Medical Writing

Writing Matters

Volume 21
Number 3
September 2012

Contents

Themes of upcoming issues of *Medical Writing*

The theme of the December issue is '**Diabetes and Obesity**'. All correspondence relating to this issue should be addressed to editor@emwa.org as should letters to the editor, general articles on medical writing and suggestions for future theme topics.

The theme of the March 2013 issue is '**Medical Writing Education**'. The deadline is 7th November 2012. Articles are requested on the opportunities and resources available, how to become a medical writer, how to teach medical writing, how to teach medical English and where to learn it, how to create a good EMWA workshop, and reviews of textbooks relevant to medical writing or any other topic which prospective authors consider to fall within the Medical Writing Education theme. Correspondence relating to this issue should be address to Phil Leventhal phil.leventhal@gmail.com

The theme of the June 2013 issue is '**Medical Writing around the World**'. The deadline for this issue is 15th February 2013. Articles are requested on medical writing needs and opportunities in regions not currently well represented or served: Northern Europe (Nordic countries); Southern Europe (Spain, Portugal and Italy); Central and Eastern Europe; East Asia (Japan, China, etc.); India & Southeast Asia, Middle East, and Africa.

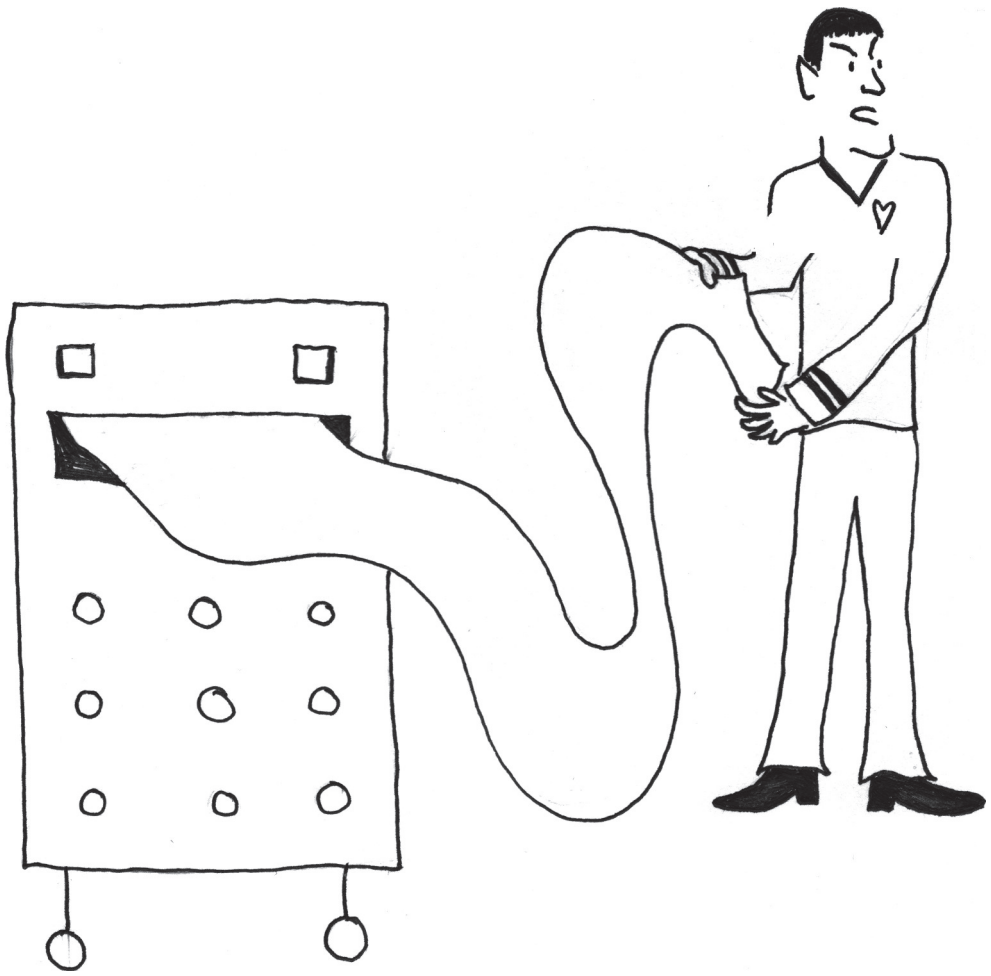


Figure 1: Captain, the medical writing machine appears to be malfunctioning. It is producing logical, plain English!
© Renee Albe

Writing matters

Phillip Leventhal

Editor, *Medical Writing*

Editorial

Correspondence to:

pleventhal@4clinics.com

Writing matters to medical writers … or at least it should. But sometimes we are more consumed with the content of a document than the writing itself. And some might even argue that detailed medical or scientific information cannot be written as simple, clear, and engaging prose. I disagree; the writing in medical and scientific documents should be not only well organised but also simple to read and comprehend.

Many books, articles, and guidelines have been written on the appropriate content of different documents, but few specifically teach medical writers to write well. *Medical Writing* is here to help. In this issue, we provide you with a series of articles that help generate simple, clear, and engaging text.

Michele Arduengo gets us started with four central principles of clear writing in her article 'Writing to make your message clear'. In the article, which is based on her scientific writing blog, she states that the main principle is to write for the reader. I can't repeat this enough to my colleagues (and even to myself)! Writing should be clear, accurate, and engaging and make life easy for the reader. Michele's article illustrates her four principles of clear writing with multiple examples, making her article an excellent basic reference for all medical writers.

