (yellow bubble). In between are activities provided by medcomms agencies, who are mostly sponsored by pharma (green bubble) and those provided by public relations agencies, who are not usually accredited for CME (blue bubble).

Amy Whereat

With the rapid development of European CME, the European CME Forum and the Good CME Practice group recently published a set of standard core principles with a view to adoption by European CME providers and other key organisations providing CME programmes. Details about Good CME Practice can be found at http://goodcmepractice.eu.

Traditionally, physicians were the main receivers of medical education, but today, participants include other health professionals such as nurses, midwives, and various allied health professionals. Increasingly, patients also seek to have access to sophisticated medical information.

This issue of *Medical Writing* showcases some different types of medical education activities in Europe and India to illustrate the various roles of the medical writer in medical education. **Susan**

Harris and **Christopher Kelly** start of with an article describing patient education in clinical trials throughout the product lifecycle. They highlight the importance of ensuring that patients are adequately informed about medical treatments that affect them. **Elodie du Potet** offers us the French perspective on medical education, which is highly regulated and is limited to communicating about a specific therapeutic area, and **Catrin Marx** and **Christopher Baethge** discuss how CME is performed in Germany and the advantages of using multiple choice questions to improve the quality of CME training units. Meanwhile, **Namrata Singh** and **Ritu Sharma** provide us with an insight into the role of the medical writer in running advisory board meetings in India. Finally, **Melody Watson** and **Mark Esser** describe how to best write a review paper, with lots of very practical advice, and **Yvonne Anderson** and colleagues share with us their experience building an independent medical education event.

Acknowledgement

I'd like to thank Eugene Pozniak, managing director of Siyemi Learning and Programme Director of the European CME Forum for giving me his valuable time to explain the facets of medical education today and sharing his views on the changing landscape of medical education.

President's Message

Dear EMWA Members,

Since my last message your committee have been busy on several initiatives. In November we held a very successful conference in Brussels with over 200 delegates. This provided 18 foundation and 10 advanced level workshops and an extended Freelance Business Forum as well as an opportunity to network with fellow professionals and taste the famous Belgian beer and chocolate. We continue to reach out to those considering or just embarking on a career in medical communications and provided a free seminar entitled 'Introduction to Medical Writing' as part of the conference.

There are a number of updates to our website planned or already available. These include a revised FAQ document and an updated Career Guide to Medical Writing which includes information on the different types of writing and employment possibilities. We are also investigating a new website platform which will significantly improve response time and allow us to develop the website further

We maintain our profile within the medical communications arena. By the end of September CORE Reference had hit 3,000 downloads and a growing list of companies have adopted, or otherwise support its use. We also worked with AMWA and GAPP and ISMPP in providing a response to an article in the BMJ criticising the important and ethical contributions medical writers make to the scientific literature. All four organisations have been working toward transparency and disclosure for more than 15 years and we believe great progress has been made although, of course, more can be done in some areas.

A survey was sent out in October as part of EMWA's commitment to representing, supporting, and training all our members, which I hope you all completed and returned. This has provided us with up-to-date information on who are members are, what they do, and what they want from the organisation, and we are currently in the process of analysing the data. The results of the survey will be reported in *Medical Writing* next year.

As we come to the end of 2016, I would like to take this opportunity to thank all those who make EMWA what it is, the volunteers and workshop leaders, the Executive Committee (EC), all those of you who contribute to our journal and of course the staff at Head office who keep everything running. This month you will receive an e-mail inviting you to apply for the vacant positions on the EC. Please consider whether this is something you would like to do. We are a friendly bunch and although it can be hard work there are also definite rewards. It is always good to have new faces and ideas.

Happy Christmas and best wishes for2017 to you all. Enjoy the holiday!

Best wishes
Alison
alison.rapley@gmail.com

EMWA News

Baby alarm in the Social Media Team! The future of EMWA's social media team is secured as we are expecting **three babies**. Utmost efforts have been taken to ensure they are equally distributed across the Twitter, Facebook and LinkedIn teams. Seriously, what a nice profession is *Medical Writing* that you can combine work and family and work from home. This is also the reason why many women coming from different professions join the *Medical Writing* community.

While one can combine the profession with family, family plus *Medical Writing* plus voluntary work can be too much. Therefore Julie Chaccour, who has led the Twitter team for many years, will step down. She is expecting her fourth child, and is moving to Mozambique to start a new job. We are very sad she is leaving, but she will still be there in the background – and we hope that we will hear more adventurous stories about Africa and eating hippo liver! It paid off that we have planned for succession management. Jen Lewis has worked at Julie's side for quite some time and is now taking over. She is supported by Evguenia Alechine who approached me during the spring conference to offer to volunteer for EMWA. Carola Krause shows the current PR-team in one of her famous infographics below. As we believe – it is always nice to have a face to a name!

Another change affects the **webinar team**. Due to organisational reasons, the webinar team was linked to the PR-team while – logically – it belongs rather to the EMWA Professional Development Programme (EPDP). I am particularly happy that we could increase the responsibility of Patrick Bohan. Patrick led the webinars in 2014/ 2015 and will now take over the full organization of webinars.

EMWA has been present at the European Health Innovation Collaborative (EUHIC) conference in London in September, at the first German MedComms Forum in October, and has sent promotional material to display at the annual meeting of Mediterranean Editors & Translators in Tarragona, Spain, in October.

SECTION EDITOR

Beatrix Dörr
beatrix.doerr@googlemail.com

Also, we start to prepare for the May conference in Birmingham.

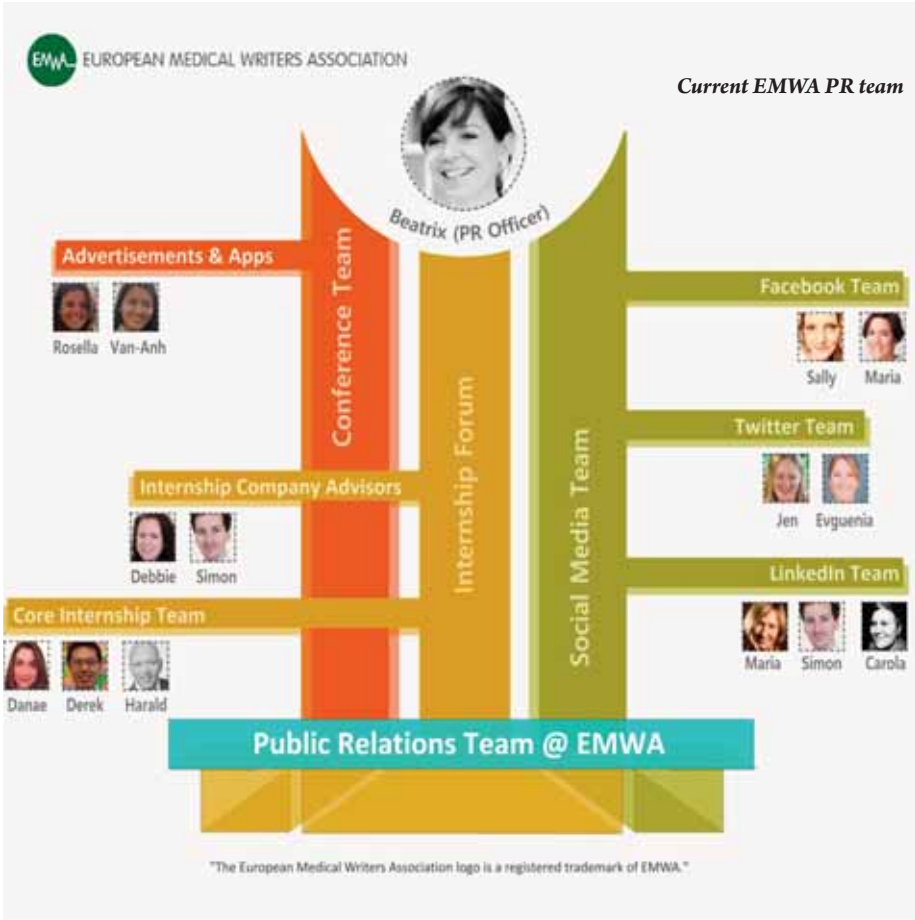


Image by **Carola Krause**Carola.Krause@codex-biomed.com

EMWA salary survey coming in January – We need your feedback!

EMWA's salary survey, previously run in 2006[1] and 2012[2], will again be conducted in January 2017. The survey will still focus on current salary levels, but the original questionnaire has been updated slightly and will, for the first time, collect data from freelancers. In addition, the survey aims to determine whether salaries have changed over the past 10 years.

We will soon be sending out an email announcement for the survey to all EMWA members that will include a link to the survey website. Please help us bring this survey to life by spending 15 minutes of your time to complete it. All answers will of course be kept strictly confidential. Publication of the results in Medical Writing is planned for September 2017.

Thank you in advance,

The EMWA Salary Survey Team
Julia Forjanic Klapproth, Ansgar Dressler, Andrea Rossi

References

1 Goodwin Burri K. Results of the 2006 EMWA salary survey. The Write Stuff. 2006;15(4):133–6.
2 Eichele K and Rossi A. Results of the 2012 EMWA salary survey. Medical Writing. 2013; 22(3):15(4):133–4.

EMWA webinars

Watch out for Monica Meyer discussing the cardiovascular system in the December webinar. The currently planned webinars for 2017 are:

- Gail Zona (January 2017) "More making Word behave as it should: Part 2 Tables"
- Inga Abed (February 2017): "New Risk Management Plan summary template"
- Raquel Billiones (March 2017) "EMA Policy 0070 on Publication of Clinical Data and its Impact on Medical Writing"
- Patrick Bohan (May 2017) "The European Union Clinical Trials Regulation 536/2014"
- Beatrix Doerr (July 2017) "Clinical study reports for medical devices"

Watch out the EMWA website and social media announcements for further details. If you would like to contact Patrick regarding a webinar proposal – feel free to use webinar@emwa.org.

Patrick Bohan
webinar@emwa.org
Beatrix Doerr
pr@emwa.org

The European Health Initiative Collaboration (EUHIC) Conference

For current and future leaders in European healthcare, science and medical devices, this event provided a platform for learning, networking and innovation to promote healthcare improvements across Europe. It was held on 22 September at Imperial College, London.

In addition to presentations across a range of medical specialties was an engrossing session about medical writing, entitled "The Future of Medical Journals and Getting Published in the Digital Age". Chaired by EMWA's PR officer Dr Beatrix Dörr, this session provided a wealth of ideas on finding information and measuring its quality (Michael Markie, Associate Publisher F1000), reviewers and reviewing issues in scientific publishing (Dr Maria Hodges, BioMed Central's Genome Medicine), ensuring transparency, reproducibility, and accreditation in research (Adrian Aldcroft, Editor BMJ Open), and finally a discussion led by Dr Anna Sharman (Founder Cofactor Science) on whether journals will be replaced by social media. The session ended with a lively panel discussion on the future of medical journals and how to get data published in a digital age.

Beatrix Doerr
pr@emwa.org
Steven Walker
steven.walker@stgmed.com

Sign up to receive Core Reference news alerts

The EMWA-AMWA CORE (Clarity and Openness in Reporting: E3-based) Reference MAILING LIST is here:
http://www.core-reference.org/subscribe
Subscribe to our new mailing list to receive the latest news direct to your inbox

News in brief

In the 5 months since launch, we have:

- Over 3,200 downloads
- Added a free Webinar (http://amwa.mycrowdwisdom.com/diweb/catalog/item/id/1165151/q/o=-d&c=185)
- Responded to all your comments received in the 6-week open comment period (http://www.core-reference.org/comments-and-responses/)
- Received testimonials from CROs, Pharma, biotechs and freelancers (http://www.core-reference.org/adoption-and-use/)

Please share this communication as widely as possible with your own networks. Thank you.

Sam Hamilton
Chair of the CORE Reference Project
E-mail: contact@core-reference.org

Call for companies to join our second Internship Forum at the EMWA spring conference in Birmingham, UK

Based on the success of this year's inaugural Internship Forum in Munich and the positive feedback we received, it was decided that the Internship Forum will be extended to four hours. It will be held on 6 May 2017 from 9am to 1pm. Raquel Billiones will give a short seminar "From Academia to Regulatory Writing". There will be space for ten companies offering internships.

Are you a company willing to provide internships, or do you know such a company? Or are you someone who would like to apply for an internship? Then please contact us at internship@emwa.org.

Danae Rokanas, **Derek Ho**, **Harald Meier**, and **Beatrix Doerr**
from the Internship Team
internship@emwa.org

EMWA INTERNSHIP FORUM

Ghostwriting statement

On August 30, 2016, an article appeared in the *British Medical Journal* attacking the important and ethical contributions of medical writers to the scientific literature (http://www.bmj.com/content/354/bmj.i4578). EMWA, in partnership with AMWA, ISMPP, and GAPP, has responded to this article. (http://www. bmj.com/content/354/bmj.i4578/rapid-responses). Our organisations have been working toward transparency and disclosure for more than 15 years and have made great progress. We look forward to continuing this important effort.

Inaugural German MedComms Meeting, Berlin

On Friday, October 7, Stgilesmedical issued an open invitation to an educational networking event at the Ellington Hotel in Berlin with the aim of providing a platform for the exchange of views on current developments in medical communications in Germany and beyond. A diverse audience of medical writers, health care professionals, scientists and patient representatives spent a pleasant afternoon enjoying a variety of presentations from an excellent range of speakers. Dr Beatrix Dörr (EMWA), Ben McLeish (Altmetric LLP), and Len Starnes (Digital Healthcare Consultant) shared their views on how digital media, social networks and online communication currently shape the way medical information is delivered, rated and exchanged. Dr Christian Wrede from the Helios Klinikum in Berlin-Buch pointed out the different approaches of clinicians and patients to acquiring medical information and highlighted frequent challenges for publishers. Representing the Health Capital Cluster Berlin-Brandenburg , Dr Florian Schlehofer described the developments within the region which have resulted in it becoming an appealing industrial location for the life science and healthcare sector. Finally, the participants discussed the benefits and risks of using online media as a source of healthcare information and shared their ideas as to how the accessibility and reliability of medical information could be improved in the future.

From left to right – Peter Llewellyn (MedComms Networking), Carola Krause (EMWA LinkedIn Team), Beatrix Dörr (EMWA PR Officer), Abe Shevack (EMWA Vice President) and Steven Walker (Stgilesmedical)

The EMWA stand was a useful addition to the meeting and was well visited, especially by students and post-docs who wanted to know how they could get started in medical writing. EMWA's PR-officer Beatrix Dörr was supported by EMWA's LinkedIn Manager Carola Krause and EMWA's Vice President Abe Shervack, both locals from Berlin.

Anne Hartmann
on behalf of Stgilesmedical
London and Berlin
annekathrinhartmann@gmail.com
Abe Shervack
aspscientist@googlemail.com

A very successful EMWA conference in Belgium

The 43rd EMWA conference, held in in Brussels, Belgium, began Thursday, November 3, 2016 and concluded on the following Saturday. The conference included 10 advanced and 18 foundation workshops, and 221 registered delegates

On Thursday evening, the conference began with an opening session by Prof. Dr Robert Colebunders of the Global Health Institute at the University of Antwerp, Belgium. Dr. Colenunders presented on 'Investigating epidemics in Africa'. Former EMWA President Rita Wellens followed with an introduction to Belgium through her presentation 'Belgium Rocks: the Heart of Europe and All that Jazz'. The opening session ended with a short introduction to the EMWA Executive Committee members, followed immediately by a lively networking session.

Friday morning, Dr Julie Charlesworth introduced a new interactive session on IT, social media, and productivity entitled 'Show IT, Share IT, Rise and Shine'. In the evening, Dr Charlesworth also introduced an extended Freelance Business Forum (FBF) in which she updated freelances on the FBF, related activities, and several other initiatives across Europe. During the FBF, Satyen Shenoy provided a brief update on recent developments in Germany. Guest speaker Marco Torregrossa, Secretary General at the European Forum for Independent Professionals, gave an inspiring, informative presentation that led to a lively open discussion and then stayed on to mingle with freelancers during the table discussion session.

Social activities at the conference were fully booked. EMWA delegates enjoyed such highlights as Belgian chocolate, beer and admired Brussel's Art Nouveau style.

With the Brussels conference over, our thoughts already turn to the next major EMWA event, the 44th EMWA conference, which will be held in Birmingham, England May 2–6, 2017 at The ICC. We hope to see you there!

Writing for mixed-media training programmes

Helen Stimpson, **Louisa Reed**, and **Caroline Sharp**
Prescript Communications Ltd, Letchworth Garden City, UK

Correspondence to:
Caroline Sharp
Prescript Communications Ltd
Suite 301, 2nd Floor, The Nexus Building
Broadway, Letchworth Garden City
Hertfordshire SG6 3TA, UK
+44 (0)1462 487400
carolinesharp@prescript.co.uk

Abstract
Effective learning and development tools are important in spreading and consolidating knowledge within any pharmaceutical or biotechnology company. Medical communications professionals may be involved in creating training materials for many purposes, from disseminating scientific concepts to helping employees refine their customer engagement skills. Creating effective training solutions that offer the right training and development opportunities for the intended audience may require harnessing a blend of virtual, self-directed, and face-to-face approaches, and will almost certainly entail an understanding of the principles of instructional design. eLearning will often form the core of a training programme, offering flexibility for both employer and learner. However, despite the current focus on digital materials, face-to-face training remains essential in any well-rounded learning approach. Whatever the training method, to ensure that newly-acquired knowledge becomes embedded, the content of each training element must be written in a style that suits the learning needs and delivery method.

Introduction

The pharmaceutical environment is constantly evolving, and is now more complex and unpredictable than ever before. One constant in this is the need for effective training programmes that allow personnel to meet the demands of their industry, from understanding scientific content through to refining the skills needed to engage a customer.

Traditional training methodologies – such as classroom training, coaching, mentoring, and 360-degree feedback (a system in which employees receive confidential, anonymous feedback from the people who work around them, typically the employee's manager, peers, and direct reports) – remain essential learning tools. Nonetheless, when it comes to developing a world-class training programme, mixing these traditional tools with digital media is vital. A phased process that comprises a variety of tailored mixed media elements can ensure that the right training and development opportunities are offered to the right people, the right way, at the right time. A training curriculum may leverage virtual, self-directed, and face-to-face approaches, as well as digital and traditional reinforcement tools to embed newly acquired knowledge.

It is critical to the success of a training programme that each element is planned, and that appropriate content for each element is written in a suitable style. Consequently, when planning each element of the programme the writer should consider the following:

- Who is the intended audience, and what is their level of understanding of the subject area and related terminology?
- What will be the value and the end goal of each piece?
- What level of referencing is required? Each document should obviously be fully referenced to support all statements, but is it necessary to provide pdfs of each reference with cited statements highlighted and/or reference management via a software package?
- Will any assessments be created to track learner performance, and if so how regularly will these occur?
- What are the timelines for each element in terms of the stages of development and for final rollout?
- How does the individual learning piece relate to other materials in the programme, in terms of rollout timing and content?
- A wide variety of training materials could be created as part of a multimedia programme. In this article, we will focus on two core aspects of a training curriculum – writing for eLearning and face-to-face training – before describing some different tools that may be used to reinforce learning.

Adult learners have different learning styles and preferences for the way that they like to receive and interpret information, so a training programme should be written in a balanced style that allows all users to remain focused and engaged throughout the learning process, whether they learn best through reading or looking at visuals, listening to audio, or doing something (so-called visual, auditory, and kinaesthetic learners).

The importance of instructional design

When creating any training programme, the principles of instructional design should be followed. Instructional design is the entire process of analysis of learning needs and goals and the development of a delivery system to meet those needs. Instructional design can ensure that the user achieves the programme goals and learning objectives, and that knowledge is retained. Adult learners have different learning styles and preferences for the way that they like to receive and interpret information, so a training programme should be written in a balanced style that allows all users to remain focused and engaged throughout the learning process, whether they learn best through reading or looking at visuals, listening to audio, or doing something (so-called visual, auditory, and kinaesthetic learners). In addition, the use of measurable behavioural learning objectives helps to establish the direction the learning will take, so that the user gets the most out of the training. Learning objectives are statements that clearly describe what the learner will know or be able to do when they have completed the training course i.e. recognise the differences between acute and chronic pain. They should contain action verbs like, analyse, compare, design, and explain that describe measurable behaviours. Verbs such as know, appreciate and understand should be avoided, as they are vague and difficult to measure.

Once the target audience is defined, and their needs and motivations are understood, the learning design process can begin. The first step is to determine the learning outcomes: this will focus the content and any stakeholder requirements. Then it is important to decide what would constitute evidence for the learner having reached the desired learning outcomes. Finally, consider the most effective and engaging ways of training or communicating the content.

In summary, instructional design dictates a backwards design process: identify desired results, determine acceptable evidence, and then plan the learning experiences and instruction accordingly.[1]

These ideas apply to all forms of training, and so should be kept in mind when writing content for any element of a training programme. In-person activities such as face-to-face mentoring and workshops are likely to involve a variety of different learning inputs, e.g. slide presentations, role playing, competitions, and group discussions. By contrast, an eLearning course could be very linear and isolating if consideration is not given as to how the information can be delivered in a variety of ways and how the user can be made to feel as though they have some control over the programme rather than it being something they 'must see through to the end'. In this regard, making good use of the ability to layer information in eLearning by using pop-up windows, or allowing the user to choose their own route through the training (neither of which is possible in traditional paper-based training), can help to engage the learner. This also applies to the use of a voiceover and in-training games or quick-fire questions.

How to put together an eLearning training programme

In today's digital world, eLearning forms the core of many training programmes. The flexibility that this type of training provides can be of great

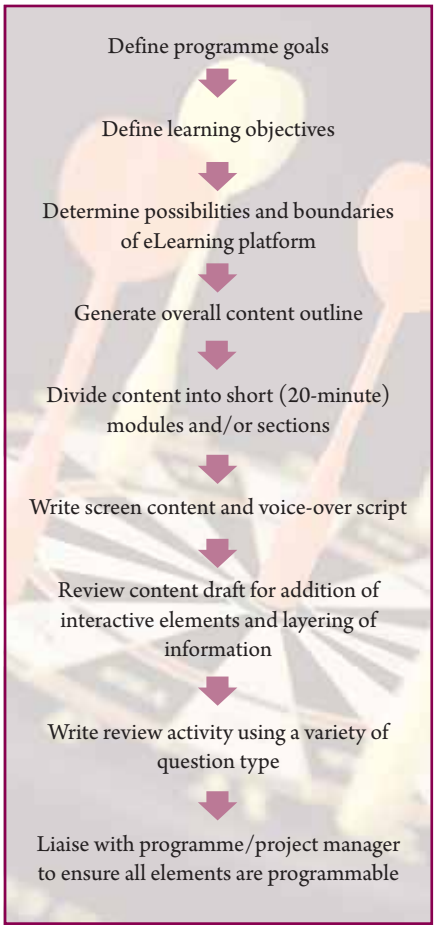


Figure 1. Process for creating an eLearning training course

benefit to both the employer and the learner. The employer is able to deliver comprehensive training without the need to organise expensive in-person courses that require coordination among multiple employees' schedules, and the learner can fit their training around their work and other commitments.

Before you start writing

Writing valuable content for an eLearning programme can be tricky, as it is likely that the learner will be undertaking this training whilst also doing their normal job. Consequently, the content needs to deliver information efficiently and in a way that holds the user's attention. This need for concise, effective content applies whether the training is on a disease or product, or about company procedures or the development of new skills, such as learning a new selling technique.

When deciding how to present information, you should keep the end user in mind at all times. What are the **learning objectives** of the training, what does the learner **need** to know? How can the content be made **engaging**? How does the eLearning element add **value** to the overall training programme? And finally, what checks can be put in place to make sure the learners actually **remember** what they have learned and can effectively **put it into practice**? To address these questions, an eLearning programme should contain the following elements:

- Well-defined course goals
- Results-oriented learning objectives
- Clear and concise text
- Layering of information – core versus in-depth
- Engaging imagery
- Numerous interactive elements
- Effective assessment activities
- A voice-over

An ideal process that a writer should follow when creating an eLearning programme is given in Figure 1.

Once the learning objectives are clear, it is important to define which platform the eLearning will be run on, as this will have an impact on the space that is available on each screen, and the capacity to incorporate unique features of eLearning such as pop-ups or animations that can help to break up text and focus the learner. It is critical to have a clear understanding of both the possibilities and limitations of the programme by liaising and communicating with the programmer or project manager, so that the full value of eLearning can be exploited and boundaries justified.

Writing eLearning-friendly content

When writing content for eLearning, smaller chunks of information across more screens is more effective and less intimidating for the learner than lots of text on one screen; if the learner doesn't see the scroll bar, they may miss important content. Identifying the size of the training piece at the outset and splitting the content into modules or sections that each take no longer than 20 minutes to complete should make the content more digestible for the learner.

Understanding the level of complexity of the content is probably going to be the greatest test of a medical writer's skills. Tailoring it to the intended audience involves an appreciation of their prior level of knowledge and the appropriate language; for example, content could patronise one audience (e.g. key opinion leaders) or baffle others (e.g. sales representatives). It is also crucial to understand whether the training is foundation-level or a refresher course. In any case, an eLearning course allows for layering of information, with core on-screen text that is critical for the learner to work through, and pop-ups that lead to in-depth information or glossary terms. The eLearning may also link to an earlier part of the course (or a previously completed course) if the learner needs to revisit a concept they have already worked through.

It is important to use concise yet clear messages rather than dense, heavy sentences and to use active rather than passive prose. Colloquial terms need to be avoided for any material that will be used in different localities, as they may literally become lost in translation. Although the content may be about serious medical conditions, don't be afraid to keep it light in places (where appropriate). Additionally, eLearning doesn't have to involve page after page of bulleted lists – there is a time and a place for these, but there are also much more creative ways of presenting your content, such as text boxes, icons, labels around a graphic, click and reveal buttons, and tables.

It is good practice to create review activities to assess whether the user has effectively digested the information in the course. These activities should tie in with the learning objectives. Creating short 'knowledge check' activities within each section can also help to refocus a learner's attention and reinforce the learning, and will particularly appeal to kinaesthetic learners. These activities usually comprise questions on the content the learner has just worked through. A variety of question types can be used including simple multiple choice questions, dragging and dropping labels onto a diagram or locating a 'hotspot' in an image e.g. pinpointing the left ventricle in a diagram of the heart.

Adding value with a voice-over script

Tailoring the eLearning for all learning styles as prescribed by instructional design should include the use of a voice-over to narrate what is on-screen. This is where the short and snappy bites of information from the screen are fleshed out to

create a full script. Be aware that as some people are not auditory learners, or indeed may simply not like the sound of the narrator's voice, they may switch off the voiceover during the training. Consequently, the script should not contain any key information that does not appear on the screen. Make sure the script sounds natural – read it aloud if necessary. In particular, consider the places where brackets, bulleted lists, acronyms, and abbreviations have been used, and make adjustments as required to improve the flow of each full sentence.

How to create a face-to-face training package

Face-to-face training can take many different forms, from straightforward classroom-based teaching, through to the development and practice of specific skills or the development of tailored action plans during workshop sessions. These in-person activities remain an essential part of any well-rounded learning approach, despite the current inevitable focus on digital materials. Writers creating training for the modern pharmaceutical industry may be asked to create slides and workshop materials to support any of these types of classroom learning. These may include materials that are directly relevant to a therapy area, as well as those related to a skillset such as customer engagement.

Initial considerations

A key challenge in writing material for face-to-face training is understanding how the session fits into the audience's broader training programme. A complete learning and development programme will often have an eLearning course at its core, with practical in-person sessions designed to complement it; alternatively, a workshop or classroom-based learning activity may sometimes need to stand alone. If the in-person sessions are designed to complement other training materials, it is important to understand what these are (and see them if possible) and then tailor the content accordingly.

As with an eLearning programme, it is essential to understand the overall objective of the face-to-face training at the outset; for example, is it to convey information, or to allow individuals to develop a plan (such as how to train their staff on a new standard operating procedure) or practice a skill such as responding to objections from doctors during a sales call? It is common for a classroom-based training session to start with an outline of the session goals, and to end by revisiting these goals, allowing the training facilitator to work with the audience to assess whether and how those goals have been met.

Once the objectives of the training are defined, it is useful to consider what activities will be needed to support them, and to develop an agenda for the session. The agenda essentially forms the outline for the content, and will determine what deliverables need to be created in terms of on-screen slide content and supporting materials (Table 1). Outlining the goals at the outset, and then creating workshop activities or slide content to address each goal, is an efficient way of structuring the content and ensuring all learning objectives are met.

Keeping learners engaged

To keep learners engaged and to appeal to different learning styles, an in-person training session will ideally include a mixture of facilitator-led on-screen information sharing and small and large group breakout activities such as those listed in Table 2. If broken up into smaller discrete activities, the training session should meet the needs of different learning styles and prevent the drift in concentration that is almost inevitable if participants are asked to sit through long slide presentations. The balance between facilitator-led and group-work activities will depend on whether the main purpose is to convey information, or to practice a skill or work through scenarios with colleagues. Table 2 contains a list of interaction types that can be included in the agenda of face-to-face training.

Facilitator guides

Another key challenge in developing in-person training is understanding the needs of the facilitator(s) who will be delivering it. If the content is for a global pharmaceutical company as part of an overall learning plan, it may be necessary to create centralised resources that can be shared with and adapted by members of affiliate organisations around the world. In this case, it is critical to realise that the facilitator may not have been privy to discussions about how the training should work and so particular care should be taken to ensure that instructions are clear and that materials are self-explanatory. Creating a facilitation guide can be helpful here. This document leads the facilitator through each

Table 1. Items that should be considered when preparing face-to-face training

Item	Description
Agenda	Should be provided to all attendees and be closely tied to learning objectives
Invitations to attendees	Informative invitations that explain the reason for the training session, any prior knowledge expected of participants, and whether attendees need to prepare anything for the session
Facilitator guide	Critical if training is a centralised resource Needs to describe what the facilitator needs to do with the training materials, clearly explain breakout activities, and highlight key messages. May also describe ideal room set up, Wi-Fi requirements, documents that need printing etc.
Exercise materials	Materials for the breakout activities, e.g. question/scenario cards, posters, source documents, PowerPoint templates, and 'how to' leaflets
Participant workbooks	Summary of the training session, with sections for the learner to complete during the training
Training evaluation	A method by which participants can give feedback on the training
Post-meeting embedding tools	A variety of tools that require the learner to recall or revisit information gained at the training session, e.g. quiz questions, follow-up video conference sessions, or online resources from the meeting
Printing guide	A document containing print guidelines to allow facilitators to print materials correctly

Table 2. Types of activity that can be used during face-to-face training sessions

Activity	Description	Content	Useful for
Role-playing	Participants work through scenarios responding 'in character' using their newly-gained knowledge	May involve writing scenarios or questions to 'seed' a role-play, or full scripts for actors that attendees have to interact with	• Practising skills • Embedding knowledge
Problem solving	Small groups work together to come up with a response to a set problem. The responses are then reported back to the whole group	Generation of one or several scenarios and thought given on how participants report back on their discussion, e.g. a PowerPoint template for each group to fill in	• Embedding knowledge • Encouraging team work
Presentations from attendees	Each participant gives a very short pre-prepared presentation to the whole group	May need to assign topics and provide a PowerPoint template	• Skill practice • Conveying information
Competitions/games	Small groups compete with each other in either a straightforward quiz or a more complex game	Develop questions and format of the game, a 'how to play' document, and a method for recording scores	• Embedding knowledge • Engaging attendees with competitive elements • Injecting fun
Creation of a poster on a topic relevant to the training	Small groups create a visual representation of an assigned topic that is then presented to the rest of the group. Photos can be taken as a record of the outcome	May need to assign topics to each group, generate an instruction leaflet to explain the activity, and generate source material for the groups to summarise	• Encouraging teamwork • Conveying information • Embedding knowledge

of the activities in the training session, explaining the aims and content developed for each activity, and how to run each of them. The guide may even provide suggested room layouts, IT and audio/visual requirements and recommended participant numbers.

Post-training: Tools to embed and reinforce knowledge

Engaging and innovative reinforcement tools can enhance and embed learning to help ensure long-term knowledge retention. Below are some examples that may be used for this purpose:

Quick-fire smartphone/tablet quiz questions provide an innovative learning solution that allows users to test their knowledge after they have undertaken a training programme. Proprietary systems and systems built by an in-house digital team can be used to deliver multiple choice questions, which are ideally followed up with a short, fully referenced rationale to accompany the answer and ensure the opportunity to learn from any mistakes. The tone, style, and level of complexity of the questions should match the training material content and be tailored to the learners.

An **online learning portal**, such as a learning management system, is a useful source of information to support and enrich the learning experience. Via an online portal, self-directed learning can be encouraged and users can access resources. As well as text for the online portal, internal communications may be created to increase awareness of this resource. These internal communications should be short yet engaging, to drive traffic to the portal. You may also consider creating questionnaires that users can complete to give feedback on the overall training curriculum. Once again, the tone and style should be aligned with all other materials.

Video conferences are simple yet valuable tools for holding live training sessions for multiple countries. These sessions may involve the trainer presenting content from slide decks that have been adapted from the eLearning programme, using the audio script as notes. Past video conferences can also be recorded and stored on the online learning portal for future reference.