Of course, writing clearly has to start somewhere. Two articles in this issue will help you get started in the right direction. In 'What's your problem?' Marina Hurley explains that the origin of a clear document is a clearly articulated problem statement. Her article includes an exercise to help a writer articulate the problem statement and then use it to guide the structure, design, and logic of the document.

In 'The joys of outlining', Robert Taylor explains that once you have the main idea, writing an outline is enormously helpful for preparing a well-written document. I have to admit that I never used outlines when I was a graduate student or even when I first started as a medical writer, but as pointed out in Dr Taylor's article, this can lead to 'wandering into wastelands of irrelevance'. I have to agree, and like Dr Taylor, I am now a staunch supporter of outlining, even for the simplest documents. As pointed out in his article, an outline gives discipline and focus to the writing process and is a great help in organising team projects. His article also details exactly how to put together a good outline.

These principles should help you build a well-written text, but how can you be sure that the document's content, style, and format are of high quality? In 'Quality control: getting the best out of your review', Nicola Haycock explains the benefits of detailed quality control. She also explains how the process should run and how to create a detailed quality control checklist.

Finally, in this issue's installment of Webscout, Karin Eichele summarizes and provides links to additional websites and PDFs on writing clear and proper English as well as on how to write for websites and the influence of technology on writing.

Readability matters too

All of these ideas can help a medical writer write clearly and produce high-quality text. But even if your content is excellent and your text well written, it won't be used if it is not easy on the eyes. How many times have you been turned off and frustrated by a document or website that was painful to look at or was badly organised?

As explained in part I of II of 'Pleasing the reader by pleasing the eye' by Gabriele Berghammer and Anders Holmqvist, this issue is called 'readability'. Their article explains how the elements in a text work together to determine whether it will be successful with a target audience. In particular, they explain how the format and design of a document must make information easy to find and extract.

In 'Writing visually for medical writers', which I co-authored with Charlotte Leventhal (that's right, my mom), we give some specific instructions on how to make a text approachable and how to make information easy to find and understand. Our instructions include details about not only how the document looks on the screen or page but

DOI: 10.1179/2047480612Z.00000000051

also how specific kinds of visuals can be used to speed comprehension of complex information.

So, both writing and readability are important in creating a successful text or document. Of course, there's a lot more to these subjects than can be covered in this issue of *Medical Writing*, but I think that these articles should be a great start in the right direction.

An important note on copyright for articles published in *Medical Writing*

All corresponding authors for feature articles and all editors of regular features in *Medical Writing* must sign a copyright assignment form assigning copyright to EMWA. We understand that this change has been difficult for some, but it is necessary. EMWA owns the journal but has granted a licence to Maney Publishing to produce the journal and to monitor the copyright. The reasons for and implications of the copyright assignment are addressed in a detailed Q&A document, which will be available by the end of 2012. These topics will also be discussed at the Freelance Business Forum during the EMWA conference in Berlin (November 8–10, 2012). In the meantime, if you have questions about copyright or any other editorial matter, please write to editor@emwa.org and see www.maneypublishing.com/authors/copyright.

Message from the President

Susan Bhatti

EMWA President

Correspondence to:

Susan Bhatti
president@emwa.org

Dear Medical Writers

The last time I wrote to you I briefly introduced myself and outlined some of the plans that I hope to realise during my year as president. However, as president I am only one of the members of the EMWA Executive Committee (EC), and I think it is important that I should also introduce the other EC members to you.

Our new Vice President, Andrea Rossi (vicepresident@emwa.org), who joined the EC in May 2012, has already shown great initiative in setting up contacts with other professional organisations who are eager to work with EMWA to spread the word about the profession of medical writing. Andrea has particularly good connections in academia and among physicians, and he is very keen to increase the awareness of EMWA within these circles, where there is plenty of need and scope for good medical writing, but little knowledge of the existence of our organisation.

Gillian Prichard is the EMWA treasurer (treasurer@emwa.org) and the keeper of the EMWA accounts. Gillian always has the financial well-being of the organization in mind when any decisions are made by the EC on the selection of conference venues or expenditure of any other nature. Due to her perseverance on our behalf, it has now been possible to set up a Merchant account for the organisation which will enable EMWA members to pay for their conference attendance fees directly by credit card.

Our Education Officer, Jo Whelan (education@emwa.org), is also a member of the EMWA Professional Development Committee (EPDC). Jo is responsible for the selection and scheduling of the workshops that are offered at each of the conferences, as well as providing input on all matters connected to training and the content of EMWA's education programme. Jo works very closely with our conference director, Alistair Reeves (conferencedirector@emwa.org) to produce a conference programme which offers EMWA members an extremely varied and very high-quality training programme, while also enabling ample opportunity for networking and socialising. Although Alistair only joined the EC in May 2012, he has a long and distinguished history in EMWA as workshop leader and regular contributor to the journal. In his new role he is already hard at work organizing the social events for the autumn conference 2012 to be held in Berlin, as well as the spring conference in Manchester in May 2013.

As already mentioned, it is important for EMWA to promote itself to the scientific and medical community, which is where our public relations officer, Farid Khalfi (pr@emwa.org) steps in. He has been busy producing a new leaflet about EMWA, which can be distributed at events such as careers fairs, in order to spread the word about our association. Farid also plays an important role in recruiting sponsors to give us financial support in return for advertising their company or services on our website, in the journal or at conferences. This is certainly a case of the more, the merrier, so if you know of anyone who might be interested in supporting EMWA, Farid would be very happy to hear from you!

Being an organisation of widely dispersed people makes the EMWA website (www.emwa.org) a vital source of the latest news about the organization. The person responsible for the website is Diarmuid DeFaoite, who recently joined the EC as website manager. You may already have noticed that Diarmuid has been posting EMWA news flashes on the entry page of the website so that these are easy to locate the moment you click on the link. In addition, he is looking to improve the navigability of the website so that information can be found more intuitively and he has posted a new updated version of the FAQ. As you can probably imagine, keeping the website up-to-date is a challenging task and Diarmuid is always looking for enthusiastic volunteers to assist him and to share new ideas, so do feel free to contact him if you are interested (emwaweb@gmail.com).