Conclusion

The way in which training material is delivered is changing, with new trends and technologies shaping the future of training. Alternative, innovative approaches are needed to encourage more adaptive behaviours and approaches to developing training programmes, to meet ever-changing organisational goals and expectations. With new approaches come the requirement to adapt writing styles, not just for the target audience but also to complement the type of material that is being created. This will ensure that the training strategy has value for the learner.

Reference

1. Wiggins GP, McTighe J. Understanding by Design. Alexandria, VA: Association for Supervision & Curriculum Development; 2005.

Author information

Helen Stimpson has worked in medical communications for the past six years, having previously worked as a postdoctoral researcher in the field of cell biology.

Louisa Reed has worked as a medical writer and editor for over 13 years, following completion of a doctorate in molecular biology.

Having previously worked as a research scientist for 6 years, **Caroline Sharp** has been a medical writer and editorial project manager since 2006.

Lessons from building an accredited medical conference: Design and delivery

Yvonne Anderson[1], **Steven Walker**[1], **Allon Hazan**[1], **Sophia Whitman**[1], **Farzad Heidari**[1], **Tahin Manjur**[1], and **Christine Oesterling**[2]

1 Stgilesmedical, London & Berlin

2 Eastmead Surgery, Greenford, London, UK

Correspondence to:

Dr Yvonne Anderson
Stgilesmedical London & Berlin
The Vestry House
60 St Giles High Street
London WC2H 8LG, UK
+44 207 836 7110
yvonne.anderson@stgmed.com

Abstract

Participation in meetings and events by healthcare professionals is part of their continuing professional development, and it is a requirement for organisers to gain accreditation for continuing professional development in order to attract delegates. We describe our experiences of building an affordable educational event without the involvement of an industry sponsor. The programme spanned a range of interlinked health topics, a research forum and opportunity to network with scientists from academia and industry across Europe. Following a de-brief with the conference team and analysis of delegate evaluations, a number of learning points emerged, including the need to start organising early, difficulties in reaching the target audience, the high cost of delivering such an event, scheduling issues, and the degree of team effort required for a successful outcome.

With increasing specialism, medical meetings are focusing on evermore narrower areas of interest. This contrasts with the current emphasis on multidisciplinary patient care.[1] Similarly, innovation and research moves forward apace across the pharmaceutical industry, medical devices, and digital health, yet these different groups seem further apart than ever. One positive development in this changing landscape is that the patient viewpoint is given increasing prominence.[2]

Participating in continuing professional development (CPD) is now a stipulation for most healthcare professionals. UK-based primary care physicians (general practitioners/GPs) for example, are required to demonstrate annually that they have participated in a range of educational activities and accumulated an average of at least 50 CPD credits annually.[3] Such credits can be awarded by a range of approved organisations whose role is to assess the educational value, quality of content, and unbiased nature of the activity.[4] Many industry-sponsored events are not eligible for accreditation.

Attending medical meetings, being involved in research, and presenting one's own data in front of peers are highly regarded facets of a medical career and essential for academic advancement.[5] The quality and educational value of medical conferences can vary: a recent survey suggests that around 40% of delegates have had a poor meeting experience.[6] Other findings were that that healthcare professionals prefer shorter events of no more than two days including travelling, while 75% were keen to have greater input into shaping the meeting agenda.[6] A new trend in some areas is the use of compressed teaching with a focus on learning outcomes delivered in a shorter time period.[7,8]

Reduced employer funding for postgraduate medical education is a barrier to learning.[9] The pharmaceutical and medical device industries continue to make a major contribution to CPD activities for healthcare professionals. Though this is generally valued, commentators argue that it could affect prescribing and should be prohibited.[10] In the US, the pharmaceutical industry is not permitted to be directly involved in CPD;[10] consequently, a number of commercial education companies have stepped in to fill this gap. The high cost of meetings and courses means that self-funding is not an option for many healthcare professionals.

There is perhaps another way of addressing some of these issues while at the same time providing medical writers with a training opportunity. Our medical communications company is built upon core values that include the importance of education, innovation and partnership working, so establishing the European Health Innovations Collaborative (EuHIC) was a natural step for us. The inaugural

event, EuHIC 2016, aimed to deliver an affordable conference for healthcare professionals that built on our senior team's educational experience and enhanced the company's profile. The event had to cover its costs. Our desired outcomes were to provide an update delivered by experts across a range of health areas, an opportunity for delegates to present their own research and an environment conducive to networking with peers, scientists and innovators, all without the involvement of an industry sponsor. This article describes our experience of organising and delivering an educational conference in a European setting.

Building the programme

The starting point was a series of discussions with practising medical doctors in the UK and abroad (Table 1). Their diverse opinions suggested that interacting with fellow delegates was as important as up-to-date and interesting content. They liked the idea of mixing with scientists and innovators from the pharmaceutical and medical devices industries and digital health. Potential delegates wanted brief presentations in varied formats with a European flavour. All of this input resulted in the establishment of the European Health Innovation Collaborative (EuHIC). Clinical commitments mean that many did not want to journey too far or to be away from their patients longer than necessary. Obtaining CPD credits was essential for many.

Meeting duration, budget, and registration fees

Based on healthcare professionals' preference for shorter programmes and greater networking opportunities, we decided on an inaugural one-day meeting with a preceding welcome evening and post-conference networking event.

EuHIC 2016 was designed as a non-profit conference, with revenue intended to cover costs. In setting our registration pricing we looked at what other similar sized medical conferences and meetings around Europe were charging for one day of attendance. Figures for full registration were found to be in the range £225–700 (€260–800) depending upon time of application. We settled on an estimated total budget of £20,000 (€23,000) based on 100 delegates paying £140 (trainee rate: €160) or £195 (full registration: €225). These figures were lower than elsewhere

Table 1. The EuHIC diary

Month	Activity
2015:	• Agreed core topics and cross-cutting themes
December	• Commissioned branding and logo design
2016:	• Located and booked the venue
January	• Purchased EuHIC domain
	• Designed "save the date" flyer
February	• Created website design and structure, began populating the site (continued to September)
	• Distributed "save the date" flyer
	• Approached conference chair and secured agreement
	• Started to approach presenters and exhibitors (continued throughout March, April, and May)
March	• Set up registration and payment system
	• Booked refreshments and entertainment for social events
	• Approached speakers from Germany, USA and Ireland
April	• First round of direct emailing
	• Site visit to conference venue
May	• Registered with RCP for CPD accreditation
	• Sent promotional material to postgraduate deans and key "gatekeepers"
June	• Set up mass emailing with Doctors.Net
	• Continued direct emailing to own contacts
	• Submitted CPD application to RCP
	• Booking of accommodation and travel
July	• Began Twitter campaign
	• BMJ ad appeared
	• Updates to website
	• Started to compile speaker biographies and presentations
	• Distributed conference flyer
	• Received 7 CPD points
August	• Re-sent mass emailing via Doctors.Net
	• Completed the programme
	• Started to compile conference documentation (e.g. evaluation form, attendance certificates, badges)
	• Increased Twitter presence
	• Refreshed website, including abstracts and biographies
September	• Finalised documentation and printed conference handbook
	• Updated delegate list, confirmed refreshments.
	• Final instruction emails to delegates, speakers and exhibitors

Abbreviations: BMJ, *British Medical Journal*; CPD, Continuing Professional Development; EuHIC, European Health Innovation Collaborative; RCP, Royal College of Physicians

but our budget also relied on being able to attract up to 12 supporters from industry to host a stand (cost £500-850; €575-975).

We used the web-based service Eventbrite (www.eventbrite.com) to manage bookings and payment, allowing both delegates and exhibitors to pay by bank transfer or credit card. The company charges a 5-7% administration fee, forwarding receipts to our bank account. While speakers were not paid for their time, we funded their travel, accommodation, and participation in the social events. Some were very reasonable in their claims, though others sought first-class travel and dinner expenses despite signing up to our catered events.

Timing

The health and medical conference calendar is crowded. The dates of September 21–22 September 2016 were chosen as being relatively free of meetings and long enough ahead of our first planning meeting. The downside was that this coincided with the holiday period during our peak advertising period of July and August. Low numbers and the UK's vote to leave the European Union ("Brexit") did at one point make us consider cancelling the event. Matters were seen to improve with a rush of bookings occurring in the first few weeks of September. This was particularly true of trainees who reported that they wished to book earlier, but could not do so until their timetables were available.

The venue

A good location attracts delegates. London is vibrant, easy to get too and has numerous potential delegates from hospitals and universities close by. We wanted a venue that not only had all the technical facilities required for a modern event, but also a connection to the theme of the conference. After much searching we were offered a lecture theatre and three adjacent smaller rooms in the medical school at Imperial College London (total cost for 100 delegates with catering, equipment, technician etc. approximately £7,500).

Speakers, programme, and format

It has been estimated that the amount of medical research output doubles every nine years.[11] Our starting point was to look at what is currently arousing interest in the medical press. The next step was to list good speakers we were acquainted with, who were interested in research and teaching. Obtaining the early agreement of Professor Andrew Krentz from the Buckingham Institute for Translational Medicine (Clore Laboratory, the Clore Institute for Translational Medicine, University of Buckingham) to be the conference president lent authority to the meeting and helped attract other speakers.

Our original contacts requested short presentations. Compressed teaching is an unfamiliar concept for many and requires an adjustment to delivery and assessment.[7] It is also far from an easy option for students.[8] Our request was that the speakers concentrate on the desired learning outcomes in 10-12 minutes without unnecessary detail. This was a challenge that most presenters achieved, with one notable exception (in excess of 20 minutes).

We wanted to offer a packed, value-for-money programme containing something interesting for everyone. The final programme comprised 16 different sessions across four rooms, delivered by 63 clinicians, scientists, and industry representatives. (The full agenda can be found at http://www.euhic.com/programme.) This in itself posed a significant logistical challenge.

Our solution was for each parallel session to include a mixture of more scientific or specialist topics alongside broader subject areas. While this worked for some, there was, for example, criticism that the primary care session clashed with the update in emergency medicine across Europe, or the gastroenterology and hepatology presentations were run at the same time as the

diabetes lectures. Our evaluation showed that while many delegates would have preferred a different order of topics, there was no consensus as to how we might best do this in the future.

An unexpected finding was that some of the sessions predicted as being popular were poorly attended and vice-versa. For example, primary care found a bigger audience than cardiology with its potential attraction of film clips showing elaborate interventional procedures. This demonstrates the dangers of anticipating delegate interests.

Attracting delegates

From the outset, we knew we had set ourselves a significant challenge in constructing a multidisciplinary programme covering diverse topics, since this did not lend itself to a focus on a discrete target. Our primary target were medical trainees through to new hospital consultants, academics and GPs from across Europe. To that end we applied for CPD accreditation from the Royal College of Physicians and were eventually awarded with seven points. One practical problem was that we had to have the programme finalised before we could apply, a factor that delayed effective marketing.

We also sought to attract scientists and innovators from the pharmaceutical industry, medical device companies and digital medicine; where we succeeded, these were mainly presenters and exhibitors.

Our own database was the starting point for selling the conference, but it needed to be augmented in a number of ways, many of which were breaking new ground for us.

Website

The EuHIC conference needed a recognisable logo and attractive website. This we developed in-house together with our digital marketing team and regular designer (Figure 1). In parallel, we designed a paper and electronic version of a "save the date" card.

One difficulty we experienced was in synchronising marketing efforts with website content. For example, an early mass email campaign was initiated before many of the speakers had confirmed and prior to obtaining CPD approval. This is likely to have resulted in early viewers of our website being put off by limited information and a less attractive format. Subsequently, we worked on this until www.euhic.com became the central repository for all conference documentation.

Direct mailing

We used online software (www.mailchimp.com) to handle mass emailing, enabling us to monitor the number of emails opened and who then clicked on the hyperlinks. To our own database we added professional contacts we had met at a range of health-related events. Being mindful of data protection, and our obligations as registrants with the Information Commissioners Office (£1,990/€2,300 per annum), we confined our approach of providing information about an educational meeting to those for whom it would be of interest.

A further electronic method was to purchase a direct email service from Doctors.net.uk (www.doctors.net.uk). At a cost of £2,500 (€2,900), the company emailed our conference details and registration link on two separate occasions to around 60,000 UK medical doctors. The first emailing was opened 20,000 times, an open rate of 32.75%. The number of clicks through to the EuHIC website was 338, a click rate of 0.54%. These rates would normally be considered good for a "cold" email. However, no registrations resulted from these first website views. Contributory factors were likely to have been our incomplete programme and unconfirmed CPD accreditation. The reminder email to the same medical doctors had almost the same open and click rates but resulted in a small number of registrations.

As the conference programme took shape, we had a series of flyers designed and printed. (Figure 2) These were mailed to postgraduate

Figure 1. Logo and website design (screenshot taken from home page)

Figure 2. Final EuHIC conference flyer: front above and back below

Table 2. Summary of learning from EuHIC conference

What have we learned?

- Planning and running a conference is stressful and hard work, especially for newcomers
  Our next one will build on this valuable experience
- Costs are likely to be higher than expected
  Find a co-sponsor
- Start planning 12 months ahead
  Send "save the date" cards at 9 months and keep sending regular updates.
  Run the build-up like a military campaign
- CPD points are a major attraction for medical doctors
  They are a mark of credibility and lend authority to the programme
- Obtain CPD approval before your main promotional push
  For maximum benefit, have your programme and presenters in place early
- Medical meetings are a crowded market
  To succeed, your event must stand out
- Avoid too broad a programme and limit social events
  Delegates' time is limited – keep things simple
- Charging a payment, even if nominal, is important
  Attendees are more likely to value an event that they have paid for
- Mistakes will happen
  (e.g., there were still some errors in the handbook)
- Reach out to delegates individually and make them feel welcome
- Expect the unexpected
  … and keep smiling!

Abbreviations: CPD, Continuing Professional Development; EuHIC, European Health Innovation Collaborative.

deans and educational centres at the 13 Local Education and Training Boards across England. More flyers were sent to our speakers, associates, and clients. As the event grew closer, we emailed individuals listed on various websites across the UK as being responsible for postgraduate education and training. For cost reasons, we decided to search for addresses ourselves rather than use commercially available lists. The metrics for the direct emails to our own database of contacts were a 20% open rate and 3% click rate. All of these rates compare favourably with established benchmarks.

Advertising

We took out a quarter-page colour advertisement at the back of the *British Medical Journal* at a cost of £3,000. On the journal's advice, this went out around 6 to 8 weeks before the event. The EuHIC conference was also listed on the journal's webpage and on the Royal College of Physicians site for courses and conferences. We consider these to have had limited direct benefit.

Social media

EuHIC is a new venture and initially had a low profile on social media, with no Facebook, Twitter, or YouTube presence. Our previous experience has been that building a following on any social media channel takes time and effort to be meaningful. In the months leading up to the conference we used both Twitter and LinkedIn as ways to attract interest in our event. Despite this, one delegate commented that he

had expected to see more social media activity from us before the meeting.

Champions and partners

The conference was supported by the British Chamber of Commerce in Germany, which promoted the event through its own European networks. Doctors Academy and other organisations also featured the conference in a *quid pro quo* arrangement. In addition, some of our faculty members and academic contacts were active in promoting the event in their institutions and across their regions. In return, we offered them a number of free places for their trainees and researchers.

Word of mouth

In the end, what proved both effective and low-cost was face-to-face marketing. Whenever the opportunity arose during a conversation or as part of an email exchange we would introduce EuHIC. Two members of our team attended "grand round" meetings at several of the major London hospitals and presented details of the conference. Our statistics showed that 50% of delegates who registered did so after hearing about the event from either one of our team or a colleague.

From the outset, we knew we had set ourselves a significant challenge in constructing a multidisciplinary programme covering diverse topics, since this did not lend itself to focus on a discrete target audience.

Outcomes

Successes

Learning points are listed in Table 2. Delegates were mostly medical professionals and/or academics (others 28%). Overall, 34/39 (87%) rated conference organisation good or excellent while 37/40 (93%) held a similar view as to the programme. Similar numbers found EuHIC a good place to engage with different areas of healthcare as well as connect with others they would not normally meet at conferences. Asked whether they would like to attend a similar event in the future, 34/36 (93%) agreed or strongly agreed. The comments below are representative of much of the feedback received:

"It was good value, the topics seemed very innovative."

"Great variety of disciplines/ specialties."

"Really good buzz around the whole day."

The day ran smoothly, with no technical issues. Our nine exhibitors reported that having a presence at EuHIC had been worthwhile, with enough visitors to their stands and genuine interest in their products and innovations.

The welcome event – a rooftop barbeque at the adjacent Baden-Powell House, home of the Scouts Association – proved a pleasant start. Similarly, the post-conference reception in the President's House and Garden at Imperial College achieved a warm, relaxed atmosphere, enabling further networking in a congenial environment.

In addition to the satisfaction of building and delivering this event, there are a number of positive outcomes for our team: we have gained experience in obtaining CPD accreditation and working with presenters, venues, and advertisers. A major benefit is in having forged new academic and commercial connections, which are likely to make subsequent meetings easier.

Challenges

Our greatest challenge was in attracting sufficient delegates to fill the rooms as well as to generate enough funds to cover our costs. Brexit did not help. In the end, we received 175 registrations, of whom around 120 attended. While the majority were from the UK, some came from Europe, including Germany, Ireland and Finland. Many of those who did not come were trainees and university staff who had signed up for the free places awarded to those without funding.

Another problem on the day was caused by delegates arriving late and leaving early due to travel issues and clinical commitments. This resulted, for example, in our 09:30 flagship session, the Christie Oncology Symposium, being poorly attended. In future, we will schedule key presentations in the middle of the day to optimise attendance. With regards to the otherwise excellent venue, a second event had unexpectedly been booked alongside ours; this caused a degree of registration confusion and clash during breaks. Similarly, there were issues with our storage room, which was double-booked for a tutorial, as well as disruption resulting from the visit of a large party of schoolchildren to the medical school.

Despite checking the text for the conference programme several times, one of the key presentation titles was wrong, resulting in a number of irritated emails from the presenter.

Finally, the meeting was not a financial success. Certain elements cost more than expected and paid registrations proved insufficient to cover our expenditure. The full reconciliation is as yet unknown, but we are likely to have made a significant loss – possibly in the region of £10,000 (€11,500).

Discussion

On the positive side, our programme, organisation, and opportunities for networking scored highly; we hope this will yield future clinical and research benefits. For our team, we have gained experience, developed material we can use again, and made many useful connections. Perhaps because of their problem-solving skills, we observed that our medical writing colleagues rose to the challenge and became increasingly confident across a range of tasks. Feedback suggests that we have raised our profile and built much goodwill. A number of delegates and companies have expressed a desire to be involved next year.

Set against the successes are a number of negative outcomes. Our expenditure exceeded income. We were over-ambitious and could have achieved a similar impact with fewer speakers, a less packed programme and more targeted marketing. A major hurdle in attracting delegates is likely to have been trying to the sell the idea of a multi-disciplinary meeting run by an unknown, non-affiliated organisation. Medical professionals inevitably belong to a specialism and the idea of an event with cross-cutting themes is for many a novel concept. Another factor is likely to be the present crowded market, with medical doctors being oversold educational events on a continuous basis. One of our authors (CO), a London GP, reports that she may receive up to 10 meeting invitations per day, many of them free to attend.

Despite the challenges, we intend to deliver a EuHIC 2017 in Berlin, building on the successes of the inaugural event and taking account of our learning.

References

1. Epstein NE. Multidisciplinary in-hospital teams improve patient outcomes: A review. Surg Neurol Int. 2014;5(Suppl 7):S295-S303.
2. National Institute for Health and Care Excellence. Patient and Public Involvement Policy. 2013 [cited 2016 Nov 18]. Available from: https://www.nice.org.uk/media/default/About/NICE-Communities/Public-involvement/Patient-and-public-involvement-policy/Patient-and-public-involvement-policy-November-2013.pdf.
3. Pulse Learning. About CPD, appraisal and revalidation. Undated [cited 2016 Oct 5]. Available from: http://pulse-learning.co.uk/promotional/about-cpd-and-appraisal.
4. Royal College of Physicians. Provide a CPD event. Undated [cited 2016 Oct 5]. Available from: https://www.rcplondon.ac.uk/about-rcp/work-rcp/provide-cpd-event.
5. McGaghie WC. Scholarship, publication, and career advancement in health professions education:AMEE Guide No.43. Med Teach 2009; 31: 574-90.
6. Ashfield Commercial and Medical Services. The formula to successful scientific meetings. 2016 [cited 2016 Oct 5]. Available from: https://www.ashfieldhealthcare.com/gb/the-formula-to-successful-meetings/.
7. Kretovics MA, Crowe AR, Hyun E. A study of faculty perceptions of Summer compressed course teaching. Innov High Educ. 2005;30:37-51.
8. Lutes L, Davies R. Comparing the rigor of compressed format courses to their regular semester counterparts. Innov High Educ. 2013;38:19-29.
9. Mathers N, Mitchell C, Hunn A. 2012. A study to assess the impact of continuing professional development (CPD) on doctors' performance and patient/service outcomes for the GMC. 2012 [cited 2016 Oct 5]. Available from: http://www. gmc-uk.org/A_study_to_assess_the_impact_of continuing_professinonal_development_CPD_on_doctors_performance_and_patient_service_outcomes_for_the_GMC_ 51707533.pdf.
10. Association of the British Pharmaceutical Industry and the British Medical Journal. CPD for doctors 2013-2023: Report of the joint ABPI-BMJ Conference held at BMA House on 26 June 2013. 2013 [cited 2016 Oct 5]. Available from: http://www.abpi. org.uk/our-work/library/industry/Documents/CPD%20for%20Doctors% 202013-2023.pdf.
11. Noorden RV. Nature News Blog: Nature Publishing Group 2014 [cited 2016 Oct 5]. Available from: http:// blogs. nature.com/news/2014/05/global-scientific-outputdoubles-every-nine-years.html.

Acknowledgements

The authors are grateful to Prof Dr Med Rajan Somasundaram from the Charité Hospital Berlin for his advice and encouragement. Sincere thanks to our excellent teams of presenters and to Suzanne Hoy and the staff of Imperial College London.

Conflict of interest

None declared.

Author information

Yvonne Anderson is Governance Director at Stgilesmedical in London and Berlin. She has a background in education and mental health, with a Social Sciences PhD. Yvonne's focus is on social media and digital communications.

Steven Walker is Scientific Director at Stgilesmedical in London and Berlin. He has degrees in medicine, education and clinical oncology. Steven's focus is on medical writing, research and effective healthcare communication.

Allon Hazan is Medical Writer and Scientific Lead at Stgilesmedical in London. He has a PhD in cellular biology with a background in oncology, dermatology and immunology.

Sophia Whitman is Medical Writer and Research Lead at Stgilesmedical in London. She has degrees in medicine, psychology and immunology, with a background in health psychology research.

Farzad Heidari is Medical Writer at Stgilesmedical in London. He has PhD degree in pharmacology with a background in hypertension and cardiology.

Tahin Manjur is Digital Media apprentice at Stgilesmedical in London, with responsibility for digital marketing and video production.

Christine Oesterling is GP Principal in a West London practice and Medical Advisor to Stgilesmedical in London and Berlin. She is active in medical teaching and research.

Medical education in a medcomms agency

Elodie du Potet
Freelance, Paris, France

Correspondence to:
Elodie du Potet
55 rue du Rocher
Paris, France
+ 33 (0)6 71 88 41 57
elodie.dupotet@yahoo.com

Abstract
Medcomms agencies provide services and counselling to pharmaceutical clients in many ways. Medcomms are currently strengthening medical education as a form of indirect communication strategy, which focuses on educating health professionals on specific therapeutic areas of a given product. This article describes the activities in a medcomms agency, why indirect communication fits in with the client's commercialisation goals and how it may match with the writer's professional interests or career prospects.

Medical communication, also medcomms, agencies provide pharma companies with strategic counsel and solutions: 1. to increase awareness of their relevant targets about new drug products and their benefits and risks to patients, and 2. how to disseminate this information at a large scale through a variety of formats and media. Thus, medcomms agencies produce promotional documents or programmes, which are later delivered to the pharma companies' targets through the pharma sales representatives taskforce or its own medical department.

Many are not aware of the activities in a medcomms agency, especially its role in medical education. The following are typical areas in which medcomms agency can provide services to their clients and describe how their role fits in with pharma sales representatives objectives.

Meetings and conferences

Activities related to meetings such as advisory board meetings, conferences and symposia, and other professional meetings are venues in which medcomms agencies provide multiple services to pharmaceutical companies. Services range from planning to execution of these meetings including producing written materials related to such meetings.

- For example, pharmaceutical clients may ask medcomms agencies to cover conferences as latest developments in therapeutic areas are presented and discussed here. Thus medcomms agencies attend conferences and produce reports synthesising the conference's main outcome, sometimes with the help of medical experts. The highlights of the conferences are presented in form of slides, video interviews, online newsletters, etc. This information may be later distributed and discussed during other professional meetings or activities, thus benefiting doctors who were not able to attend the conference.
- Agencies themselves may organise a symposium which includes planning contents and schedules of the symposium, arranging speakers and other contributors, and producing symposium-related slide kits, leaflets, posters, or advertising banners.
- Advisory boards are composed of medical experts, whose views can be used to fine-tune a clinical research programme or a medical communication strategy. These boards conduct regular meetings, which are mostly confidential. Medcomms agencies are often involved in organising them including preparing the agenda. During the meeting, a medcomms agency personnel may be responsible for chairing the meeting and may be asked to provide the pharmaceutical client with a comprehensive report including minutes of the meeting and strategic recommendations.
- Medcomms agencies carry out other professional meetings and programmes intended for physicians, pharmacists, nurses, or other health care practitioners (HCPs). These may include slide shows, videos, i-Pad applications, websites, web conferences, live broadcasts, etc. Medcomms agencies conceive, set up, and execute these programmes, which involve a lot of brainstorming, copywriting the scientific content, coordinating activities, and managing the logistics. Most of the time, the pharma sales representatives take charge of setting up the meetings (with or without the support of the medcomms agency staff) using the materials provided by the agency.

Best practice surveys

Best practice surveys are a means to assess the general practices of physicians and compare physician and patient perceptions. Knowledge of patient perception may bring interesting views and offers opportunities to improve disease management and treatment. Surveys may be carried out at a national level or may be addressed to all physicians of one or more specialities. The role of medcomms agencies in such surveys includes creating questionnaires (generally with the help of key opinion leaders), promoting survey participation, data collection and data processing. Activities involved with surveys provide pharma sales representatives with opportunities to visit medical experts and set up professional meetings.

Editing and writing promotional materials and scientific publications

Despite the actual trend for interactive media, publication is still an inescapable channel of communication, be it product- or therapeutic area-oriented. Brochures, literature reviews, patient booklets, and information leaflets are classical examples of tools that are handed over to doctors or medical institutions visited by the sales representatives. Medcomms agencies produce such materials, which involves extensive literature research, writing of innovative scientific/medical content, and sometimes editing materials written by other medical experts.

Working in a medcomms agency does not necessarily mean leaving traditional writing tasks aside. Pharmaceutical clients regularly require medcomms agencies to submit manuscripts for journal publication as well as abstracts and posters for scientific meetings. Sometimes, programmes carried out by the agency generate important results (e.g. the results of a national survey, or the successful set up of a patient-centred programme). It is the task of the agency to propose their client a structured, high-impact, and financially acceptable plan for data dissemination including publication. Thus, sometimes results are submitted in journals for publication or for presentation in a symposium. It is very rewarding and challenging for the agency personnel to submit posters or papers related to the projects he/she has personally contributed to.

General project schedule and stakeholders

No matter how complex projects can be, they are scheduled in a similar way (Figure 1). Once the project is handed over to an agency and stakeholders have agreed on a course of action, budget and deadline, medical experts are recruited as needed (as writers, consultants or members of a scientific committee). The next step is the production of the scientific content (in form of video, publication, etc.) and the creation of a visual identity. The contents and the visual identity are reviewed by the client's medico-marketing and regulatory departments. After this, the agency executes the format, layout and all other technical details with the help of its internal and/or external partners: such as design studio, video team, event agency, logistics team, professional translators, IT developers, publishing houses, etc. After the content of communication product/programme is validated by all of the stakeholders, the product is delivered (Figure 1).

Medcomms agencies produce promotional documents or programmes, which are later delivered to the pharma companies' targets through the pharma sales representatives taskforce or its own medical department.

Tasks during a project

Medcomms agencies have different structures as well as ways of assigning tasks during a project. However, similarities exist and we may distinguish three general categories of tasks, which sometimes overlap according to the size and the structure of each agency.

Client-related tasks

These tasks involve direct contact with the

Figure 1. Stages of a project in a medcomms agency showing stakeholders (in italics)

clients. In general, these positions (such as customer relationship managers along with their director) take charge of general project coordination. They directly liaise with the pharmaceutical client's medico-marketing and regulatory departments, set up the project according to the client's needs, and manage the project budget and timelines. They work very closely with the client from the beginning until the end of the project. Box 1 suggests tips on how to manage customer relationship and prevent stressful situations regarding deadlines. More experienced customer relationship managers are involved in strategic counselling. Most of the time, there are other personnel in a medcomms agency whose tasks are more involved in acquiring new customers and maintaining existing customers. They are referred to as commercial development officers.

Liaising with medical experts

The medical writing team usually liaises directly with medical experts involved in scientific committees or with project partner physicians for various tasks. Medical writers produce scientifically sound medical contents. Agencies usually recruit an internal medical services director but other agencies work with external medical experts only.

Medical writers have to have a strong background in medicine or other natural sciences as they have to be able to understand the medical literature and write or quality control many types of medical and scientific documents geared to different audiences (from the most to the least specialised) and in diverse media formats: slide kits, video, digital media.

Thus, medical writers have to familiarise themselves with various pathologies and be able to search for interesting and innovative related topics, which can meet with the client's strategic goals. This may not only involve doing literature search on the web and in medical libraries, but also identifying and interviewing specialised experts and attending related conferences.

Some agencies give medical writers the role similar to that of an editor-in-chief, which involves distributing writing tasks among external physicians and coordinating publication tasks for newsletters, brochures, etc. This role may not be the most rewarding part of the profession as there may be frustrating experience resulting from direct communication with

Box 1. Suggestions on managing relationships with client.

- Keep the client informed on the status of the project through regular reporting and follow-up.
- Formalise instructions and directives by email and phonecalls.
- Guide client in decision-making and give recommendations suited to the client's needs.
- Warn the client ahead of the project's launch regarding inevitable time lags and timeline constraints.
- Inform client as early as possible on obstacles and always come up with possible solutions.

Box 2. Tips how to liaise with medical experts professionally.

- Constant reminder of tasks and deadlines via email or phone calls. Get hold of their mobile phone numbers. Do not remind them only if the deadline is drawing near.
- Leave messages that are short but with complete and exact information.
- Be persistent but not forceful.
- Be personal. Conduct face-to-face meetings once in a while.

extremely occupied physicians, whose contributions are important from the beginning until the last stage of the project. Unwanted delays usually arise even if the medical writer reminds the physicians involved regarding deadlines. As project timelines are usually tight, the medical writer has to remain persistent. Being able to relate well with physicians in extremely difficult situations is a must for medical writers.

However, although stressful situations may come up, such situations are also an opportunity to build a close personal relationship with the physicians involved. Box 2 gives tips on how medical writers can deal with physicians.

Creative tasks

Advertising managers or project managers liaise with the studio designers, who may be external partners, on the format type (print, digital, video), and on the design and layout of a communication product.

An advertising manager or a project manager in a medcomms agency has to have knowledge of the graphic design chain aside from being flexible and interested in all types of multimedia support.

Status of and developments in medcomms

In France and in other EU countries, drug promotion legislation has been stricter thus making it increasingly harder for pharmaceutical companies to directly promote their products. Moreover, the current climate in the pharmaceutical drug industry, legislation on patent expiry, governmental pressure on physicians to decrease prescriptions, lower reimbursement prices for patients, and slower development pipeline have brought about the steady decrease in the the medical sales representative workforce. For example, there were 17,500 medical representatives in France in 2011 and only 21,900 in 2007[1]. As the actual need for medical sales representatives had started to be questioned in the last decade, a health scandal related to a weight-loss drug in France in 2010[2] reinforced suspicions. This led the French government to further regulate medical sales representatives' activities, such as the Bertrand Law (see Box 3).

As medical sales representatives deliver medical communication materials to doctors and other HCPs, these restrictions significantly influence flow and effectiveness of drug promotion.

The developments in Box 3 compel most pharmaceutical companies to realign their communication strategy, away from traditional sales activities. To meet this need, medcomms agencies are now strengthening their activities on medical education as part of their communication offering. These medical education activities in forms of covering conferences and developing other professional programmes (see section on "Meetings and conferences") have traditionally been a part of the medcomms agencies' role. These, together with performing surveys (see section on "Best practice surveys") and medical edition (publishing books or brochures from medical information), provide ways by which the pharmaceutical companies' presence in a therapeutic area can be strengthened. The above activities are also an indirect communication strategy as long as a specific product is not mentioned. Instead, the focus is on the product's therapeutic area. Target audiences of this strategy include medical doctors, nurses and other HCPs, and are opening to patients and the general public.

Advantages of an indirect promotion

Indirect promotion, by developing related programmes on medical education, is a powerful tool to attract the interest of medical experts and develop partnerships with them. Medical experts obtain the advantage of broadening their knowledge on various topics about a disease or therapeutic area. Medical education programmes are also an opportunity to promote patient-centred initiatives.

Indirect promotion has also these other advantages:

- As therapeutic classes instead of brand name appear in medcomms documents, a prior approval from the French National Healthcare and Medicines Safety Agency (*Agence Nationale de Sécurité des Médicaments et des Produits de Santé*, ANSM) is not needed. This

Box 3. Historical development of restrictions in promoting medical products in France.

- 1993 – Anti-Gift Law (*Diverses Mesures d'Ordre Social*, DMOS Law)[3] was passed prohibiting giving gifts or anything that can influence decisions or opinions of healthcare professionals (HCPs).
- 2004 – A specific 'medical representative charter' was officially signed by the Pharmaceutical Companies Trade Association in France (*Les Entreprises du Médicament*, LEEM) and the French Healthcare Products Pricing Committee (*Comité Economique des Produits de Santé*, CEPS) to ensure transparency of information delivered by the companies on their products.[4] This charter provides measures to strengthen pharmacovigilance and marketing authorisation compliance, regulate the access of medical representatives to hospital and service areas, and prohibit giving anything that may influence HCPs including free samples, invitations to lunch, etc. Companies' compliance to this charter is directly certified by the French National Health Authority (*Haute Autorité de Santé*, HAS) and was updated in 2014.
- 2011 – The so-called Bertrand Law,[5-6] the French Sunshine Act, and subsequent decrees extended the Anti-Gift Law to include disclosure of all agreements concluded between HCPs and companies.
- June 2012 – A new legal requirement was imposed that all promotional documents should be submitted for approval from the French National Healthcare and Medicines Safety Agency (*Agence Nationale de Sécurité des Médicaments et des Produits de Santé*, ANSM)[7]. Submission dates are fixed and bring about a two-month delay in obtaining an approval (or a refusal) of any promotional document.

makes regulatory procedures quicker, simpler, and therefore more efficient, and makes timelines realisable.

- Indirect communication can be undertaken throughout the entire drug life cycle, from clinical research to marketing approval, in contrast to direct promotion, which is not allowed before drug launch. Pharmaceutical companies can assert their presence in a therapeutic area at any of the following phases: pre-launch, launch, early and late commercialisation, marketing authorisation extension.

What activities are expected to change?

Formats, media, and services provided by medcomms agencies using indirect communication strategies remain unchanged. However, the topics addressed by medical education programmes stand beyond the issues addressed by direct drug communication. Instead of talking about a drug, its efficacy, risk/benefit ratio, mechanism of action, etc., medcomms can enjoy a broader range of potential topics surrounding the disease or the therapeutic area. Projects related to the entire context of the therapeutic area can be put up exploring aspects of medical economics, molecular biology, healthcare organisation, etc. Patient-centred programmes such as those that will focus for instance on the impact of secondary disease related effects, psychological issues (e.g. depression at work), care support practices, or the patient's well-being throughout each treatment stage can be promoted.

Concluding remarks

Medcomms agency activities focusing on medical education are not only advantageous in the current status of pharmaceutical companies but are also rewarding for a medcomms medical writer. This is because the medical writer does not only learn new skills related to multimedia writing, editing, and graphic design, or develops skills in relating with people of different health-care backgrounds.

The medical writer also gets to conduct a wide-ranging variety of projects with a high scientific value, directly or indirectly related to the drug. It is also a chance to genuinely help patients as activities consider implications on general patient care and well-being.

Acknowledgements

The author would like to thank Amy Whereat for her assistance.

Author information

Elodie du Potet, PhD, has worked as medical writer and a customer relationship manager at Medical Education Corpus, a French medcomms agency dedicated to medical education. She is now a freelancer specialising in medical and scientific communication in Paris, France.

References

1. Le CRIP. 2013 [cited 2013 Jun 17]. Available from: http://lecrip.org/2013/06/17/visite-medicale-vers-de-necessaires-mutations.
2. Maillols-Perroy AC, Tillet Y. Reform Act on safety of drug and health products in France: announcement effect, strengthening or upheaval? Therapie. 2012;67(1):1-10.
3. Legifrance. 1993 [cited 1993 Jan 27]. Available from: https://www.legifrance.gouv.fr/ affichTexte.do?cidTexte= JORFTEXT 000000711603&dateTexte=&categorieLien=id.
4. Le LEEM. 2005 [cited 2005 Jul 21]. Available from: http://www.leem.org/sites/default/files/import/presse/communiques/122_61.pdf.
5. Legifrance. 2011 [cited 2011 Dec 30]. Available from: https://www.legifrance.gouv.fr/affichTexte.do?cidTexte= JORFTEXT000025053440& categorie Lien=id.
6. Legifrance. 2013 [cited 2013 May 21]. Available from: https://www.legifrance.gouv.fr/affichTexte.do?cidTexte= JORFTEXT000027434029&categorieLien=id.
7. Legifrance. 2012 [cited 2012 May 09]. Available from: https://www.legifrance.gouv.fr/affichTexte.do?cidTexte= JORFTEXT000025836786&categorieLien=id.

Patient education in clinical trials and throughout the product lifecycle

Susan M Harris[1] and **Christopher G Kelly**[2]
1 Head of Scientific Affairs and Medical Writing, Site & Patient Networks, QuintilesIMS, Reading, UK
2 Integrated Market Access, QuintilesIMS, Parsippany, NJ, USA

Correspondence to:
Sue Harris
QuintilesIMS
500 Brook Drive
Green Park, Reading
Berkshire, UK RG2 6UU
+44(0)118 450 8000
sue.harris@quintilesims.com

Abstract
Good patient education supports improved outcomes and an efficient, cost-effective healthcare system. In the highly regulated, fast-paced pharmaceutical industry, the challenges that medical writers face in writing for patients are multi-fold. Patient education can be confusing given the wealth of new technologies in healthcare communications, combined with patients being more involved in decisions about their health, and different national and international guidelines and legislations to be adhered to. Furthermore, writers face complexities of trying to meet the needs of diverse populations of patients and specific individuals. In this article, we discuss the importance of effective patient education activities for specific phases of the product lifecycle (from clinical trial participation through to prescribed medicines) and of the patient journey (from disease awareness and diagnosis through to living with long-term chronic illness). The considerations and constraints of developing educational content for patients, and practical guidance for writing such materials are discussed.

Introduction
In this era of patient-centred care, a broad aim of patient education is to encourage individuals to actively participate in their own healthcare through:[1,2]

- Improved ability to make appropriate health decisions
- Ability to recognise symptoms and take actions to visit a healthcare professional
- Increased self-care
- Better management of symptoms and ability to cope
- Adherence to treatment
- Participation in a health programme

Whilst specific objectives of a given patient education initiative will vary by project, the overarching goal is generally to improve health outcomes and/or achieve a more efficient, cost-effective healthcare system.[3]

Patient education has evolved, particularly with the rise of digital media as a tool in healthcare and pharmaceuticals.[4] Patients are now more informed and more likely to actively seek education. Not only has use of the internet for accessing health information dramatically risen,[5] but greater possibilities now exist for delivering healthcare solutions digitally via technologies such as e-learning and apps. These technologies are becoming more commonly accepted and utilised in the industry,[6] and are valuable additions to the patient educators' toolkit.

Multiple challenges and nuances exist for the medical writer in navigating content development for the purposes of patient education. This is not least because of multiple legislation, industry codes of practice, and guidelines that govern various stages of the pharmaceutical product lifecycle and that also vary by country. The need for personalisation in patient education is broadly recognised.[7] To this end, knowing the target audience well (based on robust insights), and ensuring that the content, technology/ delivery method and creative aspects all work together, contribute to an end product that is engaging and understandable. Health literacy is becoming a buzz-phrase within this discipline and is defined later in this article. A specific skillset is required to take complex medical and scientific information and translate it into language that is understandable to a lay audience, as recently described by Salita.[8]

Education for clinical trial participants

Clinical trials are hugely expensive, often lengthy processes, so it is important to be as efficient as possible to avoid cost and time creep.[9] Key factors in completion and ultimate success of clinical trials are timely recruitment of participants, and compliance (to study procedures, study drug and scheduled visits) and retention of sufficient participants throughout the study to meet the sample size and power requirements.[9,10] It follows that effective education of potential and enrolled trial participants can positively influence these factors. In a study of 125 people with cancer, greater knowledge and understanding of the clinical trial were found to be associated with consent to participate, even after accounting for other demographic factors.[11] Indeed, in a global survey of 5,701 people, 35% of those who dropped out found the informed consent form difficult to understand.[12] For pre-approval trials, poor recruitment and retention can also mean a substantial delay to authorisation and availability of new treatments.

Development of content for initiatives aimed at clinical trial participants is subject to stringent ethical considerations. According to Good Clinical Practice (GCP) guidelines, all written information that is to be provided to clinical trial participants (and potential participants) must not be coercive and requires review and approval by an Independent Ethics Committee (IEC) or Institutional Review Board (IRB).[13] In practical terms, this means additional rounds of review and amends over those of the Sponsor. It is also not uncommon for a trial protocol to be updated even after start up. Updates impacting participant materials must be made and need to be re-routed through the IEC/IRB. Hence the cycle of amends, review and re-review (as well as re-printing or re-programming) can be prolonged. Tracking version number and date of document as a footnote is advantageous.

Recruitment

At the point of recruitment, the main educational goals for potential participants include fully informing them about the study and ensuring that they understand the information. This is achieved through the process of informed consent. This process involves provision of written information, which should also be explained to the patient, and the signing of a consent form. When a clinical trial includes participants who require a legally acceptable representative to give consent (e.g., children or patients with cognitive impairment), the participants nevertheless should be informed about the trial to an extent compatible with their understanding. If capable, the participant should assent, sign and personally date an assent form.[13] The Declaration of Helsinki (the origin of the ethical principles of current international guidelines) requires that all participants have knowledge and perceived understanding of all relevant aspects of the trial.[13-16] All communications must also be factual and not persuasive in terms of either agreeing to participate or, later, to remain participating.[13]

Despite the guidance, many studies show insufficient knowledge and understanding among participants. This is both an ethical and legal concern and, as noted already, can also impair successful participant recruitment. Interventions to help people overcome barriers to participation in clinical trials (for participants and/or their carers where appropriate) most commonly involve tools to support the informed consent conversation or printed educational materials. It is worth also considering more personalised and interactive interventions to address specific barriers to participation and to check understanding. For example, supplementing the informed consent process by employment of non-clinical lay staff to provide participant education and logistic and emotional support, or personalising the informed consent conversation to allow individuals to receive the information that they want or need.[17,18] Utilisation of electronic informed consent (defined as use of electronic media [such as text, graphics, audio, video, podcasts, interactive websites, biological recognition devices, and card readers] to convey information related to the study and to obtain and document informed consent), is also becoming more commonplace, with the aim of increasing retention and comprehension of information.[19] For example, videos and animation could be considered to aid understanding in populations who have reduced understanding, such as young children. Sometimes, short tests may be used to check participants' understanding.

In proposing and drafting educational content for clinical trial participants, it can be useful to consider the reasons why people may not participate in clinical trials, and address these specific barriers in other educational efforts that

Table 1. Commonly cited reasons for participation or non-participation in clinical trials[10,11,35]

Common reasons for participation	Common reasons for non-participation
Perception of personal gain (of receiving better care and extra attention) through participation	Perception of personal risk and fear (experimental nature, adverse events, study procedures etc.)
Possible eventual benefits to others, altruism, (especially for future generations of family or when cure for own condition is unlikely)	Concern about potentially receiving a placebo
Gaining access to healthcare (for example US individuals with no health insurance)	Financial cost (for example, travel, unpaid time off work, childcare cost)
Access to new treatments	Time commitment (quantity or duration of study centre visits, study duration, requirement for diary or questionnaires)
Feeling of control in own care	Perceived or real impact on carer (financial or time costs, emotional burden)
	Inadequate communication (lack of understanding, misconceptions, unanswered questions and uncertainty)

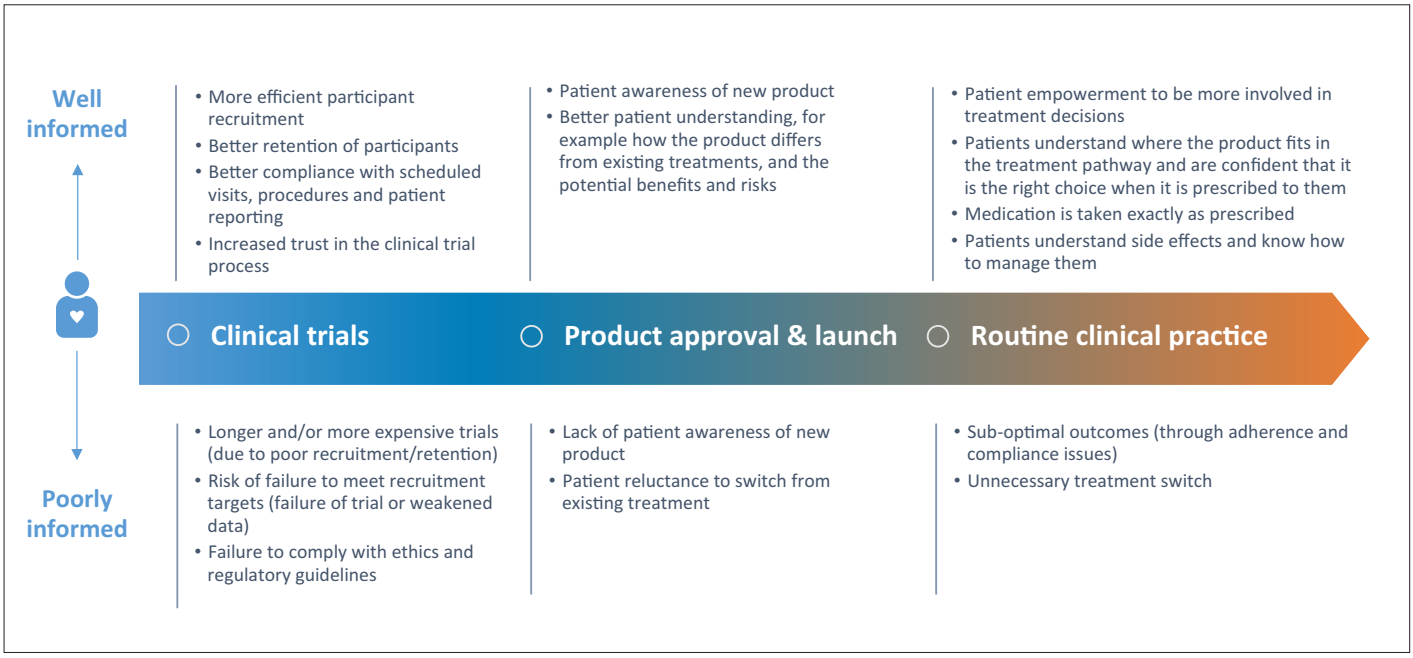


Figure 1. The consequences of informed versus misinformed patients in the product lifecycle

support the formal informed consent process. These barriers may be specific to the patient population or protocol, a reason why it is important to gather insights and personalise the approach.[11] Some frequently cited reasons for taking part or not taking part in clinical trials are shown in Table 1.

In proposing and drafting educational content for clinical trial participants, it can be useful to consider the reasons why people may not participate in clinical trials.

Retention

Particularly for studies of long duration, educational and engagement efforts should ideally be continued throughout the study, to support retention of participants. Depending on the needs of the participant population and the study specifics, this may take the form of a comprehensive, multi-channel participant support and communications programme, or may be a simple automated text messaging service that sends motivational, informational or reminder messages at set points in time. Regardless, the same constraints and ethical considerations apply to all content for participants throughout the study duration, as for recruitment. For studies over a prolonged period, it is useful to measure the effectiveness of the activities and make adjustments to the programme as necessary.

Clinical trial results

Recent regulations and public demand have driven a need for participant access to clinical trial results on completion of the trial. For studies with sites in EU member states, there will soon be a requirement for a layperson's summary of results to be published to the European database within 12 months of the last patient's last visit.[20] An overview of the regulatory guidance and resources for layperson summaries was recently published.[21] However, lay summaries do not need to be limited to the EU database. This is where communications experts can get creative and tailor the format, content and visual style of a results summary to a specific audience. Consideration should be given to the purpose of the communication – whether to satisfy the regulatory requirement, to thank participants personally for their involvement, or to inform interested patient communities about potential new medicines for their condition. Potential benefits include increased public awareness and trust in the clinical trial process, a more positive participant experience, and a greater desire to participate.

Patient education through the product lifecycle

From clinical trials to product approval, launch and use in routine clinical practice, there are always good reasons to inform and engage the relevant patients (Figure 1). Patients now are more in control of their own health and treatment decisions than ever before. With the development of a vast array of health information websites and healthcare apps, patients are able to access more, relevant, health information. This practice is less widespread with elderly patients, who often prefer verbal communications from their regular doctor for receiving information, and studies have shown that they also appreciate brief written information in a clear language.[1,22] Another useful method is the use of decision aid tools that provide evidence-based information about options and outcomes, to help patients make informed choices.[23] It is essential that healthcare professionals are receptive to shared decision making. Generally speaking, involvement of patients in the decision making process is becoming increasingly widespread and more accepted. Patients are becoming more empowered, by their own initiative and the increasing resources available to them, and by changes in practice driven by the industry and campaigns such as the European Patients' Forum Patient Empowerment Campaign.[24]

Patient education plays an important role in influencing patients to take their medication exactly as prescribed. Lack of adherence to treatment costs healthcare systems millions (approximately 1.25 billion Euros annually in the EU) and is responsible for 194,500 deaths per year in the EU.[25] Adherence to treatment is influenced by health literacy, suggesting that addressing health literacy issues can positively influence adherence.[26]

In Europe, patient communications relating to pharmaceutical products must be completely non-promotional, balanced and factual. Whilst content needs will vary, it is worth noting that patients frequently rate highly the importance of receiving information about side effects related to the products they are taking.[1]

Health education and patient support

For any given patient education initiative, it is prudent to consider where the patient is on their personal journey with respect to their disease. The information that a patient needs changes from diagnosis through the course of treatment, and depends on a number of factors such as age and education.[27] Furthermore, patients may change behaviour over time, according to the stages of change model (transtheoretical model of behaviour change), which can be a useful tool to help understand, predict and influence patients' behaviour.[28,29]

Prior to diagnosis, disease awareness campaigns (DACs) play an important role, with the overall aim of earlier diagnosis enabling earlier treatment and potentially better outcomes. The primary purpose of a DAC must be to increase awareness of a disease or diseases and to provide health educational information on that disease and its management. Regulations, such as those in the UK, stipulate that it should not promote the use of a particular medicinal product, with emphasis on the condition and its recognition.[30]

The point of diagnosis is important in terms of patient education because it sets the foundation for motivation and empowerment. To this end, it is vital that patients receive sufficient information to fully understand the condition (including prognosis), the treatment pathway and potential risks and benefits of the different therapy options. At treatment initiation (whether at the point of diagnosis, or later), patients should be informed about the available choices so that they may actively participate in that decision.

For chronic conditions, patient education initiatives can help patients in their own long-term management; for example, managing medications and self-care. An example of this is patient support programmes (PSPs) which can be used to bridge the gap between scheduled appointments and daily management of a chronic condition. Personalisation of PSPs is important because every patient has different needs in terms of the level of support required, and their preferred method and frequency of receiving information and support. Where complete personalisation is not possible (perhaps due to complexity or scale), it can be advantageous to offer patients a variety of options so that they can choose the tools that they prefer. Useful delivery channels include nurse-led support (via helplines or face-to-face online offering personalisation, credibility and accessibility), and increasingly, the use of multimedia technologies such as apps, emails that link to videos, and text messages, for example. Safety is a priority in PSPs, and the pharmaceutical company must be able to meet pharmacovigilance requirements, as well as other ethical, legal and regulatory obligations. Patients must sign informed consent to enrol in a PSP where they will be directly contacted.[31]

Practical aspects of writing for patients

Defining objectives

The art of educating patients is a delicate balance between addressing what patients (or their carers) want, and meeting the objectives of the particular initiative to achieve the desired outcome from the perspective of the healthcare provider, and/or pharmaceutical sponsor. A mismatch can render the initiative of limited value. It is imperative that appropriate objectives are defined and agreed with invested parties at the start and it is often down to the medical writer to represent and defend the patients' perspective, based on insights.

Health literacy and insights

In 2007, the Center for Disease Control and Prevention published evidence-based, guiding principles for health literacy and clear patient communication.[32] Health literacy is defined as the ability to find, understand, and use basic health information and services needed to make appropriate health decisions. The core pillars of these principles are to write and design for easy reading, involve the reader, provide relatable content that solves problems, use common language and use visuals to enhance learning.

Patient education programmes are often driven by the perceptions of healthcare providers who have not walked in a patient's shoes. To truly engage patients, programme planners and writers must understand the motivators, barriers, attitudes, beliefs, misperceptions and educational needs that patients and family caregivers bring to the table. It is critical that patients and family care-givers understand the benefits and risks of these programs. Some core patient barriers to health literacy and learning include cognitive challenges, stress related to disease burden, low motivation, poor adherence, lack of a supportive environment, complex healthcare systems and treatment regimens, lack of support and denial regarding the need and benefits of treatment.

It is also critical to understand the cultural beliefs and "language" that patients are most comfortable with. One approach to understanding these elements is immersing in the advocacy space. Advocacy organisations live and work with patients every day and best represent the tone and language of their target patients. Other channels to better understand patient insights include social listening, end-user interviews, channel analytics and peer-reviewed literature review. The most core patient insights are those that rise to the top across all of these channels and prove to be timely, relevant, actionable and accurate. These core insights should serve as the foundation of patient education offerings.

Format and channels

When educating patients about their disease and treatment options, health literacy can play a significant role in helping patients to understand and weigh the benefits and risks of treatment. Patient materials should also enhance the dialogue between patients and their healthcare providers.

The point of diagnosis is important in terms of patient education because it sets the foundation for motivation and empowerment.

In addition to clear writing and communication, the format and channel of education can greatly impact processing and retention of critical health information.[33] Patients bring a variety of learning styles to the patient education space, so multi-model educational strategies drive optimal learning

Table 2. Regulation, guidelines and codes of practice governing patient communications

Stage	Regulation/guidelines[a]
Clinical trials	
	ICH GCP guidelines[b]
	EU clinical trial legislation (Directive 2001/20/EC)
	FDA Code of Federal Regulations Title 21, part 50: Protection of Human Subjects in Clinical Trials (US)
	CIOMS ethical guidelines
	IRBs/IECs guidelines[c]
Public disclosure of results:	EU Clinical Trials Regulation 536/2014 EMA transparency policies (Access to Documents [Policy 0043]),
	Publication and Access to Clinical Trial Data [Policy 0070]
	EFPIA Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases
	PhRMA Principles on Conduct of Clinical Trials (US)
	Food and Drug Administration Amendments Act 801 (US)
General patient communications involving pharmaceutical products	
Legislation:	The Human Medicines Regulations, and Directive 2001/83/EC on the Community Code relating to medicinal products for human use, as amended by Directive 2004/27/EC
	FDA Code of Federal Regulations Title 21, part 202: Drug Advertising (US)
Industry codes of practice:	IFPMA
	EFPIA
	Each country also has its own code of practice[d]
Guidelines:	PhRMA Principles on Interactions with Patient Organizations (US)
	MHRA Advertising and Promotion of Medicines in the UK: The Blue Guide (UK)
OTC products	
Ethical criteria:	WHO Regulatory Assessment of Medicinal Products for use in Self-Medication
Codes:	PAGB consumer code (UK)[e]
Patient communications not involving specific pharmaceutical products	
	MHRA Disease Awareness Campaign Guidelines (UK)

Abbreviations:

CIOMS, The Council for International Organizations of Medical Sciences; EFPIA, European Federation of Pharmaceutical Industries and Associations; FDA, US Food and Drug Administration; GCP, Good Clinical Practice guidelines; IEC, independent ethics committee; ICH, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; IFPMA, International Federation of Pharmaceutical Manufacturers; IRB, institutional review board; MHRA, Medicines and Healthcare products Regulatory Agency; OTC, over-the-counter; PAGB, Proprietary Association of Great Britain; PhRMA, Pharmaceutical Research and Manufacturers of America; WHO, World Health Organization.

a Note this is not an exhaustive list, and national level guidelines may exist.

b Grounded in ethics principles from the Declaration of Helsinki.

c Each IRB/EC has its own set of guidelines. All are in the spirit of regulatory guidance, but if the IRB of record is known, it is worth checking their guidance documents prior to developing materials. The FDA has also published guidance for IRBs.[36]

d Most European country-specific codes of practice reflect the requirements of European and national laws, and in many cases go beyond those requirements.

e In Great Britain, PAGB pre-approves advertisements and other information for the public to ensure it adheres to regulations. Some other countries including Germany, Croatia, Mexico, Argentina and the US are governed by a post-publication control system.[37]

and outcomes. Most patient education offerings provide only the opportunity to see, read and hear health information. True learning and retention occurs when patients have an opportunity to interact with the material. Some examples of this are simulation, demonstrations, discussion and offering space for patients to write in their print materials. It goes without saying that the most engaging space for multi-modal learning is through digital communication. However, programme planners need to remember that many patients, particularly older adults, may not have access or comfort with digital communications, so we need to ensure that offline learning opportunities are always present.

Table 3. General guidance for writing patient educational content

Stage	Guidance notes[a]	References
Phase I-IV clinical trials		
Pre-enrollment of participant	• Do not use coercive language	ICH GCP General IRB guidance
	• Avoid use of drug or device name (generic or trade names) as it can be viewed as promotional, unless prior use is part of a key eligibility criterion[b]	
All stages (pre- and post-enrollment, and informed consent)	• Do not talk about 'free medical care' or emphasise 'free'[c]	ICH GCP, FDA & IRB guidance
	• Do not state that the drug is 'new' without also explaining that it is investigational	
	• Avoid implying therapeutic benefit (for example do not state 'medicine' without 'investigational')	
	• Avoid explicit claims of safety or efficacy of the investigational product	
	• Use language that is as non-technical as is practical so that it is understandable to the participant or their legally acceptable representative	
Marketed products		
	• Avoid use of 'safe' which should not be used without proper qualification	ABPI code, EFPIA code
	• Avoid claiming that a product has no side effects	
	• Include a statement about reporting of side effects	
	• Avoid use of 'new' for a marketed product of more than one year[d]	
	• Ensure that artwork does not mislead (for example implying use in a different patient population)	
	• Product comparisons must be fair and balanced and not misleading	
	• Health education materials referring to specific medicinal products must contain balanced, non-promotional information about alternative treatments	
	• Websites containing health education information must always advise persons to consult a healthcare professional for further information	

Abbreviations:

a This list contains key regulatory and ethical guidance for developing content for patients. However, it is not an exhaustive list. The relevant national and international guidelines should always be adhered to.

b Note that this does not apply to the informed consent process, which requires full transparency and an explanation of the investigational product.

c It is acceptable to mention payment (in countries where payment is permissible) for participating and free study-related medical care.

d Whilst it is acceptable to use 'new' for a product of less than one year, this does limit the shelf life of materials.

Writing styles

Written communications that are aimed at educating patients require a descriptive style that is factual and balanced, aiming to explain rather than persuade. Even with the constraints of writing in a factual style, carefully chosen language can be extremely powerful in connecting with the audience. For example, it can be more effective in terms of engagement to avoid language that defines people by their condition (e.g., use 'people with diabetes' rather than 'diabetes patients'). As already discussed, tailoring materials to the health literacy level and preferred learning style also improves understanding and therefore engagement.[3,4]

There are some occasions under the umbrella of patient education where more persuasive writing is appropriate, for example when there is a clear call to action such as finding out more about a clinical trial or signing up to a PSP. Effective persuasive writing typically uses three main techniques, as originally coined by Aristotle in his essay on rhetoric:

- Ethos (Ethical appeal via credibility, use of appropriate language, fair and unbiased content)
- Pathos (Emotional appeal)
- Logos (Logical appeal and use of reason)

Not all of these need to be addressed using words alone. Graphics can be made to effectively with the content to address these approaches. Note that persuasive writing in this context is different to coercion to participate in a clinical study or to take a particular medication, both of which are forbidden.

Navigating regulations

The multiple ethics guidelines, industry codes of practice and regulations that differ by country and region, and are periodically updated, can be challenging for the medical writer to navigate. Table 2 shows a summary of those that are most

pertinent to content for patients. Some general do's and don'ts are provided in Table 3.

Being the expert

Managing client feedback and expectations is one of the most challenging aspects of writing for patients. Most pharmaceutical clients, clinical trial study teams, and other invested parties are not experts in patient communication. It is common for materials to come back from review with proposed changes to the language that are overly complex, scientific or contain complex medical terms without explanation of their meaning. In these circumstances, it is always best to respectfully explain that the proposed language is not likely to be understood by patients, and to suggest an alternative, patient-friendly wording that conveys the same message. It is always worth remembering that medical writers and communications experts are employed for their expertise so should have confidence to advise in these matters.

Conclusion

Patient education is important for different reasons at different stages of the product lifecycle and patient journey, but broadly speaking, the main purpose throughout is to improve health outcomes and to empower individuals to take control of their own health. Effective patient education requires well-defined objectives; compliance from ethical and regulatory standpoints; personalisation; appropriate language and design that are based on health literacy principles; and the right channels for delivery, at the right time. For long-term programmes, it is advisable to build in ways to measure outcomes along the way and be flexible to adjust the approach accordingly.

References

1. Macquart de Terline D, Hejblum G, Fernandez C, Cohen A, Antignac M. PLoS One. 2016;11(1):e0146927.
2. Feudtner C. What are the goals of patient education? West J Med. 2001;174:173-4.
3. Adams RJ. Improving health outcomes with better patient understanding and education. Risk Manag Health Policy. 2010;3:61-72.
4. Hoving C, Visser A, Mullen PD, van den Borne B. A history of patient education by health professionals in Europe and North America: from authority to shared decision making education. Patient Educ Couns. 2010;78(3):275-81.
5. Powell J, Inglis N, Ronnie J, Large S. The characteristics and motivations of online health information seekers: cross-sectional survey and qualitative interview study. J Med Internet Res. 2011;13(1):e20.
6. Anderson CM. Information therapy: a prescription for the digital era. Health Care Manag (Frederick). 2013;32(3):242-5.
7. Hawkins RP, Kreuter M, Resnicow K, Fishbein M, Dijkstra A. Understanding tailoring in communicating about health. Health Educ Res. 2008;23(3):454-66.
8. Salita JT. Writing for lay audiences: a challenge for scientists. Medical Writing. 2015;24(4):183-9.
9. Gul R B, Ali PA. Clinical trials: the challenge of recruitment and retention of participants. J Clin Nurs. 2010;19 (1-2):227-33.
10. Kaur G, Smyth RL, Williamson P. Developing a survey of barriers and facilitators to recruitment in randomized controlled trials. Trials. 2012;13:218.
11. Brandberg Y, Johansson H, Bergenmar M. Patients' knowledge and perceived understanding – associations with consenting to participated in cancer clinical trials. Contemp Clin Trials Comm. 2016;2:6-11.
12. The Center for Information and Study on Clinical Research Participation (CISCRP). Perceptions and Insights Study: Report on ineligible participants and those who terminate participation early. 2013. Available from: https://www.ciscrp.org/download/2013-perceptions-insights-study-ineligible-participants-and-those-who-drop-out/?wpdmdl=6650.
13. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) E6 Good Clinical Practice: Consolidated guidance. 1996. Available from: http://www.fda.gov/downloads/Drugs/.../Guidances/ucm073122.pdf.
14. The World Medical Association. Declaration of Helsinki. 2013 [cited 1 Oct 2016]. Available from: http://www.wma.net/en/30publications/10policies/b3/.
15. Council for International Organizations of Medical Sciences (CIOMS). International ethical guidelines for biomedical research involving human subjects. 2002. Available from: http://www.recerca.uab.es/ceeah/docs/ cioms.pdf.
16. Council for International Organizations of Medical Sciences (CIOMS). Final draft CIOMS guidelines. Version 10. September 2015. Available from: http://www.cioms.ch/final_draft_CIOMS_guidelines-10_september_2015-with_watermarks.pdf.
17. Cartmell KB, Bonilha HS, Matson T, Bryant DC, Zapka J, Bentz TA, et al. Patient participation in cancer clinical trials: a pilot test of lay navigation. Contemp Clin Trials Comm. 2016;3:86-93.
18. Siegal G, Bonnie RJ, Appelbaum PS. Personalized disclosure by information-on-demand: attending to patients' needs in the informed consent process. J Law Med Ethics. 2012;40(2):359-67.
19. US Food and Drug Administration (FDA). Use of electronic informed consent in clinical investigations. Draft guidance. March 2015. Available from: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm436811.pdf.
20. European Parliament. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. Available from: http://ec.europa.eu/health/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf.
21. Gillow CL. Layperson summaries of clinical trial results: useful resources in the vacuum of regulatory guidance. Medical Writing. 2015;24(4):205-9.
22. Robben S, van Kempen J, Heinen M, Zuidema S, Olde RIkkert M, Schers H, et al. Preferences for receiving information among frail older adults and their informal caregivers: a qualitative study. Fam Pract. 2012;29(6):742-7.