Sarah Choudhury is the EMWA Honorary Secretary (honsec@emwa.org) and ensures that the administrative side of the association is kept up-to-date. Currently Sarah is working with EMWA head office to change the format of the Annual Meeting in order to enable members to vote using

DOI: 10.1179/2047480612Z.00000000052

an online system. This will not only reduce the amount of time required to hold the meeting at the Spring conference, but will also enable a larger number of members to participate and thus ensure a more representative vote.

Last, but not least (especially considering where this message will be published) of the EC members, is Phil Leventhal, our new journal editor. Phil took over as journal editor in May 2012 and has been working with Maney, our new publishers, to give the journal a really professional look and feel. Phil is always grateful for new ideas and interesting Medical Writing topics to put in our journal, because however professional the journal preparation becomes, we will always be reliant on having enough volunteers contributing articles in order to produce an interesting, varied and professional publication. So if any of you have an idea for an article or for a theme for an edition of the journal, please contact Phil (editor@emwa.org).

So that is your Executive Committee, and if you come to EMWA conferences you will of course have the opportunity to meet all of us in person, which nicely segues into the topic of the forthcoming autumn conference, which is to be held in Berlin on 8–10 November 2012. As usual there is a superb selection of workshops covering a wide range of medical writing topics, and there will be ample opportunity for networking with the EC over a glass (or two) of German beer in Brauhaus Lemke on Friday evening. So look out for the registration announcements and I and my fellow EC members look forward to seeing you in Berlin!

September 2012

EMWA news

Diarmuid De Faoite

EMWA Web Manager

Correspondence to:

webmanager@emwa.org

Word of mouse

News from the EMWA Website Manager

New role

At the recent EMWA conference held in Cyprus, I assumed the position of EMWA Website Manager. While this is a daunting task, it is a challenge I am pleased to take on.

To ensure that I was in a position to take over the reins as seamlessly as possible, prior to my official appointment, I worked closely with Shanida Nataraja, EMWA's very capable Website Manager of the past 6 years. I also previously worked full-time for 3 years as a website editor so I had some idea of what awaited me (famous last words).

Vision for the EMWA website

I would like to have a sharper focus on two main elements – news and resources – to make the website more dynamic and valuable to our members. To this end, I will be trying to extract more out of the information currently available from EMWA. I am also looking at other websites for inspiration on what new features might be added to EMWA's site.

But this cannot be a one-man show, so as much as possible, I plan to delegate responsibilities, for example, by creating a Social Media Team. There is more information on this team later in this article.

When EMWA members have had time to try out and get used to the updated and improved website, we will conduct a survey of user opinions to measure satisfaction and also to determine what other features they would like to see.

What is happening now?

I am currently conducting a root-and-branch examination of the website to update, edit, delete, or merge the content so that the information presented is accurate and up to date. However, this will take me many months to complete. In the meantime, if you spot something while browsing, please send me a quick email (webmanager@emwa.org) and I will then correct the problem as soon as possible.

It is sometimes difficult as a user to pinpoint what changes have been made to a website. Since assuming the role, I have done the following:

- Kept news and newsflashes rolling
- Added a new 'Future Conferences' section
- Worked with the Executive Committee to completely update the FAQ section
- Tweaked many small issues, such as moving the 'Share-a-Room Scheme' into the conferences section.

Updating and refining the website will be a marathon and not a sprint, but we are moving forward.

Final thought

We would all love to have a perfect, highly professional website, but please keep in mind that EMWA is a volunteer organization and maintaining and ensuring that a website is up to date is a Sisyphean task. In addition, we must live within our means, which means that some very good ideas may not be possible because of technical or budgetary reasons.

However, with additional help, we can achieve even more. So I would love to hear from you if you'd like to get involved in any capacity – whether that be writing an online article, volunteering to edit a section of the website, becoming a regular blogger, joining the social media team, etc.