23. Hirsch O, Keller H, Krones T, Donner-Banzhoff N. arriba-lib: evaluation of an electronic library of decision aids in primary care physicians. BMC Med Inform Decis Mak. 2012 Jun 6;12:48.
24. European Patients' Forum. Patient Empowerment Campaign. 2015 [cited 1 Oct 2016]. Available from: www.eu-patient.eu/campaign/PatientsprescribE.
25. European Patients' Forum. Improving the sustainability of healthcare systems through better adherence to therapies: a multi-stakeholder approach. Background briefing. 2011 [cited 1 Oct 2016]. Available from: http://www.eu-patient.eu/globalassets/policy/adherence-compliance-concordance/adherence–joint-briefing-paper.pdf.
26. Miller TA. Health literacy and adherence to medical treatment in chronic and acute illness: a meta-analysis. Patient Educ Couns. 2016;99(7):1079-86.
27. Matsumaya RK, Kuhn LA, Molisani A, Wilson-Genderson MC. Cancer patients' information needs the first nine months after diagnosis. Patient Educ Couns. 2013;90(1):96-102.
28. Prochaska JO, DiClemente CC. Stages and processes of self-change in smoking: toward an integrative model of change. J Consult Clin Psychol. 1983;51(3):390–5.
29. Prochaska JO. Assessing how people change. Cancer. 1991;67(3 Suppl):805-7.
30. Medicines and Healthcare Products Regulatory Agency (MHRA). Disease Awareness Campaign Guidelines: Appendix 7. 2012 Jul. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/407290/Appendix_7_-_Blue_Guide.pdf.
31. The Association of the British Pharmaceutical Industry (ABPI). Guidance notes for patient safety and pharmacovigilance in patient support programmes. 2011 [cited 1 Oct 2016]. Available from: http://www.abpi.org.uk/our-work/library/guidelines/Pages/patient-safety-pharmacovigilance-.aspx.
32. U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. Simply put – a guide for creating easy to understand materials. 2010. Available from: http://www.cdc.gov/healthliteracy/pdf/ Simply_Put.pdf.
33. Dale E. Audiovisual Methods in Teaching. 3rd ed. New York: Holt, Rinehart & Winston; 1969:108.
34. Giuse NB, Koonce TY, Storrow AB, Kusnoor SV, Ye F. Using health literacy and learning style preferences to optimise the delivery of health information. J Health Commun. 2012;17(Suppl 3): 122-40.
35. Walsh E, Sheridan A. Factors affecting patient participation in clinical trials in Ireland: a narrative review. Contemp Clin Trials Comm. 2016;3:23-31.
36. US Food and Drug Administration (FDA). Recruiting Study Subjects – Information Sheet: Guidance for Institutional Review Boards and Clinical Investigators. 2016 [cited 1 Oct 2016]. Available from: http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm.
37. World Self-Medication Industry (WSMI). Advertising of non-prescription medicines to the public. 2008. Available from: http://www.wsmi.org/wp-content/data/pdf/wsmi_brochureadvertising.pdf.

Conflicts of Interest and Disclaimers

The opinions and conclusions in this paper are those of the authors and do not necessarily represent the views of QuintilesIMS.

Author information

Sue Harris has worked in pharmaceutical and healthcare organisations for 16 years, 8 in medical communications. As a leader of QuintilesIMS Scientific Affairs and Medical Writing team, she oversees patient and healthcare professional engagement programmes across clinical and medical communications fields. Sue has a PhD in Cancer Research and MSc in Science Communication.

Chris Kelly has provided direct patient care, health education, professional training, and instructional design in a variety of care settings for 26 years. During this time, Chris also led the design and delivery of professional and patient education programmes for pharma companies, advocacy organisations and healthcare organisations.

Writing, publishing, and disseminating a medical review

Melody Watson and **Marc Esser**
Co.medical, Berlin, Germany

Correspondence to:
Melody Watson
co.medical
Diedenhoferstr. 8
10405 Berlin, Germany
watson@comedical.de

Abstract
Have you been commissioned to write a review? Reviews are useful for drawing attention to issues and benefits related to a product. One thing they are not, however, is something to be feared, if you are organised and have a clear idea from the beginning about how you want to approach the topic of interest. Your role as the medical writer is to draw up a brief from minutes taken at the initial advisory board meeting and, following approval, to write the review. This includes incorporating input from the authors and comments from the peer reviewers. Consequently, the entire process may take several months. In general, writing a review is a straightforward process that can actually be quite enjoyable, as you learn a lot about a particular topic in a relatively short amount of time.

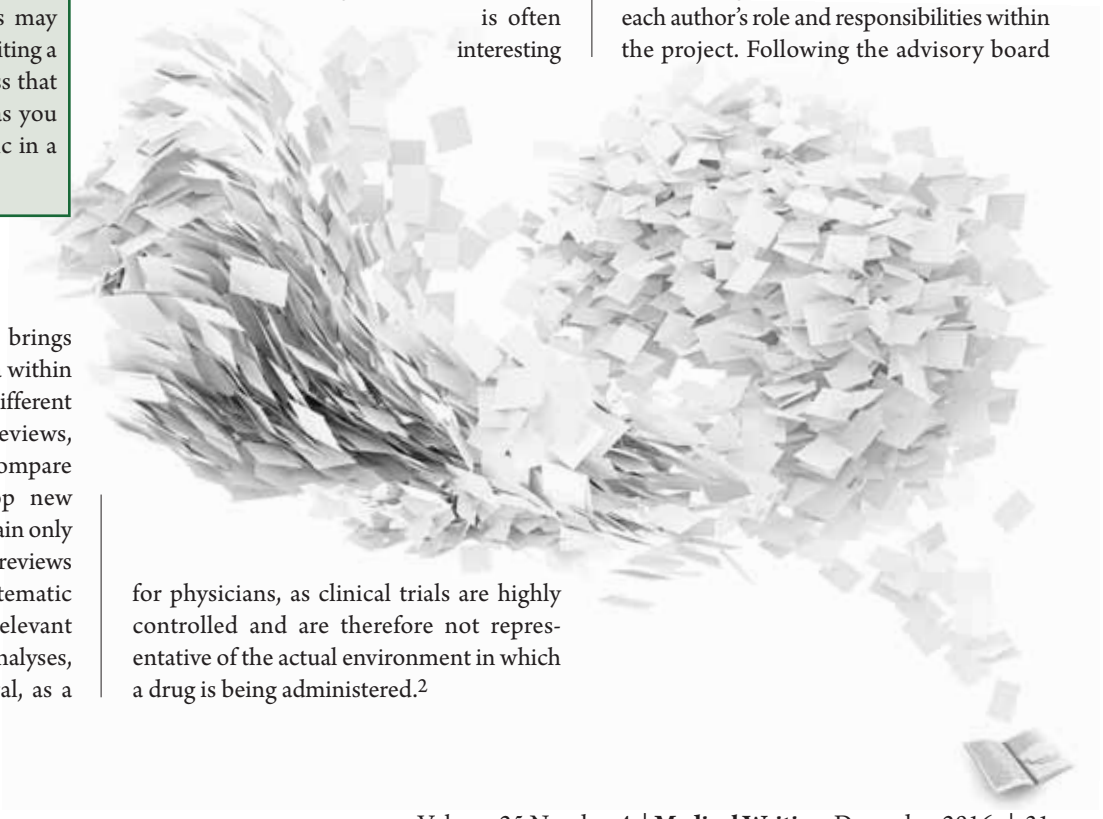
What is a review?
A review is a critical analysis that brings together published literature or data within a specific subject. There are several different types of reviews. In narrative reviews, authors summarise the literature, compare studies, discuss data and develop new hypotheses. Status quo reviews contain only the most recent research. Systematic reviews address a clear question using systematic methods to select and evaluate relevant studies and may include statistical analyses, including meta-analyses.[1] In general, as a medical writer you should be able to write most types of literature-based reviews. However, for systemic reviews that include statistical analyses or meta-analyses, you will need to have a statistical background or employ the help of a statistician.

Why are reviews important?
A review draws attention to a company's drug or medical device and strengthens a company's scientific profile. For instance, publishing a review when a product is through primary clinical trials, but has not yet been approved, creates a pre-marketing buzz around the product. Additionally, following approval, a review helps establish the product within a treatment paradigm.

Reviews are also useful when a product is older and interest in it has consequently declined or if there are specific features or concerns surrounding a product. For example, if a drug is associated with particular adverse events, you could write a review that provides information on how to best manage these adverse events. Another approach could be to report on how the drug or the medical device works in actual clinical practice, using real-world data. This is often interesting for physicians, as clinical trials are highly controlled and are therefore not representative of the actual environment in which a drug is being administered.[2]

Planning the review
Generally, the first step towards writing a review is holding an advisory board (adboard) meeting comprising experts, sponsor representatives (for example, from a pharmaceutical company), and a medical writer or two. It is crucial to match the right experts to the topic being covered and to include at least one key opinion leader. A key opinion leader is a thought leader in his or her field and is usually someone who has published pivotal research in top-tier journals or authored important textbooks. Key opinion leaders are included because they provide valuable insights and lend legitimacy to the efficacy and safety of a company's product.

During the advisory board meeting, different topics will be discussed with different input from various stakeholders. As a medical writer, your main role is to note the key points for the yet-to-be-written review, distilling the discussion into clear goals for the review, yet capturing the nuances of what is being said. You may also have to lead the group of experts through the agenda to reach a consensus, make sure the meeting remains on time, and define each author's role and responsibilities within the project. Following the advisory board



meeting, you will write up a brief describing the aims of the review and send it to the experts and sponsor for approval. Sometimes it can be hard to balance what the sponsor wants with what the experts are willing to say about a product, but in the end an agreement will usually be reached. Getting the brief right is crucial to writing a good review, or at least one that does not have to undergo too many corrections by the experts and the sponsor. Often, the medical writer is also expected to write an executive summary following the meeting. This will be sent to the sponsor.

During the advisory board meeting, there should also be a discussion about which journal the review should be published in. Fitting a publication to a target journal is no easy task. Both the pharmaceutical company and the experts will want the review to be published in a journal with a high impact factor. However, this must be balanced by how relevant the review actually is and how realistic publication in a high-impact journal would be. In order to avoid endless revisions for various journals, have a realistic approach from the beginning.[4] In addition to traditional journals, open-access journals are another option for publication. Although they may sometimes have lower impact factors, this is compensated for by having a wider audience for distribution and dissemination of your article.

Writing the review

Before beginning to write, go to the target journal's website and look for the webpage containing the instructions for authors. On this page you will be given instructions on how to prepare your document, such as the word count, line spacing, which form of English to use (if submitting to an English language-based journal), and how many tables and/or figures are permitted. It is much better to do this at the beginning of the review rather than at the end. A checklist covering the requirements for submission may also be included in the instructions for authors.

The first draft of a review usually takes between one and two weeks to write. At the beginning, take notes while reading through the literature, recording insights on how you might organise the review and collecting interesting pieces of information and thoughts on what you might write. As a result, you will have a rough draft of the review early on. This can help with motivation.[4]

You should try to use as much primary research as possible. Include high-quality studies, pivotal trials, and (not too many) other reviews. Inclusion of unpublished data should be the exception. Think about what is relevant for your topic. If the review is about a first-in-class drug, then mode of action matters. Think about your target audience. If the review is about a new formulation of a well-established drug, pharmacokinetic and pharmacodynamic studies might be interesting for physicians. Use studies that are current, but do not forget to use older studies that still contain valuable information. Additionally, do not just summarise the literature, instead carefully discuss it, pointing out methodological strengths and weaknesses. After reading your review, a reader should have an idea of the important achievements in the field, the major topics that are under debate, and which research questions are still outstanding.[5]

Include tables and figures where appropriate. Figures are particularly useful if you are trying to explain a complicated mechanism of action of a drug. For this, you will need to employ the services of a graphic designer experienced in illustrating medical topics. If you include tables, make sure they supplement the text and do not simply repeat it. This specification is often included in a journal's instructions for authors, but it is a good habit to adopt in general.

Write the abstract last. After completing the main text, you will be familiar with the content and tone of the manuscript making this task much easier than if you had attempted to write it at the beginning of the process. Selecting accurate keywords is essential for correct indexing and for getting your review to the right audience. Note terms used repeatedly in the text and terms that most appropriately describe your review, then check that they can be found in the appropriate indexing standard. In medicine, this is called Medical Subject Headings (MeSH), a National Library of Medicine-controlled vocabulary thesaurus.

After finishing the abstract and selecting the key words, send the manuscript to all of the stakeholders. They will then review it to make sure it fits with their objectives. Depending on the size of the expert group, it can take several weeks, or even months, for all of the experts to read the review, make suggestions, and send it back. Additionally, it can sometimes take several revisions for the experts and the sponsor to shape a manuscript that is acceptable to all parties. Keep in mind, however, that the experts have the last say as to what the manuscript contains.

The final steps

Sometimes a journal will request a cover letter to accompany your manuscript. Specifications for the cover letter are usually in the instructions for authors. They normally require you to state that your manuscript has not been published or is not under review elsewhere. You should also state why you feel your manuscript is important, interesting, and a good fit for the journal. Keep the cover letter clear and concise – journal editors may read dozens of cover letters per day and skim over cover letters longer than a few paragraphs. Now your manuscript (plus cover letter) is ready to be submitted to the target journal.

The submission process

Following journal submission, an editor will screen the manuscript and decide whether or not your manuscript is an appropriate match for their journal. You will hear back from the editor about this first decision relatively quickly. If the editor decides to consider your review it will be sent to at least two peer reviewers. The peer review process can be completely open, single-blind (the names of the reviewers are not revealed to the authors), or double-blind (neither the names of the reviewers nor the authors are revealed to one another). As with the initial stages, in which the experts reviewed the manuscript, peer review can last for months depending on how many reviewers have been selected and what their work schedule is like.

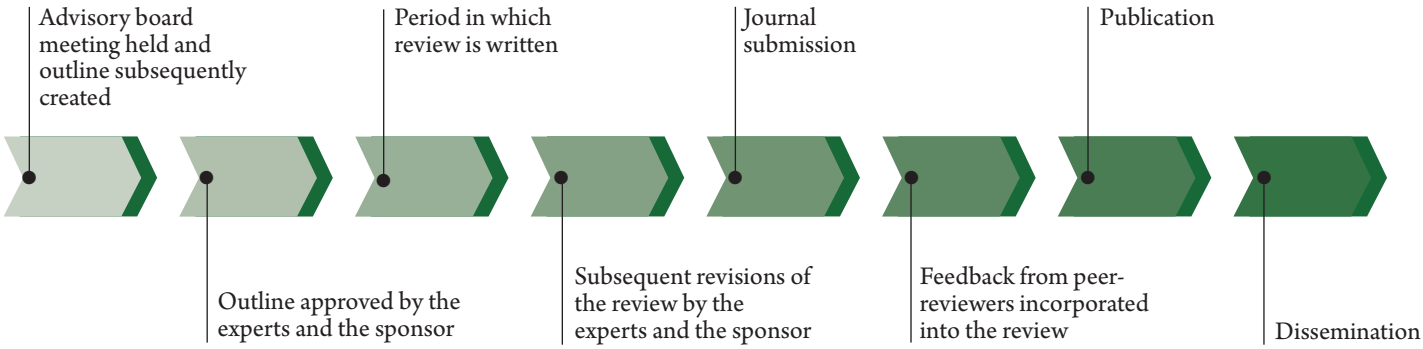


Figure 1. Steps in writing and publishing a review

The editor will return your manuscript accompanied by comments from the peer reviewers; seldom are manuscripts accepted for publication without any requested changes. Peer review is another point in the publication process in which your manuscript may be either rejected or accepted.[6] Make use of the feedback! In general, comments from peer reviewers can really help to improve your manuscript, especially as they are seeing it with fresh eyes. Peer review comments can be very direct and sometimes it can be hard to not react to negative comments, especially if you consider them to be unfair. However, try to respond politely. If you feel as though the peer reviewer has completely misunderstood your review or overlooked a crucial feature, then you can discuss this with the editor and request another review.[7]

After making the changes requested by the peer reviewers, send your revised manuscript back to the authors for their final approval. Following approval, send it back to the journal along with the responses to each peer review comment. If your manuscript is accepted without any further changes needing to be made, congratulations! If your manuscript is rejected, either in the beginning of the submission process or following peer review, then it is time to look for another journal, maybe one with a lower impact factor or a scope that better fits your review.[8] As with the first journal, you will have to format your document to fit the requirements listed in the new journal's instructions for authors. With respect to reformatting references, this is quite easy nowadays with reference management software such as Endnote.

Distribution

Following publication, it is imperative to ensure that the review reaches as many members of the target audience as possible. It is safe to assume that not every member of the target group will have a subscription to the journal the review has been published in. However, there are other ways to disseminate the review, such as including it on the sponsor's web page, using offprints in trade fair booths and having the sales force give offprints to physicians.

Conclusion

Writing a review is a relatively straightforward process that can be initiated whether or not there are new data for a product. Furthermore, reviews have more credibility, more leverage, and draw more attention to a product than marketing materials such as brochures. Remember, the key to writing a good review is its foundation – a clear brief containing the various opinions of the stakeholders. Reviews are nothing to fear – as long as you approach the process in an organised and patient manner, with attention to detail (skills that most medical writers possess), not much can go wrong.

References

1. Mayer P. Guidelines for writing a review article. 2009. Available from: http://www.plantscience.ethz.ch/education/Masters/courses/Scientific_Writing
2. Mahajan R. Real-world data: Additional source for making clinical decisions. Int J App Basic Med Res. 2015;5(2):82.
3. Moynihan R. Key opinion leaders: independent experts of drug representatives in disguise? Br Med J. 2008;336(7658):1402-3.
4. John M. The target journal: Choosing the right place to submit your paper. HSR Proc in Intensive Care Cardiovasc Anesth. 2009;1(3):60-2.
5. Pautasso M. Ten simple rules for writing a literature review. PLoS Comput Biol. 2013;9(7):e1003149.
6. Voight ML. Publishing your work in a journal: Understanding the peer review process. Int J Sports Phys Ther. 2012;7(5):452-60.
7. Wager E, Godlee F, Jefferson T. How to Survive Peer Review. BMJ Books. Pub. 2011. Available from: http://www.bmj.com/sites/default/files/ attachements/ resources/2011/07/ wager.pdf
8. Ali J. Manuscript rejection: Causes and remedies. J Young Pharm. 2010;2(1):3-6.

Author information

Melody Watson, B.Sc., is a medical writer at co.medical in Berlin, Germany. She has worked as a medical writer for over nine years, including at the publishing companies Wolterskluwer N.V. and Springer Science+Business Media LLC.

Dr. Marc Esser, a physician by training, has 20 years' experience in clinical practice, industry research, and consultancy. Dr. Esser is the founder and CEO of co.medical, a Berlin-based company that provides medical writing and other medical communication services.

CME in the *Deutsches Ärzteblatt* and the development of multiple choice questions for medical educational purposes

Catrin Marx[1] and **Christopher Baethge**[1,2]

1 Deutsches Ärzteblatt, Cologne, Germany
2 Department of Psychiatry and Psychotherapy, University of Cologne Medical School, Germany

Correspondence to:

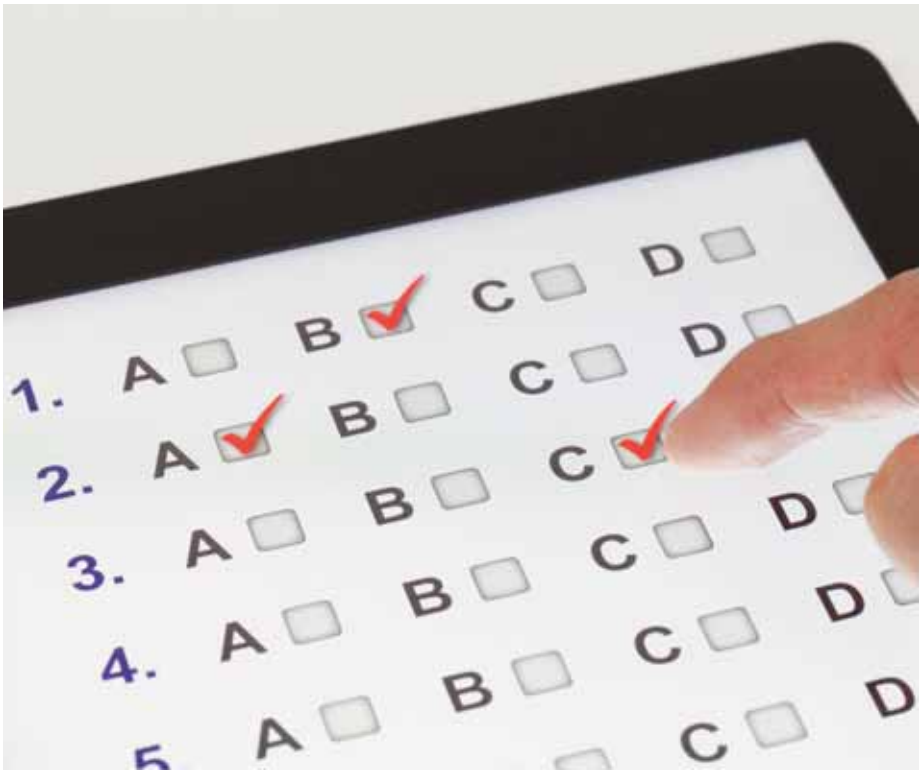
Catrin Marx
Deutsches Ärzteblatt
Ottostraße 12
D-50859 Köln
7011-135
Catrin.Marx@aerzteblatt.de

Abstract:

Continuing medical education (CME) in Germany, as in other countries, is an established instrument for the delivery of ongoing training in medicine. Since September 2004, *Deutsches Ärzteblatt* has published 155 CME papers, and, as of the 12th of August 2016, readers have logged on more than three million times to fill out a final evaluation form. The multiple-choice questions included in the CME modules in *Deutsches Ärzteblatt* have been analysed in a number of studies on medical education and compared with other German-language CME units from other providers. This article will present the mechanisms used at *Deutsches Ärzteblatt* to improve the quality of our CME units and reveal the aspects of medical education pedagogy that fed into this process.

CME

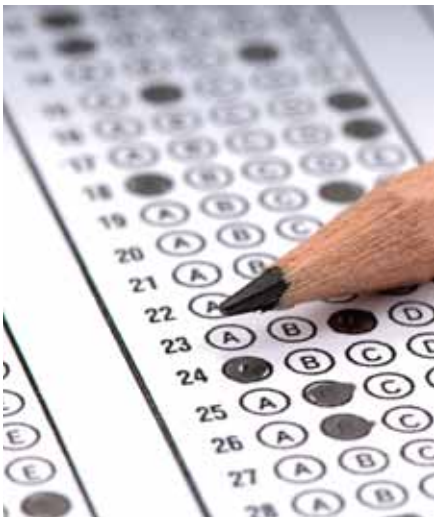
Since 2004, the modernisation of healthcare law (GKV-Modernisierungsgesetz) requires doctors working in Germany to acquire 250 continuing medical education (CME) points every five years. CME needs to be accessible and effective because if a physician fails to acquire 250 points, it can cause financial losses and, in the worst case, the withdrawal of their medical license.



CME points can be earned in various ways: by attending lectures, visiting conferences, or completing CME modules in certified journal articles. To offer CME modules in print, a journal must be certified by the relevant regional medical association. In addition, to be considered for inclusion in the CME programme, scientific papers have to pass an independent review process and their authors must declare their conflicts of interest.

Deutsches Ärzteblatt is the largest medical journal in Germany and is the official publication of the German Federal Medical Association (Bundesärztekammer) and the National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung). Every doctor in Germany receives *Deutsches Ärzteblatt*. Including a special edition for doctors who are retired or no longer in clinical practice and another for practising clinical psychologists, the circulation is about 470,000. CME articles appear in the issues regardless of edition. As proof of participation in the module, the reader has to answer 10 multiple-choice (MC) questions relating to the content of the article. *Deutsches Ärzteblatt* readers can go online to find further information compiled by the authors together with a case example that illustrates the topic in a practical way. Readers who answer 70% of questions correctly are awarded three points. After answering the questions, participants are asked to score the article for quality and for relevance to their own clinical work. Unlike in medical school finals and medical specialisation exams, the MC-questions are intended merely to demonstrate whether an article has been read; they are not intended to function as an examination in the strict sense.

As *Deutsches Ärzteblatt* is the only free of charge journal that reaches every doctor working in Germany, CME modules must be targeted at an interdisciplinary audience and emphasise topics that are relevant to all specialties. Each



module can be accessed for three months. At the end of the three months, all successful participants receive a certificate. If they have any problems relating to the content of the module, participants can contact the editorial office. Thus, problems with the answers to the MC-questions usually become clear within a week of the release of the module. By this time, the editorial office has usually logged over 1,500 participants. These early data, combined with the proportion of correct answers, make it clear where the wording is ambiguous or there are errors in the questions.

If there is an error in the actual content of a question, an application must be made to the certificating body – in our case the Academy for Continuing Medical Education of the North Rhine Medical Association – to withdraw the question, and an erratum is published after the end of the 3-month access period. Furthermore, if too many participants fail the test the North Rhine Medical Association has the authority to remove approval for CME. Therefore, it is important to have high-quality, correct MC-questions.

The multiple-choice questions and answers

The test questions are designed to be answerable solely on the basis of reading the article, so that even doctors not working in the specialist field of the article in question should be able to participate in the CME simply by reading the article. The overall objective of the CME programme is to bring doctors up to date about new treatment strategies in other specialties than their own. In 2008 almost 95% of all MC-questions on the CME articles were answered correctly by the test takers.[2,3] Nevertheless, when Kühne-Eversmann *et al.* analysed the quality of MC-Questions in German-language medical journals, including *Deutsches Ärzteblatt*, she found formal errors in the questions of all journals.[4]

In her study Lisa Kühne-Eversmann and co-authors analysed the quality of MC-questions in the journals *Der Internist*, *Deutsche Medizinische Wochenschrift*, and *Deutsches Ärzteblatt*.[4] Although the *Deutsches Ärzteblatt* preformed the best of these three journals, the study found faults in 60% of the questions. The main sources of error were described thus: "The stem was worded in such a general way that it failed to indicate what the topic was in any detail. As far as possible, the reader should be able to answer the stem without looking at the answer options." This means that questions such as 'Which of these statements is true?' or 'Which statement about XXXX is correct?' are poor questions because of the 'unfocused stem'. The main idea of the question should be placed in the stem, not in the choices. The test-taker should always know what he is asked for after having read the stem.[5]

Another common error was questions that require negative answers ('Which of the following statements is untrue… ?'). Tamir (2013) states that this is an error in form because: "negatively phrased items require about twice as much working memory as equivalent positively phrased forms of the same item. Negative words appearing both in the stem and in one or more options might require four times as much working memory as a positively phrased forms of the same item".[6]

Another point of criticism related to the existence of 'cues' in the questions or answer options. Cues are unintentional hints that indicate the correct answer. Cue words include absolute terms such as 'always', 'never', 'only', 'exclusively', or 'alone'. An example of the use of such cues might be: 'In XY, the first-line medication is [A] always glucocorticoids, [B] immunosuppressants only, [C] always to use cytostatics.' Specific determiners such as 'only' and 'always' are so extreme that they cannot be the right answer.

Furthermore, an empirical study carried out by Rotthoff *et al.*[7] examined 200 MC-questions from 20 CME units in the journals *Der Internist*, *Deutsches Ärzteblatt*, *Medizinische Klinik*, and *Klinikarzt*. In all these journals, the authors found that there were too few questions that were geared to practical clinical use and actual clinical decisions.

Taken together, these findings prompted the editorial staff at the *Deutsches Ärzteblatt* to develop some 'Rules for the construction of multiple-choice tests in *Deutsches Ärzteblatt*'. This guide was sent to every CME author. The following rules were developed partly based on the analysis of the above-mentioned two studies,[4,8] and partly on the research results of Krebs and Haladnya in the field of medical education.[5,9]

Style and format criteria

- The stem should be no longer than three sentences. The answers should be short.
- Negative words should be avoided in the stem and in the answers.
- The main idea of the question is placed in the stem not in the answers. It should be written in clear and understandable language.
- The items should not have options that give clues to the right answer (e.g. 'always', 'never', 'only', 'exclusively', or 'alone').
- Only one answer is correct.
- Do not use the choice "all of the above".
- The answers should be homogeneous in terms of content and grammatical form.
- The lengths of the choices should be the same.
- Avoid verbal associations between stem and the right answers.
  For example:
  Which *test* is to exclude Cushing syndrome?
  a. Dexamethasone suppression *test*
  b. Aldosterone renin quotient
  c. Cortisol determination
- The stem or an item of one question should not include the information for solving another question of the test.

Since then, Deutsches Ärzteblatt has also increased the emphasis on relevance to practice during the editorial development of the questions in order to ensure that the CME unit is fit for purpose in terms of the achievement of learning goals. Each set of questions must now contain at least two questions that relate to specific clinical situations, ask about clinical decisions, or are geared towards use in real clinical life.

To further increase the effectiveness of CME modules, three learning goals are now formulated at the beginning of each article. The contents of these learning goals are reflected in the MC-questions. Teaching of the most important contents is supported by special panels on each

page, giving visual prominence to short statements summarising the practice-relevant management guidelines, diagnostic classifications, and important advice about treatment.

To minimise the errors identified by Kühne-Eversmann *et al.*, all MC-questions are checked by the editorial staff against the points of criticism and revised if necessary. Then, all the questions are given a test run before publication by a team from a variety of medical specialities. In addition to the quality criteria, the team also assesses whether the questions correspond properly to the defined learning goals and whether it is possible to answer them on the basis of reading the article alone. After this test run, if required, the questions undergo final modification.

Results after the changes

In a study in 2013, Drossard *et al.* investigated the proportion of formally incorrect questions in print CME publications dating from 2012[8] and compared them to data collected by Kühne-Eversmann *et al.* in 2006.

Therefore, one data set was collected after the introduction of the new quality standard ('Rules for the construction of multiple-choice tests') at *Deutsches Ärzteblatt*, and one data set was collected prior to this introduction. This new study included *Der Internist*, *Deutsche Medizinische Wochenschrift*, and *Deutsches Ärzteblatt*. Of all of these, the *Deutsches Ärzteblatt* showed the best results, demonstrating a clear improvement in quality from 2006 to 2012 (39% correct questions in 2006 and 67% in 2012). Furthermore, in a study published in 2013, Wolfgang Öchsner and Anja Böckers[10] investigated the extent to which CME MC-questions fulfil formal quality criteria. Three journals were compared: one surgical journal, one medical (non-surgical, non-interventional) journal, and one interdisciplinary journal. According to Öchsner and Böckers, the unnamed interdisciplinary journal "was in fact *Deutsches Ärzteblatt*, the journal that did better than the others in all items of the study," (personal communication). It is evident that making guidelines and improving the procedures to be followed during editorial development increases the quality of MC-questions.

Future perspectives

Doctors encounter MC-questions from medical school onwards; this form of testing is ubiquitous in training and in continuing education. Öchsner and Böckers[10] believe, "it is important that the multiple-choice questions presented to readers of medical journals are methodologically exemplary and of high formal quality, so that they can implicitly serve as templates ready for adoption by readers who are themselves authors with responsibility for multiple-choice questions."[10] Perhaps, in the long term, good MC-questions could become a building block in the improvement of medical school final exams, and thus also increase the learning – and the enjoyment of learning – to be had from continuing medical education.

Conflicts of Interest and Disclaimers

Catrin Marx and Prof. Baethge declare that they are full-time editors of *Deutsches Ärzteblatt*.

References

1. Bundesärztekammer. Struktur der Ärzteschaft 2015 [cited 2016 Aug 8]. Available from www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/Statistik2015/Stat15AbbTab.pdf
2. Marx C. CME im Deutschen Ärzteblatt: 43 000 Teilnehmer – sehr gute Bewertung. Dtsch Arztebl 2005;102(37):A 2453–6.
3. Baethge C, Marx C, Griebenow R, Leuschner H. CME in a General Medical Journal: Three-Year Evaluation of CME in Deutsches Ärzteblatt. Teaching Learning Med; 2010;22(3):229-32.
4. Christ H, Baethge C, Lehmacher W, Loesche P, Griebenow R. Interdisciplinary CME: Is the need evident? Results of the evaluation of CME articles in the Journal of the German Medical Association. J Eur CME 2015; 4: 1-6. view/28331/pdf_13
5. Kühne-Eversmann L, Nussbaum C, Reincke M, Fischer MR. cme-Fortbildungsangebote in medizinischen Fachzeitschriften: Strukturqualität der MC-Fragen als Erfolgskontrolle. Am Beispiel der Fachzeitschriften Deutsches Ärzteblatt, deutsche Medizinische Wochenschrift und der Internist. Med Klinik 2007;102(12):993-1001.
6. Stagnaro-Green AS, Downing SM. Use of flawed multiple-choice items by the New England Journal of Medicine for continuing medical education. Med Teach 2006;28(6):566–8.
7. Rotthoff T, Fahron U, Baehring T, Scherbaum WA. Die Qualität von CME-Fragen in der ärztlichen Fortbildung – eine empirische Studie. Z Ärztl Fortbild Qual Gesundhwes 2008; 101(10): 667–73.
8. Krebs R. Anleitung zur Herstellung von MC-Fragen und MC-Prüfungen für die ärztliche Ausbildung. Universität Bern. Available from: www.iawf.unibe.ch.
9. Haladyna TM, Rodriguez MC. Developing and validating test items. London: Routledge; 2013.
10. Drossard S, Kühne-Eversmann L, Bauer D, Fischer M. Strukturqualität von MC-Fragen in der ärztlichen Fortbildung. Welchen Einfluss hat die Einführung von Qualitätsmaßnahmen? Jahrestagung der Gesellschaft für Medizinische Ausbildung (GMA). Graz 26-28 Sept 2013. Düsseldorf: German Medical Science Publishing House; 2013. DocP05_01 (P05_01).
11. Öchsner W, Böckers A. [Medical journals as implicit role models for good multiple choice questions: how far have CME tests so far fulfilled formal quality criteria?]. Z. Evid Fortbild Qual Gesundhwes 2013;107:468–74.

Author information

Catrin Marx is part of the editorial staff of Deutsches Ärzteblatt since 1994. Her work focuses on CME articles.

Professor Baethge is Chief Scientific Editor of *Deutsches Ärzteblatt* (German Medical Journal).

Covering a medical advisory board meeting and creating the report or publication: The role of the professional medical writer

Namrata Singh and **Ritu Sharma**
Turacoz Healthcare Solutions, New Delhi, India

Correspondence to:
Dr Namrata Singh
Director Medical Services
Turacoz Healthcare Solutions
H-973, First Floor, Sector-7
Dwarka, New Delhi, India
+91 9810036125
namrata@turacoz.com

Abstract
Medical advisory board meetings are an integral part of the healthcare and, in particular, the pharmaceutical landscape. These meetings serve to identify knowledge gaps in a specific therapeutic area and to suggest measures that could be implemented and followed to bridge the identified gaps. Although the preparation and hosting of these meetings and the creation of the meeting reports and publications are tasks often assigned to medical writers, there are no standard guidelines or templates on how to accomplish these tasks. In this article, we report our experiences with medical advisory board meetings and the processes that we follow to get the most out of these meetings.

Introduction
A medical advisory board is a group of healthcare professionals, headed by a chairperson who directs the meeting to discuss the available literature according to a predefined agenda and to come up with a consensus or guidelines and/or an agenda for the next meeting. The meetings are normally conducted in an informal and flexible manner and issues that were not included in the initial agenda may also be discussed.

Medical advisory boards have been a part of the pharmaceutical landscape for a long time. They provide a robust, market-informed view of unmet medical or healthcare needs. They are a good platform to combine and compare the experience and expertise of practicing healthcare professionals (HCPs) and key opinion leaders

(KOLs) with the available literature to ultimately come up with region-specific and practical solutions for healthcare issues. The organisation of medical advisory board meetings is a reliable way by which pharmaceutical companies can gain the insights required to achieve a better understanding and interpretation of the various medical benefits of their pharmaceutical products.

Other ways in which pharmaceutical companies engage with HCPs and patients are: the support of scientific congresses, data generation (pre- and post-marketing studies), implementation of educational programs for HCPs and patients, promotional material review, and by providing answers to product-related medical inquiries. Out of all the above-mentioned strategies, medical advisory boards are considered to be of the greatest value to pharmaceutical companies, as the exchange of scientific knowledge between the members leads to non-binding but informed guidance on various business aspects.

The preparation of the medical advisory board meeting, meeting attendance, and the preparation of the meeting report are tasks often assigned to professional medical writers. The present review aims to guide the medical writers through the process of conducting a medical advisory board meeting and to help them gain a better understanding of the basic composition and functioning of a medical advisory board, the various roles of the medical writer, and the development of a scientific report that can later be published or circulated among the scientific community.

The preparation of the medical advisory board meeting, meeting attendance, and the preparation of the meeting report are tasks often assigned to professional medical writers.

Composition of a medical advisory board

A medical advisory board consists of KOLs in the respective field along with a chairperson who moderates the meeting and steers the panel members to a conclusion. As a rule, the KOLs are selected by the pharmaceutical company, however in some cases representatives of medical societies (related to a pharmaceutical product or a disease state) are also engaged as KOLs. Discussions at medical advisory board meetings are usually facilitated by a chairperson who is unanimously selected by the board's members.

Although the majority of medical advisory boards are initiated by pharmaceutical companies, they are sometimes organised by publication companies or other third parties, such as sponsored or non-sponsored medical societies or by medical communication companies.

To ensure a productive and ethical discussion, a specific code of conduct and a stringent protocol is followed throughout the medical advisory board meeting. The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practice, 2012, is an elaborate code of conduct for pharmaceutical companies' engagements with HCPs providing consulting services, such as scientific consulting, market research, and medical advisory board participation.[1] In addition, in recent years many national codes have been updated to provide a pre-set code of conduct for running medical advisory board meetings, including those from the UK (Association of the British Pharmaceutical Industry, ABPI), the US (Pharmaceutical Research and Manufacturers of America, PhRMA), Canada (Research-Based Pharmaceutical Companies), and Australia (Medicines Australia).[2-5]

Purpose of medical advisory board meetings

All medical advisory board meetings are objective-driven with the purpose to identify unmet needs in a field of medicine. It is important for the medical writer to understand the purpose and objective of the meeting before he or she initiates the assignment. As mentioned above, the primary goal of a medical advisory

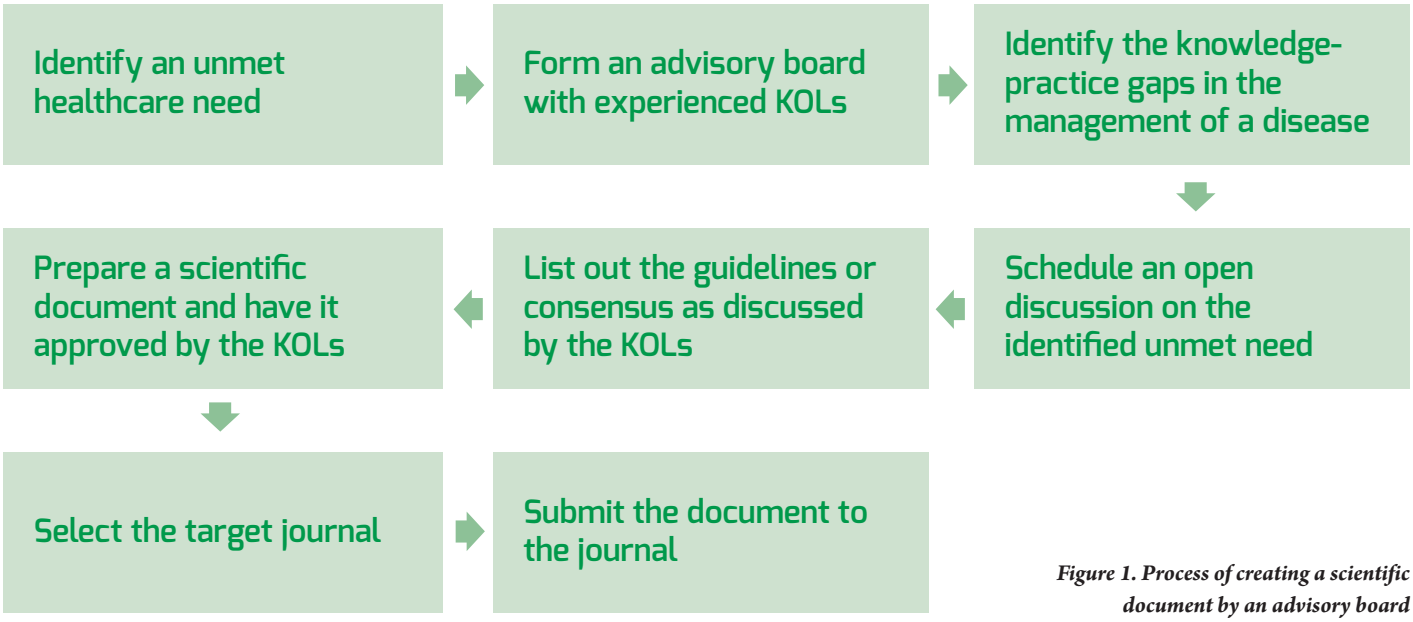


Figure 1. Process of creating a scientific document by an advisory board

board meeting is to gather insights on possible research opportunities, including guidance on the clinical development and trial protocols, as well as unmet health care needs that might drive future clinical strategies. Usually, the information collected during a medical advisory board meeting is later shared with peers and other healthcare stakeholders to achieve better patient outcomes (Figure 1). However, in some cases, if 'no consensus' is achieved after the meeting, then pharmaceutical companies might keep the information to themselves, or share it with participating KOLs only.

Usually, the information collected during a medical advisory board meeting is later shared with peers and other healthcare stakeholders to achieve better patient outcomes.

Role of the professional medical writer

The medical writer may accompany a medical advisory board from the preparation/conception stage through to the execution and finally to the writing and publishing of the report. The medical writer might be assigned various responsibilities depending on the nature and objectives of the meeting. These responsibilities may include, but are not limited to, engaging KOLs for a medical advisory board, preparing questionnaires, conducting online surveys (with the aim of understanding unmet needs), preparing a pre-meeting report to be shared with KOLs, preparing an executive summary, preparing presentations for the medical advisory board meeting, hosting a medical advisory board, capturing the minutes of the meeting, preparing the meeting report, and modifying the report into a publication-ready document (if applicable). The roles and responsibilities of a medical writer change as per the requirements of the organising body and stage of the meeting (Figure 2). Hence, as a medical writer, it is important to have a comprehensive discussion with the organising body at the start of the project in order to understand their needs and expectations.

Pre-meeting stage

Medical writers may be asked to perform multiple duties during a medical advisory board meeting, and it is, therefore, necessary that they prepare themselves well before attending the meeting. A few things that medical writers should consider are:

1. **Communication:** Clear communication with the organising body is essential for understanding the objectives of the meeting and the nature of the deliverables, i.e. it is important to know why this particular medical advisory board meeting is being conducted, what unmet needs are to be addressed, and what kind of deliverable is expected at the end of the meeting. The medical writer might also assist the organising body in selecting the KOLs for the meeting.
2. **Invitation:** The organising body might ask the medical writer to assist with sending invitations to the KOLs, along with an introductory email for the advisory meeting, if required.
3. **Getting acquainted and collecting information:** The next important step is to get acquainted with the therapeutic area to be discussed at the meeting. The medical writer should do a thorough literature search and read about the therapeutic area for which the meeting is to be conducted. For instance, if the medical advisory board has been organised to develop a set of clinical practice guidelines for a particular disease in a particular region, the writer should acquaint himself/herself with the current scenario of the disease in that region, the clinical practice guidelines followed (if any), knowledge gaps among the HCPs of that region, and global practice guidelines for that disease. This process will help the medical writer gain a better understanding of the therapeutic area to be discussed. This also familiarises the writer with the medical terminology or jargon that KOLs

Pre-meeting Stage

- Assist the sponsor in selecting key opinion leaders (KOLs) and chairpersons
- Send invites to KOLs and chairpersons
- Research the KOLs thoroughly
- Participate in discussions with sponsor/KOLs/chairperson to understand the objectives of the meeting
- Discuss the nature of deliverable after the advisory board meeting
- Perform a literature search
- Prepare questionnaire/survey questions
- Selection of target journal
- Prepare the presentation or first draft of the proposed meeting

Meeting Stage

- Reach the meeting venue with time to spare
- Dress in business attire
- Introduce himself or herself to all participating members
- Arrange for audio/visual recording
- Listen carefully and document all relevant points
- Conclude the meeting and inform the participants about the timelines for the development of the deliverable

Post-meeting Stage

- Prepare and share minutes of the meeting with the participants
- Update the executive summary according to the comments and suggestions made by the panel members
- Initiate the drafting of the publication document
- Share the final draft for approval by KOLs and sponsor
- Submit the final, approved manuscript draft to the desired journal

Role of the professional medical writer at an advisory board meeting

might use during the discussion, thereby making it easier for the writer to capture the minutes of the meeting.

It is also important that medical writers familiarise themselves with the KOLs who might attend the meeting. If permissible, it is useful to have a discussion with the participating KOLs in advance of the meeting, in order to gain an understanding of their perspectives and expectations for the meeting. This can also help the writer identify the critical points to be captured during the meeting.

If the medical advisory board meeting is an extension of one or more previous meetings, the medical writer should request the minutes and reports of the previous meetings from the organising body. This is yet another important set of information that can help the medical writer stay focused on the key points that are to be discussed.

4. **Questionnaires, presentations, and reports:** Particularly in the case of an opening meeting, the organising body may ask the medical writer to prepare a pre-meeting survey questionnaire or a presentation or reports about the unmet needs and objectives of the meeting. Hence, the medical writer needs to understand the requirements of the organising body and prepare the document as desired.

5. **Executive summary:** In some cases, the organising body may also ask the medical writer to prepare an executive summary of the problem statement, proposals, and the key discussion points to be covered during the meeting. The executive summary is intended to aid the KOLs in decision making and help them arrive at a consensus.

Meeting stage

Medical writers should reach the meeting venue well in advance. They should also be professionally dressed and carry their business cards, which will help them introduce themselves to other participants. The capturing of the minutes of the meeting is the most important duty of a medical writer at an advisory board meeting. It is relatively difficult to capture all the important information manually; hence the medical writer might have to rely on audio-visual aids to effectively capture the meeting minutes. It is therefore important that the medical writer asks the organising body to provide technical support during the meeting. This not only facilitates the collection of information, but also ensures that any information relevant to the topic is not missed. The medical writer should be prepared with an outline of the meeting with the sessions written out in his/her notes to capture the minutes of the meeting. It is important that the writer pays extra attention to the discussions; in the case of disagreement, the opinions of both sides have to be captured. The organising body might ask the medical writer to conclude the meeting and inform the participating members about the prospective timelines for sharing the minutes of

the meeting and also the updated executive summary report.

Post-meeting stage

1. **Minutes of Meeting:** Minutes of Meeting (MoM) is the first and an essential document that the medical writer has to deliver after attending the medical advisory board meeting. The medical writer is usually asked to deliver the MoM to the organising body and to the participating KOLs within 48 hours of the meeting. The MoM not only provides an overview of the meeting but also helps to lay the foundation on which the final report will be developed. There is no standard format in which an MoM is to be prepared and the medical writer should ask the organising body if they require the MoM in a specific format. Ideally, an MoM should include particulars about the meeting, information about the organising body and the participating KOLs, background information about the unmet need that was discussed, the objective of the current meeting, highlights of the discussion, and future directions (as suggested by the KOLs).
2. **Update the executive summary:** The next step is to update the executive summary (that was prepared prior to the meeting) in accordance with the comments and suggestions provided by the participating KOLs.
3. **Final report:** Once the MoM is approved by the organising body and the KOLs, the medical writer should start preparing the final report. The content of the report may vary according to the type of publication document desired by the organising body. In general, the meeting report contains detailed information about the subject discussed during the meeting and the outcomes of the meeting. Although there is no fixed format for writing the report, it is expected that the report is centred on the objective. An ideal report includes detailed background information on the therapeutic area for which the meeting was conducted, highlights the unmet needs/knowledge-practice gaps among the HCPs, contains the objective of the meeting, discusses the insights provided by the KOLs and compares them with the currently available medical literature, and mentions possible future directions. The meeting report often acts as a guide on possible research opportunities, including guidance on the clinical development and trial protocols in that therapeutic area. It should therefore be written in a manner that allows it to add value to the existing literature.
4. **Publication support:** Once a consensus is achieved, the final report is formatted as per the requirements of the selected journal and the medical writer submits the article for publication/sharing with the scientific community. However, if the meeting does not arrive at any consensus then the final report is retained by the organising body for their future reference.

Key Messages

- Advisory board meetings are an integral part of the pharmaceutical and healthcare landscape, which are used for sharing knowledge among various stakeholders.
- The medical writer should understand the objective of the advisory board meeting.
- Some of the medical writer's key responsibilities are:
  - To have a detailed discussion with the organising body and key opinion leaders (KOLs) to understand their expectations, nature of the final report, and timelines
  - To carry out a comprehensive literature search well in advance of the meeting
  - To listen carefully and document all relevant points
  - To share the minutes of meeting (MoM) within 48 hours of the meeting
  - To prepare the final report and have it approved by the KOLs
  - To submit the final approved draft (if the meeting reaches the stage of consensus) to the desired journal for publication

Acknowledgements

The authors would like to acknowledge the clients who gave them the opportunity to work on various medical advisory board projects and to develop their processes, as well as the team of medical writers at Turacoz Healthcare Solutions.

References

1. International Federation of Pharmaceutical Manufacturers & Associations: IFPMA Code of Practice. Article 11. 2012 [cited 2016 Sep 10]. Available from: http://www.ifpma.org/ethics/ifpma-code-of-practice/about-ifpma-code-of-practice.html.
2. Association of the British Pharmaceutical Industry. The ABPI Code of Practice for the Pharmaceutical Industry. 2016 [cited 2016 Sep 10]. Available from: http://www.pmcpa.org.uk/thecode/Documents/Code%20of%20Practice%202016%20.pdf.
3. Pharmaceutical Research and Manufacturers of America. PhRMA code on interactions with healthcare professionals. Washington DC: PhRMA; 2009 [cited 2016 Sep 10]. Available from: http://www.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008.pdf.
4. Canada's Research-Based Pharmaceutical Companies (R× & D): Code of Ethical Practices. 2016 [cited 2016 Sep 10]. Available from: http://www.canadapharma.org/CMFiles/Commitment_to_Ethics/WithHealthCare Professionals/Code_of_Ethical_Practices/2012_CodeofEthicalPractices_ENFinal.pdf.
5. Medicines Australia: Code of conduct. 2015 [cited 10 Sep 2016]. Available from: http://medicinesaustralia.com.au/code-of-conduct.

Author information

Dr Namrata Singh is a paediatrician and a medical writer with around 12 years of vast experience and heads the team of medical writers at Turacoz Healthcare Solutions. Her experience spans across all the major types of medical writing documents and all major therapeutic areas.

Ritu Sharma has been a medical writer at Turacoz Healthcare Solutions since 2015 and is actively involved in covering advisory board meetings, and in the development of consensus guidelines, publications, and systematic reviews.

Peer review fraud

The hijacking of peer review by authors who create false referee profiles in order to deliver favourable reviews of their own work has received prominent recent coverage in several leading journals.[1,2] At the time of writing, over 300 articles had been retracted by affected publishers, including the likes of Elsevier, Springer, and SAGE.[3]

In one recent case, the focus of an editorial,[4] the *British Journal of Clinical Chemistry* was duped by the authors of a meta-review of therapies for heart failure patients.[5] The authors suggested two referees (both cardiologists at top US universities), and the journal contravened its own policy by using both of them – and no other referees. The journal's editors did not see anything odd in the fact that both requested reviews arrived within a week, were very short and overwhelmingly positive, and displayed clumsy English that was not compatible with them having been written by leading US-based academics. More understandably, perhaps, they failed to notice that the email addresses for both referees were non-institutional, i.e. unverifiable. Catastrophic methodological errors were also missed.

This deception might have gone unnoticed had a couple of sharp-eyed readers not outlined the paper's many flaws in a scathing letter to the editor.[4] Acting decisively, the journal managed to trace one of the named referees, who claimed to know nothing about the review. After receiving an inadequate explanation from the authors, *Br J Clin Chem* issued a prompt retraction notice,[6] redeeming itself somewhat by adhering to the COPE (Committee on Publication Ethics) guidelines.[7] Importantly, the retraction notice is freely available and the retracted article can still be accessed but now boasts an unmissable translucent "RETRACTED" watermark.

So, what can be done about fraud of this kind? The *Br J Clin Chem* editors feel that additional measures to prevent similar misconduct would likely fail and risk inconveniencing honest researchers.[4] In any case, they believe their existing peer review procedures, if followed properly, are adequate. They consider themselves too busy to check study details themselves and feel that it is not their job anyway. Rather, they insist that responsibility for assuring research quality lies with the institutions where the research is performed. But how much oversight do such institutions actually have?

There are no easy fixes, and resourceful fraudsters will always find a way around any new barrier that is placed in their way. But *Br J Clin Chem* has at least identified two simple ways to minimise the problem: don't rely solely on authors' suggested referees and insist that institutional email addresses be used for correspondence with referees.[4]

References

1. Ferguson C, Marcus A, Oransky I. Publishing: The peer-review scam. Nature. 2014;515(7528):480-2.
2. Haug CJ. Peer-review fraud—Hacking the scientific publication process. N Engl J Med. 2015;373(25):2393-5.
3. McCook A. Retraction Watch. What publishers and countries do most retractions for fake peer review come from? 2016 [cited 2016 Oct 12]. Available from: http://retractionwatch.com/2016/09/27/what-publishers-and-countries-do-most-retractions-for-fake-peer-review-come-from/.
4. Cohen A, Pattanaik S, Kumar P, Bies RR, de Boer A, Ferro A, et al. Organised crime against the academic peer review system. Br J Clin Pharmacol. 2016;81(6):1012-7.
5. Lv MY, Deng SL, Long XF. Retraction. rhBNP therapy can improve clinical outcomes and reduce in-hospital mortality compared with dobutamine in heart failure patients: a meta-analysis. Br J Clin Pharmacol. 2016;81(1):174-85.
6. No authors listed. Retraction: 'rhBNP therapy can improve clinical outcomes and reduce in-hospital mortality compared with dobutamine in heart failure patients: a meta-analysis' by Ming-Yi Lv, Shu-Ling Deng and Xiao-Feng Long. Br J Clin Pharmacol. 2016;81(5):1005.
7. Wager E, Barbour V, Yentis S, Kleinert S, on behalf of COPE Council. Committee on Publication Ethics (COPE). Guidelines for retracting articles. 2009 [cited 2016 Oct 12]. Available from: http://publicationethics.org/files/retraction%20guidelines.pdf.

Stephen Gilliver
TFS, Lund, Sweden
stephen.gilliver@gmail.com

EMWA
EUROPEAN MEDICAL WRITERS ASSOCIATION

Birmingham 2017

Save the Date

The 44th EMWA Conference in Birmingham, England will be held on 2 - 6 May 2017 at the ICC.

For further information:

http://www.emwa.org/EMWA/Conferences/Conference/Birmingham_2017.aspx

News from the EMA

The articles included in this section are a selection from the European Medicines Agency's News and Press Release archive for August 2016 – Oct 2016. More information can be found on the Agency's website: www.ema.europa.eu of medicines to treat tuberculosis.

Development of medicines to treat tuberculosis

Comments on draft guidance invited until 31 January 2017

August 01, 2016 – The European Medicines Agency (EMA) has launched a public consultation on revised guidance on the development of new medicines to treat tuberculosis (TB). The guidance is an addendum to EMA's guideline on the evaluation of medicines to treat bacterial infections.

Stakeholders can send their comments to the Agency until 31 January 2017.

TB is caused by a bacterium called *Mycobacterium tuberculosis*. In Europe, approximately 340,000 new TB cases and 33,000 deaths were reported in 2014, mostly from eastern and central European countries. While TB is slowly declining worldwide, the burden of the disease is still very high with approximately 1.5 million deaths per year. Moreover, multidrug-resistant tuberculosis (MDR-TB) still poses a serious public health challenge. It often affects people from the most vulnerable communities, including migrant workers, refugees, displaced persons, prisoners or drug users.

Today's existing TB treatments cannot effectively combat the disease because they are lengthy, complex, and generally show reduced efficacy against MDR-TB, imposing a heavy burden on patients, families and healthcare systems. New TB medicines and regimens (a combination of medicines) that are simpler to administer, are of shorter duration, and can overcome drug resistance are urgently needed.

In recent years, there has been a shift towards developing entirely new regimens to treat TB, rather than focusing on single medicines. The revised guidance takes into account this development.

The guidance also clarifies the European Union's regulatory requirements with regard to data that should be generated to support the approval of new medicines or combinations of medicines, and provides direction on the following topics:

- Evaluation of the efficacy of individual new medicines and regimens in light of recently approved medicines
- Evaluation of new regimens including at least one new medicine
- Role of biomarkers to predict the effectiveness of the medicine(s) during clinical development
- Comments on the draft guideline should be sent to idwpsecretariat@ema.europa.eu using the form provided.

SECTION EDITORS

Section Editor:
Anuradha Alahari
Anuradha.Alahari@parexel.com

EMA contact:
Monika Benstetter
press@ema.europa.eu

Adaptive pathways: key learnings and next steps

EMA publishes report on pilot project

August 03, 2016 – The EMA has published a final report on the experience gained during its pilot project on adaptive pathways, a product development concept for medicines that address patients' unmet medical needs.

The pilot project, which has now ended, showed that adaptive pathways can bring multiple stakeholders together – regulators, health technology assessment (HTA) bodies, healthcare professionals and patients – to agree on a prospective plan to generate data on a medicine across its lifespan in areas of unmet medical need. Adaptive pathways can support medicine development in therapeutic areas where evidence generation is challenging, such as infectious diseases, Alzheimer's disease, degenerative diseases, and rare cancers.

Adaptive pathways can be defined as a planned, progressive approach to bringing a medicine to patients. It is not a new route of marketing authorisation; it makes use of existing regulatory tools. Under this approach, the medicine will first be authorised in a small patient population that is likely to benefit most from the medicine. Then, additional evidence is gathered over time resulting in progressive licensing adaptations to extend or restrict the previously authorised indications of the medicine.

In March 2014, EMA launched a pilot project to explore the practical implications of the adaptive pathways concept with medicines already under development. EMA invited companies to submit ongoing medicine development programmes which fulfil the characteristics of adaptive pathways: a staggered approval from very small, restricted patient

populations to increasingly wider populations; a binding plan of post-licensing evidence gathering; and involvement of key stakeholders in the process.

The pilot helped to identify a number of aspects for further reflection. These include the need for increased involvement of patients to assist in the selection of candidates for adaptive pathways, the definition of methodologically-sound strategies of real-world evidence collection to support the assessment of both efficacy and effectiveness and the potential involvement of payers – Member States' organisations responsible for decision on pricing and reimbursement – to provide input on pricing strategies.

Adaptive pathways: a lifespan approach to learning

Adaptive pathways makes use of existing approval tools, in particular conditional marketing authorisation which has been in operation in the European Union (EU) since 2006. It also builds on the experience gained with strengthened post-marketing monitoring tools introduced by the 2012 pharmacovigilance legislation.

This concept of medicine development and data gathering is not meant to apply to all medicines, but only to medicines that are likely to address an unmet medical need. The medicine development also needs to meet the characteristics of adaptive pathways.

A key aspect of adaptive pathways is the involvement of all relevant decision makers across the lifespan of a medicine, including those who decide about patient access in the Member States. It is particularly important that all involved stakeholders agree upfront on a plan of post-licensing knowledge generation for a medicine, before it is authorised, and that the marketing authorisation holder commits to carrying out this plan. Once a marketing authorisation has been granted, the post-authorisation plan becomes a legally binding regulatory obligation.

Adaptive pathways is still a developing concept which will be refined as more medicines are considered for this approach. Cooperation between stakeholders and a strong pharmacovigilance system are the basis for a systematic monitoring of the safety and the overall performance of a medicine in clinical practice.

Better monitoring of biological medicines

New chapter in guidelines on good pharmacovigilance practices

August 15, 2016 – The EMA has adopted a new chapter to its guidelines on good pharmacovigilance practices (EU-GVP), entitled "Product-or population-specific considerations II: Biological medicinal products". Good pharmacovigilance practices are a set of measures designed to ensure the robustness of the system of safety monitoring. The new chapter provides guidance on how to better monitor and manage the safety of biological medicines to optimise the safe and effective use of these products in Europe.

Biological medicines contain one or more active substances made by or derived from a biological source, such as blood or plasma. Some of them may be already present in the human body and examples include proteins like insulin and growth hormone. The active substances of biological medicines are larger and more complex than those of non-biological medicines. Only living organisms are able to reproduce such complexity. Their complexity as well as the way they are produced may result in a degree of variability in molecules of the same active substance, particularly in different batches of the medicine.

Therefore the guidance seeks to support those responsible for monitoring these medicines by:

- Highlighting specific issues and challenges for the pharmacovigilance of biological medicines, e.g. in relation to variability of the active substance or traceability of products
- Providing recommendations on how to address these specificities and challenges
- Outlining the roles and responsibilities of the various actors

The new chapter applies to biological medicines, biosimilars (medicines that are developed to be similar to an existing "reference medicine") and medicines which contain the same or a closely related active substance but are not authorised as biosimilars. It does not apply to vaccines or advanced therapy medicinal products as separate guidance already exists for these.

EU-US collaboration to boost medicine development for rare diseases

New working group will share information and best practices

September 26, 2016 – The EMA and the United States Food and Drug Administration (FDA) have set up a new 'cluster' on rare diseases to share experiences and best practices on each

other's regulatory approach to the development of medicines for these diseases.

While rare diseases are estimated to affect 30 million people in the EU and approximately the same number in the United States, each disease individually concerns a limited number of patients. Therefore, global collaboration in this area is particularly important to ensure that the limited number of studies that can be conducted, due to the small populations, can benefit all patients regardless of where they live.

The agencies will exchange information on various aspects of the development and scientific evaluation of medicines for rare diseases. These include topics such as:

- Design of clinical trials in small populations and the use of statistical analysis methods
- Selection and validation of trial endpoints, i.e. target outcomes of a trial
- Preclinical evidence to support development programmes
- Design of post-marketing studies, in particular in the context of early access mechanisms such as EMA's conditional marketing authorisation and FDA's accelerated approval
- Risk management strategies for long-term safety issues with medicines for rare diseases

The creation of this cluster is the latest step in EMA's and FDA's wider objective to expand and reinforce international collaboration. The cluster will provide a forum for confidential exchange of draft documents, policies under development, and more detailed information supporting the scientific basis for decision making on medicine development. The currently existing EMA/FDA clusters discuss issues related to patient engagement, biosimilars, orphan medicines, medicines to treat cancer, medicines for children, and pharmacovigilance, among other topics.

New medicine to protect honey bees against Varroa mites

VarroMed recommended for marketing authorisation

October 07, 2016 – At its October meeting, the Committee for Medicinal Products for Veterinary Use (CVMP) of the EMA recommended the granting of a marketing authorisation in the EU for VarroMed (oxalic acid dihydrate/formic acid). This antiparasitic medicine treats the Varroa mite infestation in honey-bee colonies, which is considered to be the most significant parasitic health concern affecting honey bees worldwide. The CVMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation.

Honey bees are essential for pollination of crops and wild plants in Europe. The European Commission estimates that pollinators, including honey bees, bumble bees and wild bees, contribute at least 22 billion euros each year to European agriculture and pollinate over 80% of crops and wild plants on the continent. However, beekeepers around the world have reported losses of honey-bee colonies, which are considered to be caused by a combination of different factors such as habitat loss, climate change, pesticide use, and also diseases affecting bee health. A continued decline of these pollinators could lead to serious biological, agricultural, environmental and economic difficulties.

The main parasite affecting honey bees is the Varroa mite, an invasive species from Asia that has affected bee colonies worldwide. The Varroa mite feeds on the circulatory fluid of bees and brood (bee larvae) and can also contribute to the spread of viruses and bacteria.

VarroMed is a liquid which is trickled onto bees in the hive. It contains a fixed combination of two organic acids, oxalic acid dihydrate and formic acid. The medicine is not expected to pose a risk to human or animal health or the environment. Treatment should only be given at times when honey is not produced by bees.

VarroMed is intended to be used as part of an integrated Varroa control programme, which includes not only treatment with medicines but also non-chemical techniques like queen trapping or drone brood removal. It can be used either as a single-dose treatment during the broodless period (winter treatment) or in the presence of brood (spring or autumn), which will usually require repeated treatments.

The effectiveness and safety of the product in the protection of honey bees against Varroa mites was tested in laboratory and field studies in different European climate conditions. VarroMed was effective in killing more than 80% of mites, which is below the effectiveness level of 90% recommended by the CVMP Varroa guideline. However, CVMP agreed that a lower level of 80% could be accepted when integrated Varroa control techniques are put in place. Repeated treatment of VarroMed might also result in increased bee mortality, and careful dosing is recommended to avoid overdosing.

The medicine has been classified as MUMS (minor use minor species/limited market), and, therefore, reduced data requirements apply, and these have been considered in the assessment. EMA's MUMS policy aims to stimulate the development of new veterinary medicines for minor species and for diseases in major species for which the market is limited and that would otherwise not be developed under current market conditions.

Journal Watch

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

SECTION EDITOR

Hervé Maisonneuve
herve@h2mw.eu

Publication record and time to publication: 85% of Pfizer-sponsored clinical trials were published in a peer-reviewed journal with a median time to publication of 31 months.

Treatment decisions made by healthcare professionals are informed by the results of clinical trials published in peer-reviewed journals. Research conducted on studies that were sponsored by the pharmaceutical industry and completed more than a decade ago highlighted issues of delayed, incomplete or biased publication of clinical trial results. For example, up to 57% of studies supporting approval of products by the US Food and Drug Administration (FDA) remained unpublished 5 years after product approval and those with favourable primary outcomes were more likely to be published. This retrospective, cross-sectional analysis included 76 clinical trials registered in ClinicalTrials.gov that completed in 2010 for approved, Pfizer prescription products in patients or vaccines in healthy participants. The primary outcome(s) for 65 (85%) studies was published in 71 manuscripts; the median time to publication was 31 months (range 3–63 months). Of the remaining 11 studies, two had been submitted to at least one journal, two had not yet been submitted and seven had no plans to publish because the study had terminated early due to recruitment challenges. Manuscripts accepted at the first choice journal were published at a median time of 28 months (range 8–63, n=31), those accepted at second choice journal were published at 32 months (3–45, n=19), and for those accepted at third choice journal, it was 40 months (range 24–53, n=13). The publication rate and median time to publication from study completion were comparable to those previously reported for combined analyses of industry and non-industry sectors. Opportunities exist for sponsors, authors and journals to explore ideas that would facilitate more timely publication for clinical trial results. However, to be effective, such changes may need to revisit the entire publication process.