A short guide for EMWA members who use our official Facebook, LinkedIn, and Twitter accounts

Social media are changing the way we are communicating, interacting, and doing business – with EMWA members, sponsors, and other stakeholders.

Although social media tools and platforms are new and evolving quickly, their function is similar to traditional ways of communication. Because of social media's high speed, levels of interactivity, and global access to any information you publish, there are particular considerations that must be taken into account.

The best advice is to approach the online world and the physical world in the same way: by using sound judgement and common sense. It is important to try to understand *netiquette* (a contraction of 'network etiquette' or 'Internet etiquette'),

DOI: 10.1179/2047480612Z.00000000053

which is a set of social conventions for interacting in the modern digital age.

*****

To aid you, we have put together some suggested guidelines (culled from a variety of online sources) for you to consider as you pick your way through the path of EMWA's social media offerings. Why are we doing this now you might ask? People posting on EMWA's social media are not members of a closed community. Many of you know that cyberspace is a communal place full of interesting (and some not so interesting!) characters. But it is a place where a throwaway comment can spark a frenzy of worried postings. Cyberspace is also the home of malicious posters (known as trolls) who deliberately try to interrupt interesting and constructive debate.

Therefore, to make posting and reading online a more pleasurable experience for everyone, please consider the following suggestions:

1. Take your time before responding on social media networks. Remember that the Internet is permanent and never forgets.
2. Don't pick a fight. Understand that you'll encounter a wide range of individuals on social media platforms. If someone is contentious and wants to pick a fight, be polite and minimize contact.
3. Be the first to respond to your own mistakes. If you make an error, be up front about the mistake and correct it quickly, as this can help to restore trust. If you choose to modify content that was previously posted, such as editing a blog post, make it clear that you have done so.
4. Adopt a warm, open, and approachable tone.
5. Use your best judgement. Remember that there may be consequences to what you publish. If you're about to publish something that makes you even the slightest bit uncomfortable, it is probably best not to publish it or at least seek further advice before publishing.
6. Be conscious about mixing your personal and business lives.

If you have personal accounts on social media make sure they are kept separate from any 'professional' channels. Although you might have a deep emotional connection to EMWA, please keep in mind that only the EMWA PR Officer is authorised to speak publically in the organisation's name.

7. Take account of the European/global audience. Be mindful that different cultures have different values, and statements that are deemed acceptable or even funny in one culture may be considered offensive in others. Keep this 'European/global view' in mind when you are participating in online conversations.

8. Only share publicly available information. Make sure to share only information that is publically available unless you have a clear mandate to do otherwise.

9. Be a 'scout' for critical issues affecting EMWA. EMWA members are our most vital assets for monitoring the social media landscape. If you come across positive or negative remarks about EMWA that you believe are important, please share them by forwarding them to EMWA Head Office (info@emwa.org) or any member of the EMWA Executive Committee. We would like to address legitimate concerns raised as soon as possible and can only do so when we know about them.

EMWA Social Media Team

Social media is an area we at EMWA are very interested in beefing up. We have a lively LinkedIn discussion group of over 1000 members, a Facebook group, and a Twitter account. If you use any of these platforms, please join our groups and add to the discussion!

The Web is ever-expanding, yet our number of eyes unfortunately not, so we have recently put together an EMWA Social Media Team to help us spread the word about EMWA. We thank Leyna Prince who for a long time has looked after our LinkedIn group, Laura C Collada Ali who is active on Twitter, and the EMWA Webscout Editor, Karin Eichele, who assists with both Twitter and Facebook. The EMWA PR Officer and Web Manager also help to oversee the team and offer support wherever possible.

Would you like to contribute to EMWA social media?

We are looking to double the size of this team to ensure that we have enough people to cover all areas. Are you the kind of person who is very active on one or more of these platforms and could spare some time to post on and to check the official EMWA pages? Maybe you use a different social media and would be prepared to launch an official EMWA channel there? Either way, please get in touch with us if you'd like get involved in EMWA's social media.

Contact us by mail – pr@emwa.org or webmanager@emwa.org.

Thanks to all those of you who are already interacting with us online. This is *your* organisation, so please do get involved!

Getting what you want from your scientific writing: tips for writing clearly

Michele Arduengo

Promega Corp., USA

Correspondence to:

Michele Arduengo, Promega Corp., Madison, WI, USA
michele.arduengo@promega.com

Abstract

Good medical writing is like good writing in any discipline: the writer should explain complex concepts and ideas clearly and accurately and engage the reader. In this article, I provide four suggestions to help clarify writing on complex subjects: avoiding nominalizations, using language precisely, using parallel construction, and placing information where readers expect to find it. Applying these principles to science and medical writing can help readers understand difficult concepts more easily the first time they read your document.

Keywords: Parallel construction, Clear writing, Nominalisations, Plain language

Introduction

Good medical writing is like good writing in any discipline: the writing communicates an idea or concept to the reader in a clear fashion. A science or medical writer should not try to sound smart or elitist by using vague verbs and abstract nouns that make the reader search for meaning. Instead, the writer should explain complex concepts and ideas clearly and accurately and engage the reader.

The writing can be evaluated by the reader's response. Did the target reader understand and remember the message? Did the reader follow the instructions successfully or make the necessary decision? Did the reader do what you wanted (i.e. take medication properly or fund a grant)?

In this article, I present four suggestions for improving writing. These techniques help to improve clarity so that your readers can more easily understand the message the first time they read your work.

Avoid nominalisations. Rescue the verb!

When I wrote for my courses in college and graduate school, my target audience was my professor, and I wrote to impress. To sound 'smart' I nominalised verbs and used passive voice and as much jargon as possible.

The problem with writing to sound smart is that I would often create sentences that required the reader to perform a great deal of mental gymnastics. That is, I made my reader work too hard to understand my writing. Complex subject matter does not require impenetrable writing. Scientific and medical information can be communicated both clearly and accurately. Now when I write, I strive to create clear sentences that convey the message on the FIRST read. To this end, one of the first things I do after writing an initial draft is look for nominalizations.

Nominalisations are nouns made from verbs. They dominate scholarly writing, and they are often associated with awkward passive constructions. In English, you can recognize many nominalisations by looking for words ending in '-tion' or '-ment', although not all nominalized words take these forms. Looking at the nominalisations in a sentence and 'rescuing' the verbs can help to make writing more understandable.

Consider the following:

Draft sentence: 'Often, the challenge is selection of the best assay for inclusion into the secondary screening programme.'

'Selection' and 'inclusion' are both nouns created from verbs.

Suggested rewrite: 'Often, the challenge is selecting the best assay to include in the secondary screening programme.'

Draft sentence: 'Indeed a major impediment to the interpretability of microarray data is the current lack of comparability from laboratory to laboratory, resulting in the inability to independently verify published data.'

The verbs 'interpret' and 'compare' are almost screaming 'Rescue Me!'

Suggested rewrite: 'Because microarray data from different laboratories often cannot be compared

DOI: 10.1179/2047480612Z.00000000041

directly, independently verifying published microarray data is difficult.'

Use language precisely, use language that you understand, and proofread

A friend of mine told me about an incident that happened during a speech-crafting workshop for professionals. One of the members was given the task of selecting a word to introduce and define for the group. The other members of the group were supposed to incorporate that word into their conversation during the workshop.

The word selected was 'enervate', and the presenter defined it as meaning 'to energise or excite'. Although several people at the workshop knew that 'enervate' means 'to destroy or weaken', nobody corrected the presenter because nobody could figure out how to do it tactfully. As a result, workshop participants were blithely inserting 'enervate' into their conversation during the workshop, describing how a vacation or interactions with their children enervated them.