Reference: Mooney LA, Fay L. Cross-sectional study of Pfizer-sponsored clinical trials: assessment of time to publication and publication history. BMJ Open 2016;6:e012362. doi:10.1136/bmjopen-2016-012362

To make replication studies more useful, researchers must make more of them, funders must encourage them and journals must publish them

Nature published a survey of 1,576 researchers who took a brief questionnaire on reproducibility research. More than 70% of researchers have tried and failed to reproduce another scientist's experiments, and more than half have failed to reproduce their own experiments.

Most journals prefer to publish innovations, refusing to consider replication studies. A *Nature* proposes that researchers submit replications of experiements. Conventions around replication are in their infancy – even the vocabulary is inadequate. Nowadays, researchers who want to tell the scientific community about their replication studies have multiple ways to do so. They can chronicle their attempts on a blog, post on a preprint server or publish peer-reviewed work in those journals that do not require novelty. The editorial lists journals that have a column dedicated to replication studies.

Nature concludes: *'To foster better behaviour, replication attempts must become more common. We urge researchers to open their file drawers. We urge authors to cooperate with reasonable requests for primary data, to assume good intent and to write papers – and keep records — assuming that others will want to replicate their work. We urge funders and publishers to support tools that help researchers to thread the literature together. We welcome, and will be glad to help disseminate, results that explore the validity of key publications, including our own'.*

References:

Baker M. 1,500 scientists lift the lid on reproducibility. Nature 2016;533:452-4.

Go forth and relicate [editorial]. Nature 2016;536:373.2016;536:373.

The family wasn't aware that playing bagpipes was the cause of the death: consent for publishing patients' data is mandatory

Family members learned a bagpipe musician died from inhaling mould and fungi from a case study reported in *Thorax*. The family was told he had a fatal condition called pulmonary fibrosis and a heart condition had caused his death. The family's distress was extensively covered by the UK's mainstream media. The hospital has apologised; the journal, however, did not issue a retraction. The Thorax paper says the patient gave consent, and according to the co-editor-in-chief of the journal, consent was sought from the family. But the patient's daughter told RetractionWatch that neither the next of kin nor the patient were approached for consent.

This observation reminds us that obtaining signed consent from patients is mandatory to publish any case report. This is not the first case report to cause distress to the family of the deceased.

Reference: Chawla DS. Despite apology, bagpipes study not slated for retraction. 2016 [cited 9 Oct 2016]. http://retractionwatch.com/2016/09/07/despite-apology-bagpipes-study-not-slated-for-retraction/

Suboptimal systematic reviews and meta-analyses can be harmful given the major prestige and influence these types of studies have acquired.

This 30 pages paper was based upon a talk given at the Cochrane Colloquium in Vienna, October 2015, by JPA Ioannidis, director of the Meta-Research Innovation Center at Stanford (METRICS). The production of systematic reviews and meta-analyses has reached epidemic proportions. Currently, there is massive production of unnecessary, misleading, and conflicted systematic reviews and meta-analyses. Instead of promoting evidence-based medicine and health care, these instruments often serve mostly as easily produced publishable units or marketing tools. A total of 9,135 meta-analyses were published and 28,959 systematic reviews were indexed in PubMed in 2014, which is more than articles on new randomised trials. It is debatable whether systematic methods for searching and integrating evidence has been followed in generating all of these reviews. China has rapidly become the most prolific producer of English-language, PubMed-indexed meta-analyses. The most massive presence of Chinese meta-analyses is on genetic associations (63% of global production in 2014), where almost all results are misleading since they combine fragmented information from mostly abandoned era of candidate genes. Many contracting companies working on evidence synthesis receive industry contracts to produce meta-analyses, many of which probably remain unpublished.

Suboptimal systematic reviews and meta-analyses can be harmful given the major prestige and influence these types of studies have acquired. The publication of systematic reviews and meta-analyses should be realigned to remove biases and vested interests and to integrate them better with the primary production of evidence

Reference: Ioannidis JPA. The mass production of redundant, misleading and conflicted systematic reviews and meta-analysis. Milbank Q 2016;94:485-514.

Systematic reviews of drugs might be improved by including protocols and clinical study reports in addition to published articles

Little is known about how adverse events (AEs) are collected and reported in clinical trials. Gøtzsche *et al.* (Nordic Cochrane Centre) analysed seven randomiwed placebo-controlled trials (4,225 participants) conducted between 1992 and 1996 in the US and Europe, on orlistat, an anti-obesity drug that was approved by the European Medicine Agency in 1998. In 2011, the FDA issued a warning regarding 13 cases of liver failure associated with orlistat. The authors identified important disparities in the reporting of AEs between protocols, clinical study reports (CSRs), and published papers. Reports of these trials seemed to have systematically understated the AEs. None of the protocols or CSRs contained instructions for investigators on how to question participants about AEs. All AEs were coded by the sponsor using a glossary that could be updated by the sponsor. Between 3% and 33% of the total number of investigator-reported AEs from the

The SAGER guidelines encourage a more systematic approach to the reporting of sex and gender in research across disciplines

Sex and gender differences are often overlooked in research design, study implementation and scientific reporting, as well as in general science communication. This oversight limits the generalisability of research findings and their applicability to clinical practice, in particular for women but also for men. The Sex and Gender Equity in Research (SAGER) guidelines are a comprehensive procedure for reporting of sex and gender information in study design, data analyses, results and interpretation of findings. The SAGER guidelines are designed primarily to guide authors in preparing their manuscripts, but they are also useful for editors, as gatekeepers of science, to integrate assessment of sex and gender into all manuscripts as an integral part of the editorial process.

The SAGER guidelines are the result of collective effort by the EASE (European Association of Science Editors) Gender Policy Committee. A panel of 13 experts representing nine countries developed the guidelines through a series of teleconferences, conference presentations and a 2-day workshop. An internet survey of 716 journal editors, scientists and other members of the international publishing community was conducted as well as a literature search on sex and gender policies in scientific publishing.

Sex refers to a set of biological attributes in humans and animals that are associated with physical and physiological features such as chromosomes, gene expression, hormone function and reproductive/sexual anatomy. Gender refers to the socially constructed roles, behaviours and identities of female, male and gender-diverse people.

The underrepresentation of women in research can result in adverse consequences. Among the ten prescription pharmaceuticals withdrawn from the US market between 1997 and 2001, eight caused greater harm to women than men. More recently, the FDA issued a safety communication, recommending half a dose of zolpidem for women, due to greater susceptibility to the risks of the drug. It is acknowledged that many studies are not "designed" to analyse sex and/or gender differences.

As a general principle, the SAGER guidelines recommend careful use of the words sex and gender in order to avoid confusing both terms. The term sex should be used as a classification of male or female based on biological distinction to the extent that this is possible to confirm. In animal studies, the term sex should be used. In cell biological, molecular biological or biochemical experiments, the origin and sex chromosome constitutions of cells or tissue cultures should be stated. In other disciplines, such as the testing of devices or technology on humans, authors should explain whether it will be applied or used by all genders and if it has been tested with a user's gender in mind.

The SAGER guidelines are summarised in Table 1.

Table 1. Sex and Gender Equity in Research (SAGER) guidelines

General principles

- Authors should use the terms sex and gender carefully in order to avoid confusing both terms.
- Where the subjects of research comprise organisms capable of differentiation by sex, the research should be designed and conducted in a way that can reveal sex-related differences in the results, even if these were not initially expected.
- Where subjects can also be differentiated by gender (shaped by social and cultural circumstances), the research should be conducted similarly at this additional level of distinction

Recommendations per section of the article

Title and abstract	If only one sex is included in the study, or if the results of the study are to be applied to only one sex or gender, the title and the abstract should specify the sex of animals or any cells, tissues and other material derived from these and the sex and gender of human participants.
Introduction	Authors should report, where relevant, whether sex and/or gender differences may be expected.
Methods	Authors should report how sex and gender were taken into account in the design of the study, whether they ensured adequate representation of males and females, and justify the reasons for any exclusion of males or females.
Results	Where appropriate, data should be routinely presented disaggregated by sex and gender. Sex- and gender-based analyses should be reported regardless of positive or negative outcome. In clinical trials, data on withdrawals and dropouts should also be reported disaggregated by sex.
Discussion	The potential implications of sex and gender on the study results and analyses should be discussed. If a sex and gender analysis was not conducted, the rationale should be given. Authors should further discuss the implications of the lack of such analysis on the interpretation of the results.

Reference: Heidari S, Babor TF, De Castro P, Tort S, Curno M. Sex and Gender Equity in Research: rationale for the SAGER guidelines and recommended use. Res Integrity Peer Rev (2016) 1:2.

trials were reported in the publications because of post-hoc filters, though six of seven papers stated that "all AEs were recorded."

In one trial, the majority of patients had multiple episodes of the same AE that were only counted once, though this was not described in the CSR. Participants treated with orlistat experienced twice as many days with AEs as participants treated with placebo (22.7 d versus 14.9 d, p-value <0.0001, Student's *t* test). Furthermore, compared with the placebo group, AEs in the orlistat group were more severe. None of this was stated in the CSR or in the published paper.

This was an explorative study, restricted to one drug tested in the mid-1990s; therefore, the results might not be applicable for newer drugs as the standards of reporting CSRs and publications have improved since. However, many drugs approved in this time period are currently in the market. The authors highlight the need for detailed analysis plans for harms data.

Reference: Schroll JB, Penninga E, Gøtzsche P. Assessment of adverse events in protocols, clinical study reports, and published papers of trials of orlistat: a document analysis. PLOS Med 2016;13(8):e1002101.

In the Bookstores

SECTION EDITORS

Alison McIntosh
alison.mcintosh@iconplc.com
Stephen Gilliver
stephen.gilliver@gmail.com

Guidelines for Reporting Health Research: A User's Manual

By David Moher (Editor), Douglas Altman (Editor), Kenneth Schulz (Editor), Iveta Simera (Editor), Elizabeth Wager (Editor)
Wiley Blackwell, 2014.
ISBN: 978-0-470-67044-6 (paperback)
32.99 GBP. 344 pages.

The need for accurate scientific reporting is more important than ever. With thousands of articles indexed monthly on PubMed alone, there has never been such a wealth of knowledge and research. But with this wealth comes the potential for error; the ever-increasing need to publish means that selective reporting and over-reaching conclusions are common among the scientific literature. In *Guidelines for Reporting Health Research: A User's Manual*, the book's editors, in association with the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) network (www.equator-network.org) and over 60 individual contributors, present a collection of respected and commonly used guidelines for reporting health research, with the purpose of increasing the clarity, completeness, and transparency of reported research. This book is aimed at a range of professions and roles within the medical and academic fields, including authors, editors, peer reviewers, and funders. From a medical writing perspective, it provides some fundamental background knowledge on the necessity, generation and application of guidelines for publishing research.

This book is separated into four parts. Part 1 (Chapters 1 to 6) looks at some of the fundamental errors in health reporting. In particular, it describes the risks of selective reporting, highlights the prevalent use of inadequate statistical tests, and questions the use of peer review in preventing the reporting of inaccurate data. Furthermore, it provides several examples of deficiencies in published articles and cautions against drawing conclusions from insufficient data. This part also highlights the knock-on effects of poor reporting on systematic reviews. Specific chapters look at the importance of transparency in health research, the structure set in place to develop a reporting guideline, the characteristics of available reporting guidelines, and how to use a reporting guideline effectively.

The penultimate chapter of Part 1 (Chapter 5) looks at ambiguities and confusion between reporting and the conduct of research. It highlights that the misuse of reporting guidelines may impact the conduct of a study and that the purpose of the guidelines is to state what needs to be reported rather than saying what is good or bad. It also provides useful scenarios of excellent, ambiguous/incomplete, and poor reporting of study conduct. The final chapter of this part focuses on how the EQUATOR network – an online library of reporting guidelines – can be used to maintain high standards of reporting in health research, namely by providing a comprehensive online resource for health research reporting with up-to-date information, tools, and materials, as well as by developing, promoting, providing training in, and assessing reporting guidelines.

> This book provides some fundamental background knowledge on the necessity, generation and application of guidelines for publishing research.

The CONSORT (CONsolidated Standards Of Reporting Trials) 2010 Statement has been endorsed by over 600 journals worldwide, is supported by the Council of Science Editors and World Association of Medical Editors, and is recommended by the International Committee of Medical Journal Editors (ICMJE). Part 2 (Chapters 7 to 24) looks in detail at over a dozen specific guidelines in health research, with a primary focus on the use of the CONSORT Statement in various trial designs. Chapter 7 describes SPIRIT 2013, a 33-item checklist for use in developing clinical study protocols. With key aspects relating to outcomes, sample size, and administrative information, SPIRIT 2013 aims to improve protocol design by promoting completeness and to improve study conduct. Chapter 8 describes the use of CONSORT for abstracts of randomised trials in journal and conference articles. It provides guidance on key information to maximise the transfer of knowledge within a typical 250 to 300 word limit. Chapter 9 describes the main CONSORT Statement, in addition to the CONSORT Flow Diagram and 25-item CONSORT Checklist. This chapter primarily describes the use of CONSORT (originally published in 1996 but updated in 2001 and 2010 to provide more comprehensive guidance for randomised clinical trials) in relation to randomised two-group parallel trials, but also extensions of its use to other designs. CONSORT's use in non-pharmacological treatments, pragmatic trials, cluster randomised trials, and non-inferiority and equivalence trials is detailed in Chapters 11 to 14.

Subsequent chapters go on to describe a further 10 guidelines, including TREND (Transparent Reporting of Evaluations with Non-randomised Designs), a 22-point checklist for assessing the completeness of evaluations in non-randomised trials, and STROBE (STrengthening the Reporting of OBservational studies in Epidemiology), a 22-item checklist guideline for use in case, cohort, and cross-sectional observational studies. Additional,

perhaps less well known, guidelines discussed include STARD (STAndards for Reporting Diagnostic accuracy studies), SURGE (SUrvey Reporting GuidelinE), COREQ (COnsolidated criteria for REporting Qualitative research), SQUIRE (Standards for QUality Improvement Reporting Excellence), and REMARK (REporting recommendations for tumour MARKer prognostic studies).

Part 2 concludes with Chapter 24, which describes PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses). Widely endorsed and with extension guidelines for abstracts and equity-focused reviews, this 27-item checklist is an expansion of a previous guideline, QUORUM (QUality Of Reporting Of Meta-analyses), and is for use in broad-spectrum systematic reviews and meta-analyses.

Overall, Part 2 is well-structured and insightful, with many chapters containing checklist items for the guidelines in addition to highlighting the key aspects of each guideline, the development of the guideline, how best to use it, and its future directions. The authors evaluate each guideline critically for its merits and limitations and are careful to emphasise that the aim of the guidelines is not to determine the quality of the data presented but instead to clarify what should be included to ensure completeness and transparency.

Part 3 (Chapters 25 to 28) looks at the use of guidelines on how to present statistics, tables and figures, and clinical and laboratory images in publications. Chapter 25 reviews the SAMPL (Statistical Analyses and Methods in the Published Literature) guidelines, which outline the general principles for reporting some of the most commonly used statistical methods. Chapter 26 looks at guidelines for presenting tables and figures in scientific manuscripts, while Chapter 27 looks at the CLIP (Clinical and Laboratory Images in Publications) principles and includes a useful excerpt from an article on how to document magnetic resonance images.

Part 4 concludes this book with Chapter 29, which discusses the need for journals to adopt a coherent reporting guideline policy to ensure guidelines are effectively followed. The authors of this chapter outline an 8-step process that journals can follow in order to implement a reporting guideline, based on their personal experience of launching a reporting guideline adherence policy at an international journal.

Overall this book provides a valuable resource for authors, editors, peer reviewers, and funders to ensure the appropriate guidelines are chosen and correctly applied. I would highly recommend it to any medical writer looking to broaden their knowledge of how best to report health research.

Online resources and details of guidelines are available from the EQUATOR network website (www.equator-network.org).

Reviewed by
Nicholas Churton
Medical Writer
Clinical Research Services,
ICON, Eastleigh, UK
Nicholas.Churton@iconplc.com

Recommended reading in *European Science Editing*

The August 2016 issue of *European Science Editing* (ESE) boasted a fascinating discourse on whether ICMJE (International Committee of Medical Journal Editors) and other guidance on authorship discriminates against non-native English speakers.[1] According to the ICMJE criteria, an author should contribute to "drafting the work or revising it critically for important intellectual content" and give "final approval of the version to be published".[2] How can someone who knows little or no English fulfil these criteria? Unsurprisingly, translation was a central theme of the discussion, with one contributor citing GPP3 (Good Publication Practice): "If needed, translation services should be provided to authors to ensure they can provide detailed feedback and contribute fully".[3] However, not everyone was satisfied by this provision, with another contributor expressing concern that it could be undermined by faulty translation of manuscripts. The discussion progressed to acknowledging the involvement of translators in scientific papers. Some translators were worried that mistakes introduced by the author *after* translation could make them look bad if they were named on the manuscript. I myself have had a similar concern when working as an editor!

A second, briefer discussion covered the thorny subject of editing assistance for PhD students.[4] Is it acceptable to copy edit a PhD thesis or the papers a thesis comprises? A pertinent consideration was highlighted: the thesis might be judged on writing quality. In the apparent absence of any consensus or universally accepted guidance, perhaps the best thing to do would be to consult the guidelines of the examining university and to explicitly acknowledge any help received.

References

1. Langdon-Neuner E (complier). EASE-Forum Digest: March to June 2016. Do authorship criteria exclude authors whose first tongue is not English? European Science Editing. 2016;42(3):79-80.
2. Defining the Role of Authors and Contributors. Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals International Committee of Medical Journal Editors. 2015 [cited 2016 Oct 11]. Available from: http://www.icmje.org/recommendations/ browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html.
3. Battisti WP, Wager E, Baltzer 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):461-4.
4. Langdon-Neuner E (complier). EASE-Forum Digest: March to June 2016. Is helping students to achieve academic grades by editing their papers/theses ethical? European Science Editing. 2016;42(3):80.

The Webscout

Medical education in the online era

Whatever topic you are interested in, you will find relevant educational content on the web. The media used range from written texts, slide decks, and animated videos to interactive webinars or online classes. You will also find helpful resources on how to create educational materials.

The website www.facultyfocus.com/articles/online-education/six-tips-preparing-online-course/ provides some basic advice to consider when you are about to prepare an online course. "Be clear, concise, and comprehensive" – you probably heard that one before in various contexts. Some rules apply to preparation of training course content, as with preparing a manuscript or report. However, you have far more possibilities. Depending on your educational goal and the complexity of your topic, you might decide to use different activities and resources.

The web invents and re-invents educational media and breathes new life into rather conventional resources. For example, the paper-based poster is rivalled by its modern relative, glogs – multimedia interactive posters. The www.glogster.com platform helps you create your own glogs and gives you access to a glog library that also includes templates. Currently, glogs are predominantly used in school classes, but shouldn't they work for adult education as well? Although I haven't yet seen them being used in a scientific context, I think interactive posters are a valuable and appealing educational resource and would be a great idea for traditional conference poster sessions.

You can of course also use PowerPoint-based presentations for educational purposes. However, there are more appealing ways of presenting your content, for example by means of an alternative presentation software package like Prezi. Prezi's main distinguishing features are its non-linear presentation mode and its zoom and rotation functions. Instead of working slide by slide you work within an unlimited canvas, which offers more flexibility in presenting. You can jump into and out of ideas and zoom to emphasise the areas of interest. Presentations based on Prezi or similar tools are commonly used in online training videos. This video gives you a short tutorial on the basic features of Prezi: www.youtube.com/watch?v=ArGh6FurR0Q. But be aware that you can give your audience an awkward "Death by Prezi" experience. This video describes "Death by Prezi" and how to avoid it: www.youtube.com/watch?v=nEpUPRGON-8. Briefly, overuse of Prezi's rotation and zoom features can really make you feel sick. So only use these features with good reason!

SECTION EDITOR

Karin Eichele
info@mediwiz.de

Sex and gender in health research – An online training example

The Canadian Institute of Gender and Health offers an online training course on sex and gender in health research at www.cihr-irsc-igh-isfh.ca/. It was designed to educate researchers and peer reviewers (amongst others) to account for sex and gender in their research planning and in publications. It is free, but you have to register.

The content is interesting from two points of view. On the one hand, in line with our present topic, it lets you experience well prepared medical education. On the other hand, the topic itself is important: sex and gender matter in medicine. Think of myocardial infarction. The symptoms can differ between men and women. Also, while it is common to think of a myocardial infarction when a man complains of chest pain, the symptoms are often trivialised in women. For these reasons, an infarction is more likely to be overlooked in women. Effective research is needed to learn more about such differences and their implications.

The training consists of three modules: Sex and gender in 1. biomedical research, 2. primary data collection with humans, and 3. analysis of data from human participants. Each module follows a didactic concept. You start with a pre-test and afterwards you can enter the content section. Each module requires a final test and once you have passed it you will receive a certificate. Additional resources are proposed in case you want to deepen your knowledge. It will take you about two hours to complete the whole course; however, you can interrupt and continue at any time. I can fully recommend this course.

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

Good Writing Practice

Syntactic structure

- Nonprofessional tone
- Nonthematic focus: First person
- Subjectification: Personalism first person

SECTION EDITORS

Wendy Kingdom
info@wendykingdom.com
Amy Whereat
amy.whereat@speakthespeech.fr

Introduction

Personalism results from a story-line narration rather than a thematic-focused description. This story-line narration is focused on agents as sentence (or clause) subjects and their actions as verbs, rather than themes represented by noun subjects and the verb *to be* linked to a subject complement.

Personalism in a journal article may be reader friendly; however, personalism is distracting because it deviates from expected professional formality.

Examples of first person personalism are arranged according to section of a journal article and conceptual component: 1. Introduction; 2. Materials and Methods; 3. Results; 4. Discussion.

Part 1 – Introduction section

In an Introduction section, the use of explicit markers of anticipated conceptual components (such as an objective) is thematically focused, especially in contrast to the non-thematic investigator-focused *we*.

Example 1: research objective

We *hoped to develop an injection therapy for women whose cancer cells over-express this oncogene.*

Revision

The objective *was to develop an injection therapy for women whose cancer cells over-express this oncogene.*

Notes

The perspective was at the time preceding the actual experimentation; therefore, the past tense is appropriate (i.e., *the objective was…*). The more grammatically accurate past perfect *the objective had been* seems stilted.

The research problem pertinent background citing an author(s) published (or unpublished) research can be indicated by a reference, rather than *we did this* and *we did that*, especially when reference citations are indicated by author name, date rather than by citation number. However, without explicit reference to the authors, their identity as authors of the article being cited is not obvious, justifying statements, such as ***We*** *previously identified a cell line with a single base pair deletion in exon 11 of the Smad2 gene* (Ref).

Example 2: research problem

We were unsure *about the mechanism for CKI cessation enabling the initiation of the cell cycle.*

Revision

An unanswered question was *the mechanism for CKI cessation enabling the initiation of the cell cycle.*

Note

The Revision involves creating a nominal conceptual subject *an unanswered question*, the use of the descriptive verb *to be*, and the subject complement 'the mechanism'.

Part 2 – Materials and Methods section

In most situations, is it not important to the reader to be informed who performed the experiment. In fact, the use of the personal pronoun *we* is often disrespectful to the technical staff who actually performed the experimentation, but whose names may not appear as authors in the article.

Example: method

We *exposed the auditory cortex in the right hemisphere by craniotomy and durotomy.*

Revision

The ***auditory cortex*** *in the right hemisphere was exposed by craniotomy and durotomy.*

Notes

In the Revision, along with deletion of *we*, the active voice *exposed* is transformed into the passive *was exposed* concomitantly with thematic focus on *the auditory cortex*.

Part 3 – Results section

The author-focused (often egotistical) *we did this* and *we did that* can be avoided by shifting from who did what to what was shown.

Example: data-based preliminary interpretation

We *demonstrated that epidermal growth factor-activated Ras-signaling enhanced pol I transcription (Table 1).*

Revision

As shown by the ***data*** *(Table 1), the epidermal growth factor-activated Ras-signaling enhanced pol I transcription.*

Although the present tense *can* is appropriate for the time-independent intent of a conclusion, the past *could* conveys the professional tone of understatement.

Notes

A typical revision for an agent sentence subject and a noun clause direct object (*we demonstrated that*) is the orientation by an elliptical adverb clause (*as shown by the data*) and reduction of the noun clause into the noun phrase subject of the sentence *the epidermal growth factor-activated Ras-signaling.*

Two of the anticipated components of the Results section are data verbalisation (e.g., *pol I transcription was increased 50%*) and data-based preliminary interpretation (e.g., *epidermal growth factor activated Ras-signaling enhanced pol I transcription*).

Some authors may be less accepting of the past tense for conveying a preliminary interpretation, but the past tense is circumspect, befitting the understatement characteristic of incomplete understanding.

Usage of the personal pronoun *we* seems most appropriate for accepting responsibility for an opinion, such as, for a hypothesis or conclusion, or preliminary interpretation. However, personalisation connotes some assertiveness, which may be less appropriate than a de-personalised statement.

Part 4 – Discussion section

Of all the sections of a journal article, the Discussion section seems the most likely to contain first person personal pronouns because accepting personal responsibility for an inference or conclusion modulates the presumptions. However, in the example, the authors are emphasised at the expense of the information.

Example: conclusion consequence

We *conclude that this algorithm can be applied to many geometry-based systems.*

Revision

In conclusion*, this algorithm could be applied to many geometry-based systems.*

Notes

The conclusion, being a component of the scientific method, is in response to the hypothesis, not casually equivalent to *in summary*.

Although the present tense *can* is appropriate for the time-independent intent of a conclusion, the past *could* conveys the professional tone of understatement.

Summary

First person personalism creates a distraction in scientific journal articles because it is at the expense of thematic focus and deviates from the expected professional formal tone.

Michael Lewis Schneir
Professor, Biomedical Sciences,
Ostrow School of Dentistry,
University of Southern California,
Los Angeles, CA, USA
schneir@usc.edu

Medical Communications

SECTION EDITOR

Lisa Chamberlain James
lisa@trilogywriting.com

Editorial

Most medical writers cut their teeth on manuscripts, and these documents are often mistakenly believed to be 'easy' to write. However, the truth is that with all documents, they are easy to write badly but require skill and knowledge to write well. A quick scan of any journal will quickly (and depressingly!) reveal the sheer number of poor quality manuscripts in circulation.

Producing a high quality manuscript from a clinical study report can be even more challenging. Not only do writers have to deal with the report itself, which may be of "less than ideal" quality, but they then have to tease out the vital messages from what may be a tangle embedded in the report, and also juggle the team – all of whom may be pursuing their own agenda for the manuscript.

In this issue, Michael Riley gives us his top tips for navigating these tricky waters. With many years of experience honing the skills needed to produce clear, accurate and ethically sound manuscripts, Mike is ideally placed to lay out the pitfalls and suggest how to avoid them when writing manuscripts from clinical study reports. His article has something for everyone, even if you have been writing manuscripts for years.

It only leaves me to wish you the best wishes for the season – a happy and healthy 2017, and in the words of Irving Berlin "may your days be merry and bright, and may all your Christmases be white".

Bestest.

Lisa

How to write a clear, complete and accurate clinical study paper: A medical writer's tips, and the importance of reporting guidelines

According to the ethical principles in the Declaration of Helsinki, researchers "are accountable for the completeness and accuracy of their reports",[1] while the Good Publication Practice 3 guidelines (GPP3) state that "professional medical writers have a responsibility to ensure that findings are presented clearly, accurately, and without any intent of misleading readers".[2] However, criticism has been levelled for incomplete reporting of results and methods, such as selective reporting of positive outcomes and inadequate reporting of adverse events (AEs), which may misinform the reader about the benefits and risks of particular treatments.[3] These issues may have various underlying reasons, including lack of awareness and use of reporting guidelines (such as the Consolidated Standards of Reporting Trials [CONSORT] guidelines for randomised trials), and inadequate knowledge of how to write a clinical research paper. In a recent study, papers produced with vs. without medical writing support were more likely to completely report at least 50% of CONSORT items (39.1% vs. 21.1%) and were more likely to be written in acceptable English (81.1% vs. 47.9%).[4] However, these data also suggest that considerable further improvements could often be made to manuscripts even when authors are assisted by a medical writer. This article aims to raise awareness of and encourage routine use of reporting guidelines, in order to improve clarity, completeness, accuracy and transparency in clinical research papers, and provides tips and links to further reading that may assist medical writers in creating clear, complete and accurate study papers.

Reporting guidelines and the EQUATOR Network

The EQUATOR Network (Enhancing the QUAlity and Transparency Of health Research) was set up in 2006 as an international 'umbrella' organisation of researchers and publication professionals, with the mission "to achieve accurate, complete, and transparent reporting of all health research studies to support research reproducibility and usefulness".[5] One of the EQUATOR Network's main aims is to actively encourage the use of reporting guidelines. A comprehensive list of over 320 reporting guidelines is available on the EQUATOR Network website; some are provided by study type (e.g. the CONSORT guidelines for randomised trials, the STROBE guidelines for observational studies in epidemiology), others are specific to particular medical conditions (e.g. response definitions for chronic myeloid leukaemia are proposed by the European LeukemiaNet).[5] Reporting guidelines by study design, such as CONSORT, comprised a checklist and a statement, both of which should be read. The statements may explain and clarify what is meant by each item on the checklist and why each item is important.

Some journals stipulate in their 'instructions for authors' that reporting guidelines should be followed, and may request submission of a checklist showing which items have been reported in the paper. Even if not asked for by the journal, reporting guidelines should routinely be used to improve completeness, accuracy and transparency when writing a research paper.

In addition to reporting guidelines, professional medical writers should be familiar with other important guidelines and regulations related to reporting of results, study conduct, and authors' and medical writers' roles and responsibilities (such as GPP3, ICMJE, the Declaration of Helsinki, and EMWA guidelines).

Practical tips and resources for medical writers to produce clear, complete and accurate clinical study papers

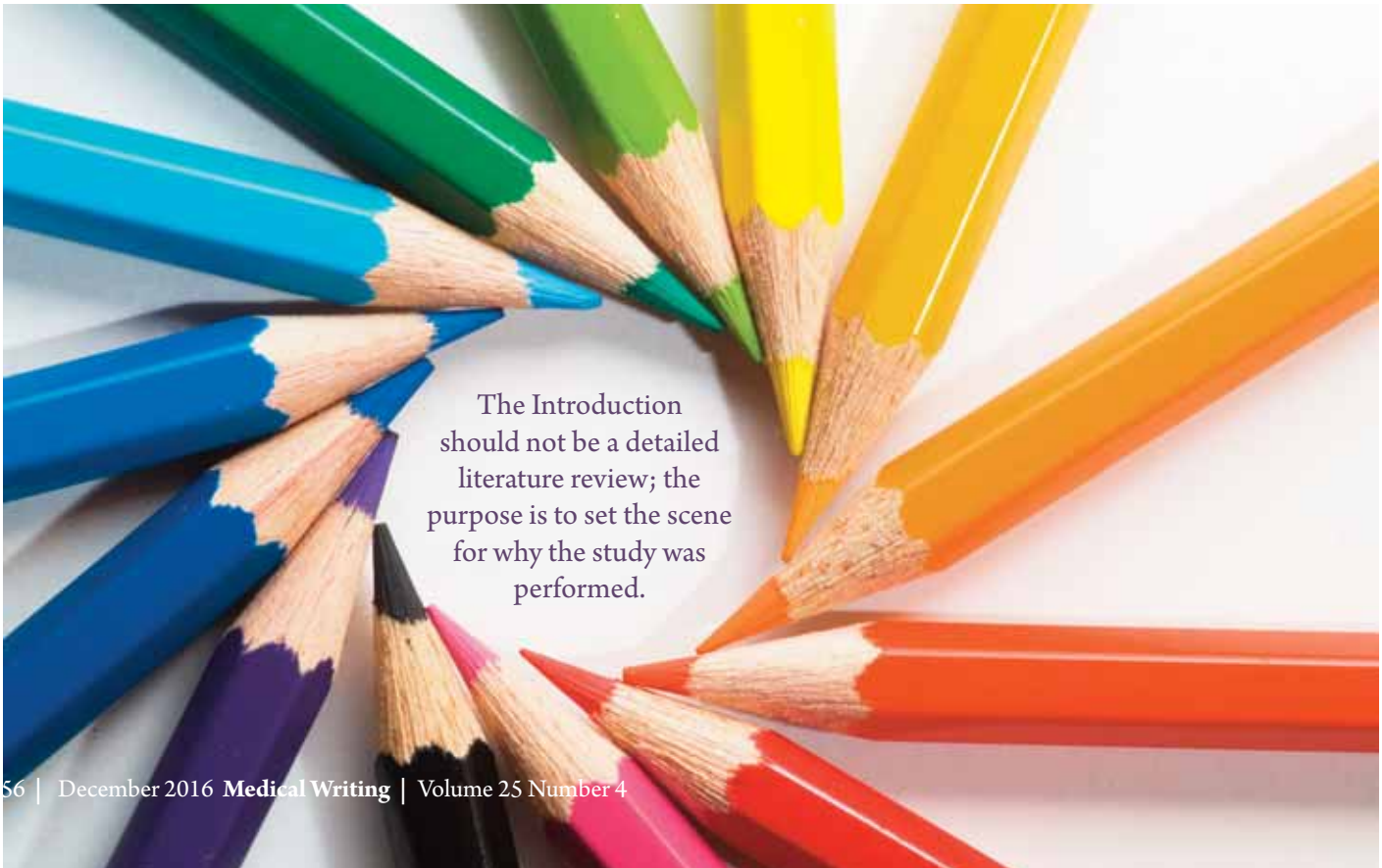
Besides reporting guidelines, other valuable tools are also available via the EQUATOR Network website. These tools include a scientific paper that is annotated with practical advice,[5,6] and an overview of the layout and key contents of a generic medical research paper alongside a list of reporting guidelines.[7] Based on my own experiences of medical writing, and on published papers about scientific writing style including the aforementioned annotated scientific paper,[6,8,9] a few basic medical writing procedure and style tips are shown in Box 1. Hereafter I provide additional practical tips from my own experiences and also from published papers and reporting guidelines.[4-12]

Clear, complete and accurate reporting: general tips

Before writing the paper, the first step should be to ensure that you identify the key data and messages that should be communicated. As your starting point when becoming familiar with the project, it may be appropriate for the study sponsor or an author (or you, the medical writer, in early discussions with the sponsor or author) to physically highlight the key data, messages and methods in the source document. The sources may be one or more of several documents, including a clinical study report (CSR) and associated tables, a congress presentation, or a file of tables generated post hoc that may have no explanatory document. The latter source can be particularly confusing without appropriate guidance. If the paper is based on a CSR, it may be clear which are the key data, methods, and messages, although these are still often worth discussing. For example, if mean and median values are reported for the primary endpoint in the CSR, you may need guidance about whether one or both should be included in the paper. Similarly, even if the primary objective was to study efficacy, should other important issues (e.g. cost-effectiveness) be discussed in relation to efficacy in the paper, even if they were not addressed in the study or in the CSR Discussion section? You may ask the sponsor or authors for key papers and, if necessary, to identify the key messages in these papers that should be included in the Introduction and/or Discussion.

It may also be appropriate to remind or inform the sponsor and authors of the existence of particular reporting guidelines or of specific items before and during the writing process.

Be proactive about completeness, accuracy and transparency, both when presenting data and methodological details from the study and also when discussing other studies in the Introduction and Discussion. For example, when discussing other studies, key factors that may



affect the data, such as study design, should be stated; and if an author adds or changes data in the paper, don't presume it is correct – check the source files. Contact the sponsor or authors if you see an important issue and, if you can, suggest possible solutions. For example, if an author includes the absolute numbers of subjects who experienced AEs in the text without the percentages but the treatment groups were unequally sized, should the percentages be included in the text?

Clear, complete and accurate reporting: Tips by paper section

An often neglected item in reporting guidelines such as CONSORT is that the study design should be included in the title, i.e. 'randomised' in the case of CONSORT.[10]

The Abstract should have sufficient detail to accurately reflect the benefits and harms, methodological details and conclusions that are described in the paper and, as with the rest of the paper, should follow applicable reporting guidelines. For example, CONSORT has issued reporting guidelines specifically for randomised trials reported in congress and journal abstracts.[11]

The Introduction should not be a detailed literature review; the purpose is to set the scene for why the study was performed. It should be as concise as possible (about 350 words in 3 or 4 paragraphs) and, as with all sections of the paper, it should flow logically. Introductions often start with a brief summary of relevant information about the disease, followed by other relevant information about the therapy area and study drug (often about previous trials the study drug has been through), in order to then highlight the gap in the literature addressed by the study. The Introduction should then finish with the overall objective of the study.

The subsections of the Methods are sometimes stipulated in the 'instructions for authors' sections of journal websites. The Methods should be complete, transparent and accurate enough that the reader knows what was done and could actually repeat the study. There should be a method for each result and vice versa. Typically, the Methods will begin with a description of the study design, subjects, settings and locations (e.g. "a multicentre, randomised, double-blind, parallel-group, placebo-controlled trial of drug X in adults with disease Y in hospital outpatient clinics in Germany, Spain, and the US") and a statement that the study was conducted ethically (usually mentioning the Declaration of Helsinki). If available, the study identifier (for registries such as www.clinicaltrials.gov and www.clinicaltrialsregister.eu) should also be included somewhere in the paper (often early in the Methods), potentially allowing the reader to check whether a study is truly prospective and whether all the objectives and outcomes have been reported in the paper. Some studies, such as observational clinical research, may be exempt from registration on www.clinicaltrials.gov. Subsequently, the Methods include the inclusion and exclusion criteria for the subjects, the objectives of the study (primary, secondary, exploratory, etc.), and more detailed information (e.g. doses, schedule) about the interventions and outcomes (variables), and statistical methods. For randomised trials, disclosure of how randomisation and blinding were achieved, and the sample size calculation, are often inadequately reported.[4,10] Similarly, changes to investigated endpoints, relative to the original study protocol, should be disclosed. Post hoc analyses should be clearly identified in the Methods and elsewhere in the paper. If technical information has already been published in detail, then it may be appropriate to refer to the publication and not give full details, as long as they are available in the referenced publication. For commercially available materials and methods (e.g. biomarker test kits, computer software), report the name of the company, city, state and country.

Journals will often have word limits for papers, which may seem detrimental to complete reporting. However, they often allow the use of sections that may be termed "Online Supplementary Materials". Thus methodological information and results that are relevant, although not of the upmost importance, can be reported here and referred to in the Methods or Results sections of the paper.

Most of the text in the Results section will usually describe the figures and tables, highlighting and summarising the key data and patterns, thus making it easier for the reader to understand the figures and tables and vice versa. The text should not merely repeat all the data that are in the figures and tables, and interpretation of what is shown by the data should be left for the Discussion. The Results often begin with a subsection about the subjects' characteristics at baseline, which should allow the reader to determine how well balanced the treatment groups were and also how similar the subjects were relative to those that may be in the readers' clinical practices. Similarly, include a flowchart, such as a CONSORT diagram, at the beginning of the Results so that the reader can compare how many subjects (absolute numbers and percentages) discontinued and why. Reasons for discontinuations are not always reported in papers, but they should be as they are informative; treatments that are more efficacious than placebo tend to have less discontinuation related to lack of efficacy (which supports efficacy analyses of the study), although discontinuations due to AEs are more likely with active treatment and could mask the lack of discontinuations related to lack of efficacy if reasons for discontinuation are not provided.

After describing the baseline characteristics and flow of subjects, it is often logical to then describe the results of the primary analysis, followed by the secondary and exploratory analyses. All analyses should be based on the intention-to-treat principle, otherwise findings can be skewed by discontinuations; in randomised trials, all randomised subjects should be included in the analyses, even if they didn't receive the intervention. Results can be shown for the per-protocol population, which excludes subjects who discontinued, but only as a secondary endpoint. Disappointing results should not be left out. Similarly, there should be accurate, complete and transparent reporting of the potential harms of treatment, e.g. it may be appropriate to only include AEs that occurred in >5% of subjects, although it may be necessary to report some AEs reported by a smaller proportion of subjects, such as serious events, in the paper. Also, think about what types of figures are needed to accurately and clearly show the data and whether you can improve the clarity of figures and tables, e.g. by making rows in a table stand out from each other with alternate shading or indentations to the text.

The Discussion section explains the meaning of the findings, and usually starts with a brief recap and interpretation of the main results in 1 or 2 paragraphs and includes a brief conclusion. Thereafter, the paragraphs should flow logically, perhaps in the following order: compare the findings to those from previous studies, further consider the clinical and scientific implications of the findings of the study (including discussion of negative or unexpected results, and their possible causes), discuss the strengths, limitations and generalisability of the study, and summarize the conclusions again in a final brief paragraph. If relevant, a discussion of possible or planned additional research can be included, perhaps demonstrating that one or more limitations will be remedied.

In relation to strengths and limitations, some issues that could or should be in the Discussion, and perhaps elsewhere in the paper, include discussion of study design and potential sources of bias. For instance, was the comparator group appropriate (if there is a current established

therapy, this should be included as a comparator group), was a surrogate outcome used and what evidence supports its use (see Govani and Higgins[12] for inappropriate use of a surrogate outcome with lethal consequences), was the sample size appropriate, how was missing data addressed? It may also be appropriate to define (perhaps in the Methods or Discussion) what is meant by a "clinically relevant" difference in the study, particularly as this may differ from small but statistically significant changes. Generalisability of the study outcomes to public health practices, which may have different subject characteristics than the subjects in the study, should also be discussed. Issues such as these are discussed in detail by Govani and Higgins.[12]

Finally, medical writing is not ghost writing. Medical writers usually do not fulfil all the criteria for authorship. However, for completeness and transparency, always be acknowledged on the paper for the work that you've done, usually in an appropriately worded sentence in the Acknowledgements section, e.g. 'Michael Riley at Trilogy Writing & Consulting Ltd, Cambridge, UK, provided medical writing services on behalf of XYZ Ltd'.

References

1. World Medical Association (WMA). Declaration of Helsinki – Ethical principles for medical research involving human subjects. 2013 [cited 2016 Aug 18]. Available from: http://www.wma.net/en/30publications/10policies/b3/.
2. Battisti WP, Wager E, Baltzer 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):461-4.
3. Altman DG, Simera I. Responsible reporting of health research studies: transparent, complete, accurate and timely. J Antimicrob Chemother. 2010;65(1):1-3.
4. Gattrell WT, Hopewell S, Young K, Farrow P, White R, Wager E, *et al*. Professional medical writing support and the quality of randomised controlled trial reporting: a cross-sectional study. BMJ Open. 2016;6(2):e010329.
5. EQUATOR Network. 2016 [cited 2016 Aug 18]. Available from: http://www.equator-network.org/.
6. Author Aid. Annotated journal article. 2013 [cited 2016 Aug 18]. Available from: http://www.authoraid.info/en/resources/details/648/.
7. EQUATOR Network. Structure of a medical research paper: key content elements, writing tips and examples of reporting guidelines from the EQUATOR website. 2013 [cited 2016 Aug 18]. Available from: http://www.equator-network.org/wp-content/uploads/2013/10/Handout-Structure-of-med-res-paper-RG-checklists_FINAL.pdf.
8. Wells WA. Me write pretty one day: how to write a good scientific paper. J Cell Biol. 2004;165(6):757-8.
9. Kallestinova ED. How to write your first research paper. Yale J Biol Med. 2011 Sep;84(3):181-90.
10. Hopewell S, Dutton S, Yu LM, Altman DG. The quality of reports of randomised trials in 2000 and 2006: comparative study of articles indexed in PubMed. BMJ 2010;340:c723.
11. Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, *et al*. CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. PLoS Med. 2008;5(1):e20.
12. Govani SM, Higgins PD. How to read a clinical trial paper: a lesson in basic trial statistics. Gastroenterol Hepatol (N Y). 2012;8(4):241-8.

Michael Jonathan Riley
Trilogy Writing & Consulting Ltd,
Cambridge, UK
michael.riley@trilogywriting.com

Box 1. A few basic procedural and writing style tips for clinical study papers

- It's often appropriate to write a basic outline with a few sentences, tables and figures (maybe placeholders), and to check that the study sponsor, author and/or a senior colleague is happy with it before writing the first draft.
- Try to overcome writer's block by:
  - Writing the easier sections or parts of the easier sections first, i.e. often in the order of Methods, Results, Introduction, Discussion.
  - Not labouring over choice of words (an author may rewrite text that you spent hours beautifully constructing anyway!), e.g. leave sentences and paragraphs unfinished or not worded perfectly, as you can complete them later in this draft or they may not need further revision, maybe after seeking advice from a colleague.
- Scientific papers are often written with personal "we did" and "our study" statements, particularly in the Methods and Discussions sections, whereas authors of clinical study papers often prefer less or no use of personal pronouns, e.g. instead of "We randomly allocated patients to …" consider stating "Patients were randomised to …".
- Subheadings in the Methods and Results sections will often aid readability.
- Use transition words (e.g. "however", "although", "while", "whereas", "conversely", "in addition") at the beginning of sentences and midway through sentences, particularly in the Introduction and Discussion, in order to allow trains of thought to connect and flow.
- When discussing the study and other studies in the Introduction and Discussion, it is often appropriate to use words such as "suggest" rather than "demonstrate" to avoid overstating the implications of the findings.
- In the Discussion, when discussing several strengths or limitations, flow and readability may be aided by starting sentences with "First, …", "Second …" etc., and "Finally".
- Avoid using multiple terms when one will suffice, particularly if it could confuse the reader, e.g. "patients", "subjects", "participants", or "individuals" – some authors use "healthy volunteer" and "patient", although it is worth remembering that patients are also volunteers!
- For clarity and readability, keep the paper succinct, possibly replacing data in the text with tables and figures or by rewriting or deleting text; however, keep essential data and information in the paper so that the study is reported completely.
- While readability may be enhanced by using various sentence lengths, try to avoid exceptionally long sentences (>40 words may be too long, particularly without appropriate punctuation with commas, brackets and semicolons).

Getting Your Foot in the Door

SECTION EDITOR

Raquel Billiones
rbilliones@clinipace.com

Editorial

It's been almost six months since the first EMWA Internship Forum (IF) in Munich. See what our IF team have to say about their first IF experience on pages 62-63.

Even though we are already planning the next one for the spring meeting in Birmingham in May 2017, we also need to look back at the lessons we learned in Munich. And more important, we want to know whether the IF is serving its purpose. So I requested IF participants to share with us a status update on their quest of getting into medical writing. We are happy to hear from Sara Rubio who landed an internship through IF. Zou Yen Lee did not get an internship but nevertheless is determined to get into the field and finding creative ways of gaining knowledge and experience while applying for medical writing jobs. Ananya Malladi missed the IF by a couple of months. But she's making up for lost time by gobbling up all information she can find on the EMWA website and other resources about medical writing. Three aspiring medical writers with three different stories to share. I think we all agree, they have come to the right place.

Finally, I thank Kathryn Lee for sharing with us her experience as speaker at a careers event in the UK. We need more people like her to engage with and mentor the likes of Sara, Zou Yen and Ananya!

Raquel

EMWA's first *live* Internship Forum: Bringing opportunities to life

When I first read about the EMWA Internship Forum (IF) earlier this year, an exciting thought crossed my mind: "This must be it! The opportunity I need!" I had been looking for an entry-level position as a medical writer for months, but none of my applications had the happy ending I was hoping for. Coming from a basic research academic environment, the path to a role in the fast-paced, commercial environment of medical communications is not easy. Neither for me nor for the many people in my same situation whom I met along the way. But difficult does not mean impossible… and my example is just one of the many cases out there.

Back to May 2016. There I found myself, along with some people I had met during the EMWA conference, at the *Live* IF in Munich. The first detail I noticed was the excellent onsite organisation, which was in line with the great online information about the EMWA internship programme on their webpage. The second feeling, immediately noticeable, was the excitement and eagerness of both the applicants and the company representatives to start meeting and chatting. Wasn't that a sign of how this initiative was much needed?

Sara Rubio

The first half of the *live* IF consisted of appointments that we had booked beforehand via the application on the EMWA website. In my case, I did not have so many prearranged meetings, but the organisers solved this situation by matching me with free slots that some companies still had (again, thumbs up for the awesome organisation!). The company representatives were genuinely enthusiastic and made the most of the ten-minute chat with each applicant. I had the time to show my motivation, hear about the company and the potential internship, and still ask a few burning questions.

During the free time between appointments with companies, we had the chance to speak with some of the IF organisers who were sharing advice on how to improve and showcase our skills, how to get that elusive first interview… Actually, one of the best aspects of the forum in particular, and of the EMWA conferences in general, is the ease of interaction with everybody and the willingness of people to help others. I am still amazed at how many delegates I talk to every time I go to an EMWA conference!

The second part of the forum was an informal meet-and-greet session, where people were able to mingle whilst having drinks. Many participants stayed well after the official closure of the session, again showing how productive the experience was. I am glad to hear the forum is intended to be a recurrent event at the spring conferences. Even more, I would suggest implementing an autumn session in the future, logistics allowing, to make room for the many companies and applicants that I am sure would like to join the initiative in the coming years.

The icing on the cake of my experience is the amazing internship I started recently at Costello Medical Consulting (UK), where I am learning so much and putting my skills into practice in real projects… and that's thanks to the EMWA IF! I am indebted to the organisers and to all the people I had the chance to interact with. As I mentioned earlier, the transition from academia to a career in medical writing is a challenging journey, but one definitely worth taking if you are passionate and have the skills for it. Fortunately, initiatives such as the EMWA IF are easing the way to applicants while providing the medical communications industry with enthusiastic and dedicated people.

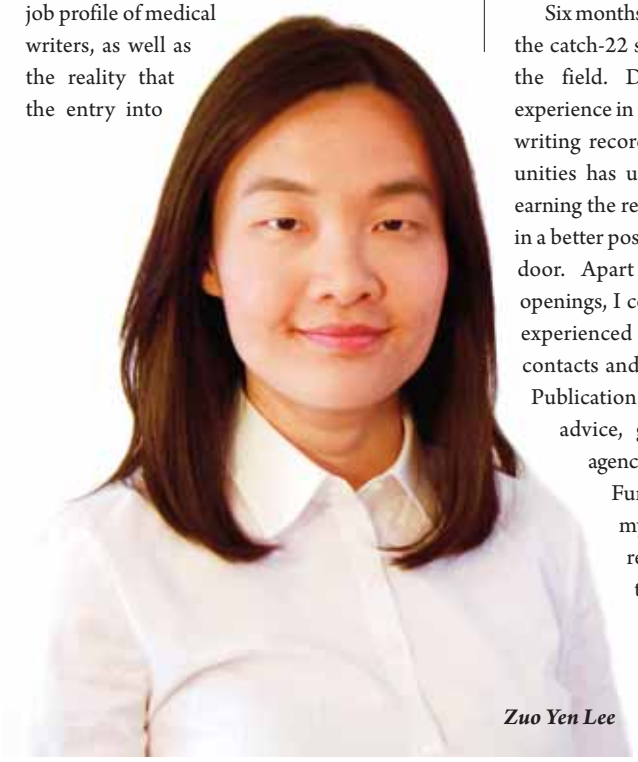
Sara E. Rubio
PhD in Biomedicine
University of Barcelona, Spain
Costello Medical Consulting
Cambridge, UK
sara.e.rubio.a@gmail.com

Editor's Note: *Check out the Costello Internship Programme in the GYFD, MEW Sept 2016 issue.*

EMWA Internship Forum: My journey six months on

Towards the mid-term of my PhD study, I knew that I would leave academia and research, but I did not have a clue to which field I would make my career move. One thing that was certain was that wherever I go, I wanted to use my scientific training. I talked to alumni of my institute who have made their move to the industry, visited career fairs to find out the industrial options available for life scientists, and attended workshops to learn to identify what other competencies I possess apart from scientific research. None of the job roles seemed to have the glowing attraction I needed for making the decision – that was until I wrote my paper and dissertation towards the end of my PhD. I rediscovered the joy of writing! So science plus writing give an evident answer: medical writing is the career step I want to take.

In the process of searching for an entry into medical writing, I was excited to come across the Internship Forum (IF), which was held in conjunction with the EMWA 2016 Conference in Munich, catered to beginners wishing to step into the profession. Nothing is more direct than gaining hands-on experience in a professional environment in preparing for a medical writing career. On the same day of the forum, I attended both Helen Baldwin's Introduction to Medical Writing and Phil Leventhal's Getting Your Foot in the Door seminars. They provided illuminating information on the job profile of medical writers, as well as the reality that the entry into medical writing might not be as "grand" as I imagined it would be. The registration for the participation in the IF was straightforward. Ten companies were offering internships and seven of them were present in the forum. I was lucky enough to be granted a slot by two companies, and grabbed the chance to introduce myself to the others at the following open session during which everyone was invited to interact with their companies of interest. It was an encouraging atmosphere to find numerous other aspirants around me responding to questions and discussing with the companies' representatives. Moreover, I truly enjoyed the informal and flexible setup of the forum.



Zuo Yen Lee

From the overwhelming response of attendees in the forum, the internships available were way outnumbered by the applicants, with more than half of us bound to be turned down. I only hope that there will be more companies willing to jump on the internship bandwagon and hence offer more opportunities to motivated beginners. With the rapid growth of pharmaceutical and biotech industries in Asia-Pacific, multinational companies should create more internship opportunities in medical writing in this region. This could potentially kill two birds with one stone; it not only increases the availability of internship positions, it may also smooth the transition of biotech professionals originating from Asia-Pacific region to take up a position where they could maximise both their scientific expertise and inter-cultural competence.

Six months on since the forum, I have realised the catch-22 situation for an academic to enter the field. Despite having some years of experience in the diagnostic industry and a good writing record, the scarce entry level opportunities has urged me to be more creative in earning the relevant experience that will put me in a better position in making my first step in the door. Apart from burrowing through job openings, I continue to network with new and experienced medical writers through personal contacts and attending events like the Global Publication Planning 2016 in order to seek advice, gain information about writing agencies and any window of opportunity. Furthermore, I am also equipping myself with clinical research and regulatory affairs knowledge by taking online courses and participating in the Regulatory Affairs Certificate Program run by the Regulatory Affairs Professionals Society (RAPS) to boost my competence specifically in regulatory medical writing. Through these, I have learnt not to limit myself on one single path to enter medical writing but to utilise my writing skills and the newly gained knowledge for positions in regulatory affairs and clinical trial management, which to an extent share overlapping functions with medical writing.

The IF has indeed provided me a few important road signs in my transition from academia to medical writing. The journey is still going on, and 'all roads will lead to Rome'.

Zuo Yen Lee
PhD in Biology
Swiss Federal Institute of Technology
Switzerland
zuoyen.lee@gmail.com

Editor's Note: *One of the major hindrances that non-EU citizens like Zou Yen face is the issue of work permit. We hope to address this in upcoming editions of GYFD.*

Getting on the medical writing train

I have spent all my life studying. No, not because that's what I chose, but because I'm only finishing my Master's degree now at age 22. Schooling wasn't my choice. By the time I could fully comprehend why I had to go to school and that school just wasn't all about sharing lunch with the other kids, I was a quarter through. Then came the time to elect the majors. I went for biology because algebra and trigonometry were my worst nightmare's worst nightmare. Fortunately, though, I fell in love with the subject and spent three years learning the basics of microbiology (a favourite), genetics, and molecular biology. Then I set out to Germany to do my Master's degree in molecular biology, with the aim of pursuing a PhD afterwards. Going through the innumerable job search websites and a bunch of rejections later, I realised I had no special trick up my sleeve. I never learnt a computer language nor specialised in operating a complicated microscope. English fluency was my strongest card and I was looking for options where I could put this to the best possible use.

After spending a whole week with an existential crisis, one fine day, a PhD student in my lab asked if I could help her with a grant she was writing. Having never written a grant in my life, I was frank about my inadequacy for the said task. She said it didn't matter at all because I just had to check the grammar (as she wasn't a native English speaker and I was). Observing the ease

with which I could present her subject in a polished way, she recommended a book called *Career Planning for Research Bioscientists* by Sarah Blackford. This book briefly details the alternative career options available for bioscientists and helps one figure out through a series of activities the best fit. Twenty pages into the book, I was shocked to realise there existed a career option called Medical Writing. A few quick web searches later, I was planning a life around medical writing as a special skill and a field for my PhD.

The first link of contact was a freelancer in Berlin. I thought it would be great to write to her, ask her if I could work as an apprentice under her supervision and get the basic understanding of the workings in this field. I was pretty optimistic, because who wouldn't want free help? Right! Right? Only then came the very polite reply about how she wasn't writing anymore but was teaching how to write. On the bright side, though, she provided me with a bucket of useful information about organisations that could help people like me. The first was EMWA. It was close to three months ago when I first opened their homepage. I took my own time to get familiarised with the organisation, their events, the way it works, all the previous and the upcoming events. Then I started attending the webinars, one at a time, all of them. I always had the EMWA page open in one of the tabs, and I was watching every update they posted, like a stalker.

Ananya Malladi

By this time medical writing was no longer a skill I wanted to acquire, it was a career choice. I was so passionate about this field, I had a nagging sense of unfulfilment when I didn't do anything related to medical writing for a day or two. During these searches, I found a whole lot of reading material on the internet. Two of the most helpful reads to start a journey to this field are *Science Research Writing* by Hilary Glasman-Deal and *From Academic to Medical Writer* by Annick Moon. After getting the basic knowledge I was suddenly worried my inexperience would haunt me and took every opportunity to change this. I took a poster that summarises the work of our research group and translated it from German to English with my elemental knowledge of the former. It was very basic, but it gave me a boost of confidence. The more I searched on the internet, the more resources I found. I attended a free course on the basics of medical writing offered by Duke University. I made copies of any reading materials I found on medical writing, including articles from *The Write Stuff* archive and carried them everywhere I went. I read the articles during my daily commute, during lunch hours and as bedtime tales. During my stalking, I stumbled upon the volunteer section and approached the members of the EMWA executive committee (EC). I enquired if I could help as a volunteer despite my lack of experience in this area. I received a response within hours and my first task was to help them review a draft of *A Career Guide to Medical Writing* from a beginner's point of view. Working on that document, I learned more about a career in medical writing than I did during the three months of wandering around the web. I also had the opportunity of interacting closely with Raquel, an EC member and EMWA journal associate editor who answered my numerous questions. Another useful source of information is MedCommsNetworking Community (www.medcommsnetworking.com). Their weekly letter is a wonderful compilation of tips for freelancers, reviews of past events, updates on upcoming events, and job vacancies.

So what's on the horizon? After having been advised on the importance on having knowledge over a vast number of subjects, I started attending a free online course on statistics. This has proven to be more fun than I anticipated. I also have an online medical writing course at the Stanford University coming up (due to students' perpetual poverty, free online courses are a boon). As it is already evident that I am a big fan of EMWA, I look forward to spending some quality time on my application for the Geoff Hall Scholarship. I am also eager to contribute to the EMWA journal, starting with this piece.

Ananya Malladi
MSc in Molecular Biology
University of Jena, Germany
ananyamalladi13@gmail.com

Engaging with tomorrow's medical writers

In May 2016, after volunteering to help with a careers event at the University of East Anglia (as a freelancer living locally), I was asked to speak about medical communications at a session for PhD graduates and research staff.

After providing an overview of the different types of medical writing activities, my presentation focussed on regulatory writing within the pharmaceutical industry, including the skills required, personal tips for success and raising awareness of available resources (including EMWA). Representatives from medical communications agencies spoke about recruitment and example career pathways; the session concluded with an interactive question and answer session.

The event was very well attended and positive feedback indicated a strong interest in medical communications as a career option. Students felt informed about the diverse backgrounds and careers of medical writers and gained an understanding of skills which could be transferred from academic research.

From a personal viewpoint, as someone in the Out On Our Own community, it was an excellent opportunity to share knowledge and experience to inspire others. I was subsequently asked to consider joining the University student mentoring programme – allowing further sharing of expertise and promotion of our rewarding profession.

Kathryn Lee
Kathryn Lee Medical Communications Ltd,
Norwich, UK
kathrynlouiselee@btinternet.com

Profile

SECTION EDITOR

Beatrix Doerr
beatrix.doerr@gmail.com

An Interview with the organisers of the first Internship Forum

When I attended my first conference as Public Relations Officer in Dublin, I was approached by "newbies" looking for a job. I was quite impressed that people invested such a considerable amount of money to attend the conference in the hope of increasing their chances at finding a job. Anyone this motivated certainly deserves some assistance.

As I realised that many people are unaware of their strengths and how to "sell" them, my first idea was to develop a mentoring programme. It turns out that life had a different (and in hindsight better) plan. It was at the November 2015 Autumn conference that Danae Rokanas and Derek Ho independently approached the Executive Committee with the same idea – to develop an Internship Forum. At first I was not convinced at all as I didn't see why people with a university degree should work for minimal pay. But who am I to know the situations of the newcomers better than the newcomers themselves? Further, I saw this also as an opportunity for experienced medical writers to explore other fields of medical writing outside their own expertise, which is typically difficult for freelancers.

The "greenlight" of the Executive Committee was obtained at the same conference and we had the go for a pilot Internship Forum at the Munich Spring conference. Danae and Derek both agreed to work on the organisation of the Forum and soon Harald Meier joined. It was a tough journey as time was very short and there were myriad things to do, but it was also fun. I very much enjoyed working in a multi-cultural, "multi-lingual", "multi-experienced", and "multi-aged" team, as it brought different yet complementary skill sets to the table. It is now my pleasure to lead the interview with my fellow teammates: Danae, Derek and Harald.

Harald Meier

MEW 1: Danae and Derek, how did your idea of an EMWA Internship Forum start?

Derek: I obtained my EMWA foundation certificate after the Fall 2014 conference in Florence. Despite having acquired a strong theoretical foundation from the workshops, I certainly didn't feel ready to work as a professional medical writer without additional training and mentoring. This is why I didn't want to begin my medical writing career as a freelancer as some colleagues suggested; I didn't feel confident enough.

Furthermore, despite having an EMWA certificate on my resume, I wasn't consistently getting responses when I submitted job applications. Many medical writer job announcements, even for junior level positions, require some degree of professional experience, which I didn't have.

To make a long story short, after receiving my EMWA certificate I felt like I was in a "now what?" situation. It was at this time that I emailed all of my EMWA colleagues and asked them for their opinion on the following question: what if EMWA could develop some kind of an internship program where junior medical writers are connected with companies willing to provide them with training?

Danae: My idea to start an EMWA internship forum came around the same time that I joined EMWA: November 2015. The first conference I attended was EMWA's 41st held at The Hague, Netherlands. At the time, I was one of the "newbies". For two months I had been frantically looking for an entry-level job in medical communications and had been repeatedly turned down – either due to a lack of adequate higher-level qualifications (a PhD was preferred) or lack of relevant experience. I soon came to realize that there were no real 'entry-level' jobs. So, how could I get a job without experience and experience without a job? That was the question!

I joined EMWA for some guidance. I was surprised to meet so many young, like-minded individuals facing a similar predicament and decided to take matters into my own hands. Finally, I used the networking session as an opportunity to approach Ms Sam Hamilton, EMWA's President at the time. I proposed my idea: *What if EMWA could create an internship programme whereby graduates (fresh out of university and with no prior experience) could be introduced to interested companies who could offer them a career in the field?* Ms Hamilton was enthusiastic about the idea and introduced me to Phil Leventhal who then introduced me to our team. The rest is history!

MEW 2: What was your motivation in participating in the Internship Forum team?

Derek: My motivation was pretty

Derek Ho

simple. If I suggested the idea of an Internship Forum, and if I wanted it to happen, then I needed to play an active role in getting it off the ground. Being an active participant in the development and planning of the Internship Forum also gave me a chance to shape the program in a way that I felt would best suit everyone involved.

Danae: My motivation was fuelled by a realisation. After much research and many job applications, I finally came to the conclusion that there was a gap in the job market for young graduates aspiring to start a career in medical communications. My intention was to bridge this gap with EMWA's help; to leverage EMWA's prestige and high standing in Europe to help introduce young graduates to interested companies in the field. No such programme existed, so we created it. I am very proud of what our team has achieved in only a few months.

Harald: During my many attempts to find a job in Munich, I was told the same thing by numerous CROs: "We acknowledge that you are well educated, and have valuable skills to offer, but you do not have any experience in the field of medical writing." So how could I get experience? My question remained unanswered.

Soon enough I attended my first EMWA conference at The Hague where I met young, smart and talented biologists who shared similar problems getting into the industry. They were either unemployed due to a lack of relevant (or prior) experience, or had obtained a job offer without promise of pay. I was very pleased when I heard from Beatrix about the idea of an Internship Forum with a view to support prospective talents in medical writing on their way into the industry. I immediately jumped on board!

The Internship Forum team can be contacted at:
Danae Rokanas
danae.rokanas@outlook.com
Derek Ho
derek.ho@helsinki.fi
Harald Meier
meierh@in.tum.de

MEW 3: What did you like best about the pilot Internship Forum in Munich?

Danae: Undoubtedly, for me, it was the atmosphere. The enthusiasm and positive energy in the room. The wide spectrum of nationalities and ages present. The genuine interest in our event was truly overwhelming. It was very encouraging to see our project welcomed and positively received by so many. Overall, the fact that *all* participants were satisfied with their meetings with applicants or companies; that participants asked for follow-up events with a more extensive programme lasting half a day at the next Spring Conference; and that 82% rated our event 4/5 or 5/5; are all positive indicators of an all-around successful programme definitely worth developing further. Our hard work paid off!

Harald: The work over several months – from the first ideas to the promotion of the event, from the continuous attempts to attract companies and encourage internship applicants to participate, to the final decision on how to place the tables at the Forum's launch – it was all guided by one concern: "will it work?"

Minutes before the Internship Forum launch event, I was pretty nervous. We had attractive companies, many internship applicants, and the tables were perfectly arranged.

Then it started. All nervousness was suddenly gone. All the applicants found their way through the tables to their assigned company representatives. They spoke about their business and envisioned a possible future together. Our idea had worked. I definitely liked that best!

Danae Rokanas

Clarity and Openness in Reporting: E3-based (CORE) Reference

An Open Access Resource to Support Authoring of Clinical Study Reports for Interventional Studies

DOWNLOAD THE LAUNCH PUBLICATION: http://dx.doi.org/10.1186/s41073-016-0009-4

DOWNLOAD THE USER MANUAL: http://www.core-reference.org

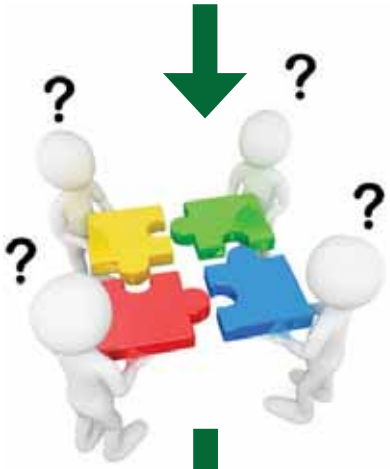
WRITE OR REVIEW CLINICAL STUDY REPORTS (CSRs)?

WRITE OR REVIEW STATISTICAL ANALYSIS PLANS (SAPs)?

YES

NEED HELP INTERPRETING ICH CSR AUTHORING REQUIREMENTS?

NEED HELP UNDERSTANDING PUBLIC DISCLOSURE REQUIREMENTS FOR CSRs?



WHAT IS 'RESPONSIBLE CLINICAL TRIAL DATA SHARING'?

HOW DOES PUBLIC DISCLOSURE AFFECT CSRs AND PRESENTATION OF DATA?

SHARING KNOWLEDGE TO HELP YOU WRITE FIT-FOR-PURPOSE CSRs

Working in these areas?

- Medical Writing
- Regulatory Affairs
- Statistics
- Clinical Research
- Publication Planning
- Medical Communications
- Clinical-Regulatory Document Public Disclosure
- Regulatory Document Publishing

You should know about: http://www.core-reference.org

Please inform your senior colleagues

Consider CORE Reference a 'User Manual' that may be used in conjunction with company Standard Operating Procedures to support the authoring of Clinical Study Reports fit for today's modern drug development environment.

Out on Our Own

SECTION EDITORS

Julie Charlesworth
julie@atreeoflifesciences.com
Satyen Shenoy
sshenoy@describescientific.de

Editorial

In this edition of OOOO, we are pleased to bring to you four diverse and thought-provoking articles, and some practical tips. We thank you for your contributions and once again invite you to submit any articles that you wish to share with your fellow EMWA members.

At the EMWA Conference in Spring 2016, we introduced the Freelance Business Forum (FBF) to the concept of informal local get-togethers as an opportunity for freelancers to interact and network with others with similar and related interests in close proximity. This idea has already made solid ground in the UK and freelancers based there are meeting regularly. In her article on local get-togethers in the UK, Corinne Swainger, with inputs from fellow UK freelancers, relates how this came about and how relatively simple it can be to organise such gatherings. We think these pointers and tips would be very useful for others who wish to set up such events in their region. It is also very heartening to see that some of our freelancers are now taking the initiative to facilitate local networking in other countries such as France and Germany. Carola Krause and Paul Wafula, two of our members based in Germany recently organised a local get-together in Berlin and in their article they share their experience of what was clearly a wonderful evening.

Freelancing as a profession is growing Europe-wide and increasing numbers mean that, the 'solopreneurs', require adequate representation when it comes to policies and guidelines relating to self-employment framed at a national and regional level. So, what are the issues? Continuing the theme from his article in the previous edition of OOOO, Marco Torregrossa, the Secretary-General of the European Forum of Independent Professionals, advances a discussion about how our numbers are making a statement at the European level when legislation regarding labour markets is being drafted.

As professionals, we value our work, give our best to our clients, and expect a suitable remuneration in return. However, as in any business, negotiating the rates for our services is a constant concern requiring careful consideration. In bringing to you an article by IPSE on negotiating pay rates, we hope to give you that extra leverage when next your clients say, "We'd like you to do this project for us. Please send us a quotation."

As the holiday season approaches, we'd like to wish you all a very enjoyable and relaxing time and a Happy New Year. Finally, we hope that you will continue to provide us with articles and suggestions in order that we may continue to further the freelance cause. Happy reading

Julie Charlesworth
and Satyen Shenoy

Successful informal freelancer meet-ups increase local UK networking

Although I really value the freedom and flexibility that I've had over the past ten years as freelance medical copywriter, I often find that it can become very socially isolating – despite being surrounded by social media 24-hours a day. And I'm not the only one. Various studies also show that it's important for people who work remotely to regularly interact with real people, especially their peers.[1]

Annual and bi-annual industry conferences, organised by professional groups such as EMWA, offer an excellent opportunity for freelancers to enhance their specialist skills, hear opinion leaders' views, and network with other freelance and full-time colleagues. But while you may stay in touch with them online, the reality is that you probably won't see them again on a face-to-face basis until the next major conference.

That's why, towards the end of 2014, I was very interested to see that two established UK freelance medical writers – Jane Tricker and Michael Shaw – had each started small, informal get-togethers on a regional basis. They were promoting these gatherings on LinkedIn through the MedComms Networking website (http://www.MedCommsNetworking.com), which is a social networking community for professionals working in and around the pharmaceutical communications industry.

Word spreads fast

Since 2014, word about the success of these informal, regional meetings has spread fast. Over the past year, other medical freelancers have started organising their own gatherings in various regions of the UK, including Kent, Cheshire, North West London, Cambridge/East Anglia, Leeds, North Wales, Brighton, Central Scotland, and North East UK.

Jane Tricker, who organised the first of these initial informal freelancer gatherings, explains what prompted her to get started. "I was on a panel of experienced medical writers at three of the original MedComms Freelancers Workshops that Peter ran, held in London, Oxford and Macclesfield. There, I got the strong impression that medical freelancers benefit hugely from sharing their experiences in informal surroundings – in terms of practical hints and tips and moral support."

"I held the first get-together in November 2014. I just chose a pub and a date, and let people know through the MedComms LinkedIn pages. We had seven people that evening, including five freelancers – writers and editors – from across Kent and one copywriter from London. I thought about raising some subjects that freelancers might want to talk about, such as training or time management, in case it was difficult to get it going, but once everyone had introduced themselves, the conversation flowed quite naturally."

New freelance colleagues

After contacting Jane and Michael for their advice, I decided to arrange an informal get-together of my own in June 2015. After posting an invitation on the MedComms LinkedIn page, I wondered if anyone would reply to it. However,

I didn't have to wait long. Six people attended our first get-together in North West London, which included three freelance medical writers, a medical editor and a project manager. Some were members of EMWA or other professional industry groups, while others were not. But having a mix of different freelancers really fuelled our discussion about the challenges of balancing life, family and finances as a medical freelancer, and generated some laughs about dealing with difficult clients.

Since we began, the NW London group has had three more informal meetings. It's been great to stay connected to new colleagues. The numbers of attendees have varied depending on each individual's schedule. However, even three people in July 2015 were enough to have a good chat, discuss personal and professional freelance issues, and gossip about local and international events. At one get-together, we were joined by an in-house writer who was thinking about going freelance and wanted to hear our first-hand experiences of life as a medical freelancer.

Keep it informal

Because these local informal groups are not necessarily 'owned' by any one professional association, they are open to all medical freelancers. So you don't need to pay any membership fees, event fees or major transportation costs. Essentially, they are a great way of complementing larger associations, rather than competing with them.

Smaller informal meetings for new and experienced medical freelancers help to spread the word about upcoming opportunities across regional, UK and global communications. Each group tends to adapt these meet-ups to match their own needs but there's one overriding message each of the organisers mentioned: "Keep it informal."

> Informal freelancer meet-ups are an excellent way of discussing your own business challenges, sharing freelance opportunities, making new local friends and laughing about life.

"Personally, I wouldn't want to do anything too formal and I think medical freelancers just enjoy talking to other freelancers. You don't need to set up any structured meeting. News about industry topics and training sessions just gets passed on through our casual conversations," says Jane.

Definitely worthwhile

Jen Lewis, a freelance medical writer and director in Norfolk, started a regional group across the Cambridgeshire/East Anglia area. "It's definitely worthwhile organising an informal freelancer meet up. From my point of view, it's a great way of sharing your experiences in business, and just knowing that there are others in the same boat as you are," she says.

"We try and meet a few times a year at different locations, alternating between two towns in the middle of our rather large geographical area," she explains. "We also meet on different days of the week and at different times of the day or evening. Rather than pre-book a table, we generally just meet at a certain pub that is likely to be able to accommodate us, and let everyone decide what to do about food or drink once we've arrived. One exception to that was our Christmas meal, where we did book a table. A few of us had been reminiscing about office Christmas parties, so we thought we'd have our own last year. It was a fun night and great for creating a stronger bond within our small group."

Make it easy to access

"The North West UK group is small and spread out across various areas," says Lisa Stewart, a freelance writer who organises an informal group in Cheshire. "We meet at a pub-restaurant that is conveniently located on a motorway junction so this makes it easy to access, even for people who don't know the area that well. We are aiming for quarterly get-togethers around 8pm. The first time it was just a drink, although a couple of people chose to eat. For the first meeting, I took a little sign that said 'Med-Comms' to identify myself. But since then we have booked a table in the restaurant section so people can ask the staff where we are sitting. I'd say about three-quarters of our attendees now eat there. Some people have asked about lunch meetings but there seems to be very little enthusiasm for that."

New work opportunities

Fiona Weston, who runs Weston Editorial Services, organised a local Leeds get-together in July 2016. "It was attended by about 5 people in addition to me," she explains. "We opted for a lunch meeting since everyone involved had to travel a fair distance, and evenings were difficult for a few freelancers because of children and other domestic responsibilities. I booked a

8 tips for launching local freelancer meetings

Although there are no set rules for organising your own medical freelancers' gatherings, the following tips may help:

1. **Choose a convenient date:** try to avoid scheduling these in the Summer holidays; too close to Christmas, or other major medical freelancer or industry events
2. **Find an easily accessible location:** such as a local pub or restaurant with close links to public transport and low-cost/free parking
3. **Post these details on LinkedIn pages:**
   - Post your local meeting details on your own LinkedIn page and ask any freelancers who are interested to contact you through that
   - Also contact Peter Llewellyn (peter@networkpharma.com) to post the details on the MedComms Networking site
4. **Spread the word:** encourage all local medical freelancer professionals you know to attend, including members and non-members of EMWA, such as independent medical writers, editors, project managers, directors, translators and consultants
5. **Give people at least 4-6 weeks' notice:** before the event, and send out frequent reminders through emails and your LinkedIn page during that time
6. **Keep it informal:** at the gathering, introduce yourself as the organiser, and allow all freelancers to just network amongst themselves, and decide if they personally want to eat or drink
7. **Consider using Doodle to schedule future dates:** try setting up a Doodle poll (http:// doodle.com/) to arrange a future get-together for attendees who are interested in meeting again. This is a quick way to find the most convenient date and time for everyone.
8. **Try meeting around 3-4 times a year:** depending on your attendees' availability

restaurant with the aim of us all eating lunch, and then I brought along a voucher for that, which meant we all saved money on the cost, pleasing everyone!"

"We all seemed to enjoy meeting fellow medical freelancers in the region. One of the people who attended it asked another freelancer to do some work for her when she got behind with a project. So it worked out well for both of them, as they had not met before until that lunch."

"I think it is worth planning meetings locally to keep contacts going and to give us all a sense of being connected – freelancing can be a lonely business for some. We are planning our next meeting later this year in October."

Regular real-life benefits

"I think these informal get-togethers are very valuable as it's very easy to become isolated as a freelancer," points out Michael Shaw who held the second informal freelancers meeting in Brighton and Hove on the south coast of England. "We're a small group, and always meet in a pub with good transport links and reasonable parking. At least one of us will have a photo on LinkedIn, so recognising each other isn't a problem! We just meet informally – some people eat there, others don't."

Personally, one of the key benefits for me in organising and attending the group in North West London is the chance to interact with real, live colleagues on a more regular basis. I enjoy finding out how other freelancers are handling their businesses and lives within this industry. Some freelancers have recommended local website designers and accountants. And now that we know each other a bit better, we have passed on opportunities to each other about potential new freelance projects.

On average, most informal groups tend to meet up around three times a year, and usually announce any meetings around 4-6 weeks in advance. It helps to avoid scheduling meetings in the school holidays or too close to major industry, communications or freelancer events, such as the EMWA conference.

Open to all medical freelancers

Peter Llewellyn, founder and manager of the MedComms Networking community (http://www.medcommsnetworking.com/) has played a major role in promoting and encouraging these informal events. He says:

"Freelancers by definition, work alone much of the time. Sharing experiences and gaining support from other freelancers is very valuable, especially where there is common understanding of the specific issues involved. So local informal gatherings of freelancers working in and around medical communications can only be useful for everyone.

"I applaud those who have already taken the initiative to arrange these informal UK events. They are open to all medical freelancers. I hope we'll see many more such gatherings happening, and I'll certainly help spread the word about any I know of."

Just go for it!

If you're thinking of starting your own group, then Michael Shaw says: "Just go for it! There are no hard and fast rules – I get the impression that the various get-togethers around the country all have different formats, and all seem to be quite successful and worthwhile."

Reference

1. Parry L. Is freelancing a lonely business? 2014 [cited 2016 Sept 29]. Available from: https://www.theguardian.com/money/work-blog/2014/jul/22/freelancing-lonely-business

Acknowledgments

Thank-you to the following individuals for their contributions to this article: Jenny Fanstone, Jane Tricker, Michael Shaw, Fiona Weston, Jen (Jackson) Lewis, Lisa Stewart, Peter Llewellyn and Julie Charlesworth.

Corinne Swainger
MediQuill
Greater London, UK.
corinne@mediquill.com

EMWA encourages local meetings for medical writers and communicators

"EMWA is supportive of local medical freelancer gatherings which are often particularly useful to freelancers," explains Julie Charlesworth. She and Satyen Shenoy became the new co-hosts of the Freelance Business Forum (FBF) in January 2016. "We have promoted these informal meetings on the EMWA LinkedIn page. We have encouraged attendees to discuss this topic at the FBF in Munich earlier this year and also highlighted these meetings at the FBF in Brussels in November."

The FBF is a meeting held at the bi-annual EMWA conferences. It provides a platform for EMWA freelancers to share best practice and network informally with other freelancers from various countries in Europe. Julie and Satyen are also the new co-editors of Out On Our Own (OOOO), which is the freelance section of *Medical Writing*.

Networking through informal gatherings, the way in

One of the many take-home messages from the Freelance Business Forum (FBF) at the Munich conference was the call to expand networking activities among freelancers in their local areas under informal settings. The objective was simple but effective; to create an opportunity to help and support each other in solving daily challenges affecting freelancers in their businesses or even simply to just interact and get to know colleagues in our local areas. Some of us were attending the conference for the first time and being relatively new in the business, there was a need for such a forum not only for freelancers but also for those interested in the profession.

Taking heed of this message, we embarked immediately on planning to set up a meeting for colleagues in Berlin and its environs. The concept of local gatherings which involves minimal travel and minimal cost was inspiring. Together with other colleagues in Berlin and Brandenburg, we finally managed to organise our first meeting mid-summer this year. We would like to share with you our experiences in regard to the active involvement in the process.

More contacts

Setting up the informal gathering brought with it new contacts. This was in two phases; within the organising team itself and to a large extent, with the colleagues who were invited to the gathering. It was very encouraging that so many people accepted our invitations to attend. Those who could not make it expressed their willingness to join the next meeting. The reaction was impressive. In this business, networking and business contacts are important: the process helped us to expand our business contact circle.

Business opportunities

Getting to know new colleagues and interacting at a personal level brought more exposure to business opportunities. It led to getting referrals for business opportunities in cases where colleagues who got offers were not able to take up projects due to their other commitments at particular times. During the gathering itself, ideas on how to create more business opportunities and how to share them within contacts were also proposed. In addition, we saw it beneficial not to restrict our gathering entirely to freelancers as colleagues in fixed employment were interested to interact with other medical writers. This we saw as an important link to business opportunities in future.

Support, mentorship, and education

During the informal gathering, participants shared professional experience, information and how to approach new projects and contractors. It was encouraging to see the willingness of the more experienced medical writers to help out new colleagues in the business. The need to have education topics in our future meetings was suggested as a way to support others in areas we had expertise in. There was an atmosphere of everyone wanting each other to succeed.

Simply unwinding

In a relaxing atmosphere we also had the chance to have interesting general discussions on wine, food, and Berlin's history and culture. It was interesting to note that among the group, we had experts in aspects of life, other than medical writing. We shared our "positive accidents" of how we became medical writers and discovered we had more in common than being medical writers … we simply connected. We had colleagues who were reconnecting, having been workmates years before and not having met for a while.

All in all, it was an evening well spent; new professional friendships and contacts were made, we shared the goal of making each other better through business interactions. The responses of the community in general were great and led to the setup of our own "Freelance Medical Writers' informal gathering, Berlin-Brandenburg LinkedIn Group (www.linkedin.com/groups/8553972) and the initiation of periodic gatherings in the Berlin-Brandenburg area.

Acknowledgments

The Authors would like to thank Julie Charlesworth and Satyen Shenoy for the inspiration and the continuous support. Additionally, we like to thank Claudia Frumento, Henrike Bergmann and Ricardo Wilches for their assistance in organising the informal gathering in Berlin.

Participants at the second informal gathering at Café Orange in Berlin

Carola Krause
codeX-bioMedical Writing services
Potsdam, Germany
Carola.Krause@codex-biomed.com
Paul Wafula
Freelance Regulatory Medical Writer
Berlin, Germany
ojiambowafula@yahoo.com

How European solopreneurs are creating the future of work

Solo-entrepreneurs (solopreneurs) are fast becoming a very important part of the EU labour market. But those who work for themselves need better support from policymakers to ensure legislation is clear, accessible, and not overly burdensome.

Look around: the EU is experiencing a surge in independent working and the trend is growing. Coworking spaces have sprung up in towns across the continent and new independent professions are emerging. In the wake of the forthcoming EU Directive on the Single-Member Companies – currently debated in the European Parliament – support for solopreneurs is gaining ground across Europe.

Suppose tomorrow morning Mr Juncker wakes up and says: "I will never be able to create all the jobs I need in the present economic climate. So, I have to focus on generating as much quality work as I can for my fellow European citizens and attract more people into the labour market. I will focus on flexible and independent work instead. I will focus on empowering solopreneurs".

New ways of working have already transformed the entertainment, media, and publishing industries and the same is now happening in many other sectors – from transportation to accommodation, finance to education. Goods and services are becoming more readily and cheaply available, in smaller parts, and from a larger number of suppliers. Consumers expect to be able to order a cab, a movie, or even a doctor on demand. Today's companies, too, expect workers to be available on short notice, for particular tasks, with specialised skills. This means work is more available than ever, but in a different way than before. Instead of one job from one employer, workers now hold several jobs at the same time that originate from several places, and come in many shapes and sizes. Numerous sources of income and the ability to scale up or down according to time and need has become a growing feature of our economy.

To achieve the full potential of this emerging shift, policy makers must have a more heterogeneous, and less monolithic understanding of an evolving independent workforce, and begin shaping solutions that reflect this new reality of work.

The first step towards improving conditions is for solopreneurs to realise they are not alone. According to a 2015 press release from Eurostat, about 2.3 million enterprises were created in 2012 across the EU and most of them (71%) had no employees.[1] Solopreneurs represented 47% of all people employed in newly-born enterprises, making up the smallest of small businesses and the fastest growing segment of the EU labour market. Yet, to truly empower this new breed of entrepreneurs, we'll need to reimagine and reinvent the way public policy views micro-businesses.

There is no such thing as the "typical solopreneur"; they are an extremely diverse group of people and range from consultants to journalists, IT experts, artists, translators, and sportspeople. They can also be found in a growing number of new professions in the healthcare, finance, social, and education sectors. They often work in partnership with each other and as complements to employees, driving growth and work creation in enterprises. Yet, they are not only a source of innovation, as being one's own boss is also associated with greater professional satisfaction, job quality and improved work-life balance.

Despite all this, the significance of independent working is still not sufficiently taken into account in European legislation for micro-enterprises, as heard in an event organised by EFIP last December in the European Economic and Social Committee. European institutions should be bold enough to create more ambitious policies in support of solopreneurs. Solopreneurs should be defined as a unique subset of micro-enterprises with demonstrable value as economic agents in their own rights and proper recognition in official statistics. They need better regulation that specifically considers their needs, for instance by adapting the SME (Small and Medium Enterprise) Test and the "Think Small First" approach in impact assessments to the one-person SMEs. Finally, they should be given access to social security programmes, training schemes, funding instruments and tax benefits that are designed for people with steady paychecks and not for solopreneurs with variable income streams.

With these recommendations in mind, the forthcoming EU Directive on the Single-Member Companies[2] which will facilitate the provision of services for small business, is an opportunity to give fresh support to solopreneurs, above all those willing to establish and operate at cross-border level in the EU Internal Market.

The opportunity to fuel a whole new wave of innovation and support an expanding solopreneurial population is now. The future of work is here, and it's no longer just about creating jobs or matching supply and demand through online platforms. It's about creating the right infrastructure for people to find multiple and better alternatives than a traditional employment and build a framework in which progressive solutions can leverage this structural change.

References

1. European Commission – EUROSTAT. 9 out of 10 enterprises in the EU employed fewer than 10 persons – more than 1.6 million new solo-entrepreneurs in 2012. November 2015 [cited 2015 Dec 17]. Available from: http://europa.eu/rapid/press-release_ STAT-15-6109_en.htm
2. European Commission. Proposal for a Directive of The European Parliament and of The Council on single-member private limited liability companies. April 2014 [cited 2015 Dec 17]. Available from: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX: 52014PC0212

This article has previously appeared as a post on LinkedIn at https://www.linkedin.com/pulse/how-european-solopreneurs-creating-future-work-marco-torregrossaon [2015 Dec 17].

Marco Torregrossa
European Forum of Independent Professionals
Brussels, Belgium
marco.torregrossa@efip.org

How to negotiate the highest fees for your medical writing services

"Double your rate, double your practice," says the theory.

By being more expensive, not only is the work you do more profitable, but you somehow also become more desirable to clients, and you are able to land many more projects than before.

Does this sound too good to be true?

Does it work in the 'real world'? After all, why would clients pay twice as much as the going market rate?

Before you decide, consider this experience recounted by a freelance writer:

"I was listening to a webinar about marketing for freelancers. The coach was explaining how we tend to have a more rigid idea of the 'market rate', than our clients do, when in fact they may be willing to pay quite a lot more than we think. The only way to find out, he said, is to be bold. As a rule of thumb, you want about 20% of potential clients to turn you away because you are too expensive. If you are winning every single project you pitch for, it suggests that you could be undervaluing yourself.

"The coach urged us to double the price tag next time we were asked to quote for a project. To me this sounded like a ridiculous idea!

"Not long after that came the chance to quote for a year-long contract. It was a golden opportunity and I couldn't afford to mess it up. Despite that, I found myself thinking about the webinar. I felt I owed it to myself to give it a try. So, in a moment of madness, I quoted twice the rate I had charged on my previous contract. When I heard the number come out of my mouth, it sounded absolutely outrageous!

"I couldn't believe what happened next – they accepted without hesitation! And what's more, not only did they say yes, they also renewed the contract the following year, and for quite a few years after that."

This is a true story, although it's fair to say that not everyone will have such a smooth ride. Sometimes it requires skilful negotiation to achieve the highest possible fees without losing the deal.

But the story does illustrate how it can pay off to take a bolder approach to charging fees.

If that has inspired you, here are some techniques to improve your chances of success…

1. Focus on the things your clients really care about

In discussions about a potential project or contract, you are likely to have a deep understanding of the scientific context you're going to be writing about. But have you also considered the broader strategic context?

Often that is where your clients' real problems lie, and that is where you can find additional opportunities to add value.

For example, one writer was asked to produce a video script to explain the mechanism of action of an opioid medication for the treatment of chronic pain. On the surface, what the client cared about was how to communicate the drug's efficacy and safety in a way that could be understood by a wide audience, including patients.

However, by digging deeper during the conversation, the writer was able to discover the core challenge the brand was facing – primary care practitioners were reluctant to prescribe the medication because they associated it with a 'street drug'. This was the broader strategic context which the clients hadn't thought to share with the writer because they were focusing purely on the scientific messages that they wanted to include in the video.

When presented with the initial brief before being awarded the contract, the writer asked follow-up questions, such as "what other challenges are you facing?" This opened up a discussion around the strategic context, which inspired the writer to weave historical and social themes into the proposal, alongside the purely scientific material. This gave the clients confidence that the writer could produce work that was not only scientifically robust, but also closely aligned to the overall business goals.

It's also worth remembering that the thing that your client most cares about might not be purely professional. Is he or she wearing a sophisticated looking running watch? Are you passionate about running yourself? If you find a match like that, then you have a prime opportunity to create a strong connection, and a strong connection paves the way for a successful negotiation on price!

2. Emphasise your scarcity

"Well, it certainly was a record for polyester", remarked the auctioneer having just collected $145,000 for John Travolta's white suit from *Saturday Night Fever*.

The story is recounted by Dr Robert Cialdini, whose in-depth investigation into the psychology of sales and negotiation is captured in the international bestseller *Influence: science and practice.*

It shows the effect of scarcity on the human psyche. The suit was one-of-a-kind and the bidders were so gripped by the fear of losing out on this scarce item that it completely clouded their judgment, becoming locked in a fierce bidding war that went beyond all rational levels.

Marketers capitalise on this effect, often using artificial ways of creating scarcity, such as creating waiting lists or limiting the availability of a product to build a frenzy of desire – hence why people are willing to camp overnight on the street outside the Apple store before the launch of the latest iPhone.

But as a freelancer you don't have to fake scarcity. There are many attributes that can turn your writing services into a scarce resource. It certainly helps if you have researched your therapy area so deeply that very few people can match your knowledge on the subject. Do you have a PhD? Less than 2% of the population does, so if you're one of them, your knowledge is a scarce resource already. Don't forget to capitalise on that by charging accordingly!

But scarcity doesn't only come from deep knowledge. It can also come from broad knowledge.

Broad knowledge allows you to combine different elements to create uniqueness. For example, can you write to a high standard in more than one language? Or could you do a creative scriptwriting course and then adapt the skills to write medical video scripts?

Note: Mix and match your skills to become a 'cheeky scientist'. Find out more at www.cheekyscientist.com

The best option of all is to have knowledge that is both deep and broad – also known as being a 'T-shaped' freelancer.

In other words, the way to become a scarce resource is to focus on your points of difference. At the same time, it is important that your difference provides a solution to the problems that your clients need solving. Once you have identified, developed and refined your difference, don't forget to tell clients why you are different, how they will benefit, and why that commands the higher fees that you wish to charge.

Note: A useful tool to help focus the mind on the client's problem areas is the Value Proposition Canvas, which can be downloaded free of charge from www.businessmodelgeneration.com/canvas/vpc

3. Reverse the risk

Clients will often have hidden concerns that inhibit them from greenlighting a project. This could be anything from fear of being criticised internally for their decision, to perceptions of value, or even an irrational fear that freelancers might vanish into thin air in the middle of a project.

So it's very important to address these concerns early on in the negotiation. Matt Craven, who advises freelancers on CV and interview techniques offers the following advice:

During the initial interview or project pitch meeting there is usually a point during which the client asks "Do you have any questions?" Craven suggests you answer with: "Yes, is there anything that could prevent you from awarding me this project?"

Note: You can read more tips by Matt Craven at www.ipse.co.uk/advice/winning-work/closing-sale-turning-interviews-client-pitches

This is a direct approach, but it gives the client the opportunity to voice any concerns or objections. In turn this allows you to provide the relevant reasoning or evidence to show why the concerns are unfounded.

Another useful way to minimise the risk for the client is by crafting a strong guarantee. For example: "I charge 50% up-front and 50% upon delivery. As per my satisfaction guarantee, the second half will only be payable if you feel that the value created by the work has exceeded your investment". This would make it easier for you to compete with another freelancer who charges half your fee.

4. Believe

Patrick Forsyth, author of *The Negotiator's Pocketbook*, writes: "There is one additional source of power, one of major significance: confidence. If others believe they are dealing with someone confident, competent, organised and efficient then they may be less certain of their own position. Confidence comes from preparation, a structured approach, knowledge, and belief. Convince yourself of your confidence and you will convince them that you are a power to be reckoned with. As the saying goes: 'If you can fake confidence, then everything else is easy!"

This self-belief is what allows you to follow Forsyth's first rule of negotiating: aim high!

Note: IPSE Plus members can download *The Negotiator's Pocketbook* free of charge via www.ipse.co.uk/academy/virtual-ashridge

5. Continue to invest in your visibility

The first four tips relate to the actual negotiation itself. This final one is more about the ongoing activities that will put you in a stronger position whenever you sit down at the negotiating table.

Daniel Priestley, author of *Key Person of Influence*, makes the point that in every single industry there is a select group who earn more and have much more influence than the vast majority of people in that industry.

What is their secret? According to Priestley one of the key things they have in common is that they publish content regularly, whether through books, articles, blog posts or any other medium.

As a writer, publishing content is clearly the main thing you do. But are you only publishing content commissioned by clients?

The opportunity lies in publishing your own material as well, to become known as a thought leader in your field. For example, if you have a PhD, how could you make the best use of all that research? Perhaps you can turn your thesis into a series of blog posts. Or are there any public speaking opportunities you could explore? Do any of your current or potential clients publish an in-house magazine – could you offer to submit articles, or even a regular column, to build your visibility within that company?

Building visibility is hard work. However, a study by Hinge Research Institute, suggests that it is an excellent investment.[1]

They surveyed 130 consultants and divided them into five levels. Those on level 1 in terms of visibility were recognised as experts by their clients and colleagues, but not well-known outside of their immediate circle. Those on level 5 were globally recognised 'gurus'. The difference in earning capacity was enormous – those on level 5 charged 14 times more than those on level 1.

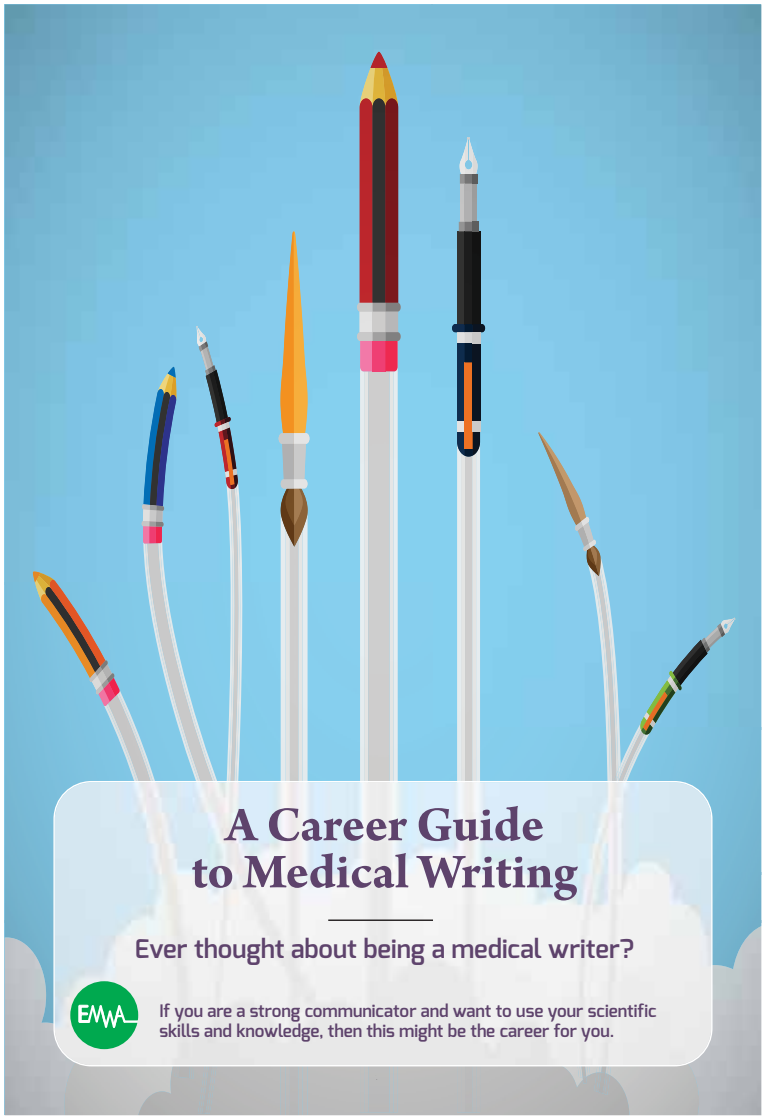
So it's worth thinking creatively about all of the potential channels where you could demonstrate your expertise to your target audience. After all, in the digital age, the possibilities are endless, and if you only manage to shift from level 1 to level 2, that is still a big jump in earnings!

Reference

1. Frederiksen, LW. Visible Expert Research Study: Management Consulting Edition. Hinge Research Institute, 2015.

Michelle Lane and **Tim Bradburn**
Association of Independent Professionals and the Self-Employed
London, UK
michelle.lane@ipse.co.uk
www.ipse.co.uk

EMWA's New Medical Writing Career Guide is now available!



Included in the guide:

- What is medical writing
- The different types of medical writing
- The skills and qualifications needed to be a medical writer
- Where medical writers work and what they do
- How to get started
- How much to expect to get paid
- Career prospects for medical writers

Check it out on the EMWA website under Training.

Themes of forthcoming issues of **Medical Writing**

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.

The deadline for feature articles is March 13, 2017.

September 2017:
Observational studies

This will include articles on designing, analysing, and reporting observational studies.

The deadline for feature articles is June 12, 2017.

CONTACT US

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

http://journal.emwa.org/