I can't help but smile when I envision these accomplished professionals in this speech workshop becoming so 'enervated', but what happens if one of those professionals writes a follow-up note after a job interview and describes the interview as being an enervating experience?

When you write (or speak), avoid the temptation to open a thesaurus and use the synonym with the most syllables. Instead, be precise with your language.

If you are writing on a subject out of your area of expertise, go over your text with someone who knows the subject to ensure that you use the terminology correctly.

Proofread, even if you are an expert in the field and know what you are trying to say. Read, reread, and have someone else proofread your work. Often what we write doesn't always communicate what we intend.

Consider these examples:

Draft sentence: Initially, the transformed *E. coli* were **reticent** to express the seven-pass transmembrane protein.

Who knew that bacteria were capable of self-awareness and reflection? 'Reluctant' won't work here either.

Suggested rewrite: 'Initially, the seven-pass transmembrane protein could not be expressed in *E. coli*.'

Draft sentence: Multiplexed assays were used to **hone** in on mitochondria that were shut down by drug treatment.

Suggested rewrite: Multiplexed assays were used to **home** in on mitochondria that were shut down by drug treatment.

Draft sentence: As part of the wellness initiative, the company offers a free employee assistance programme, which provides eligible members and their families with marriage, family, and relationship problems; alcohol and drug abuse problems; and emotional, personal, and stress-related problems.

The material here is not complicated, and I suspect the writer knew what she meant. However, did she really mean to say that the assistance programme provides employees with problems? In this case, clarity and accuracy are improved when you divide the material into two sentences and eliminate the 'problems'.

Suggested rewrite: As part of the wellness initiative, the company offers a free employee assistance programme. This assistance programme provides eligible members and their families with marriage, family, and relationship counselling, alcohol and drug abuse treatment, and emotional, personal, and stress-related assistance.

Guide your reader with parallel construction

Items and ideas of equal importance should be presented using equivalent grammatical structures, as '**parallel constructions**'. If two or more ideas or items are connected by a coordinating conjunction such as 'and', 'but', or 'or', then those ideas should be expressed in parallel or equivalent grammatical constructs. Items in a list should be parallel. This includes all verbal phrases, all nouns, etc. Parallel construction guides your reader and helps your reader organize concepts and see relationships quickly.

Consider this list of writing tips:

- Know your audience.
- Read and follow the instructions to authors.
- Use, but do not trust, spell-check programs.
- Avoid unnecessary passive voice.
- Use parallel structure.
- Provide context for new ideas.
- Proofread and review your work.

Each of the items in this list is a complete thought written in the imperative voice. The items in the list are parallel. The uniform structure allows the reader to focus on the content of each writing tip, rather than trying to sort the tips into categories or groups. The parallelism has done the sorting for the reader.

Parallel structure is important for sentences too, particularly long ones.

Consider these examples.

Draft sentence: 'Medical writing ranges from editing patient education materials, physician EMR help manual writing, to creating clinical research protocols, to writing of pharmaceutical information sheets and other treatment and therapy pertaining instructions'.

This sentence contains several items, presumably all of equal importance, yet they are presented in a variety of grammatical constructs. The reader has to strain to figure out what the writer is saying.

Suggested rewrite: 'Medical writing involves editing and writing many kinds of documents including online help files for EMR software, clinical research protocols, pharmaceutical information sheets, and patient-directed materials.

Draft sentence: 'The protocol is both a long procedure and very tedious'.

Suggested rewrite: 'The protocol is long and tedious'.

Parallel structure can guide your reader, providing clues to equivalent ideas by putting them in equivalent grammatical constructions. Using parallel constructs aids in the rhythm and flow of your writing, and will help your writing be clearer.

Place information where your reader expects it

Your writing will be more easily understood if you place the information where your readers expect to find it. Western readers read from left to right, and readers expect old material, which provides context, on the left. The new material is on the right. Use this information as a guide when building tables and graphs to present data. Put the 'known' (old) material that provides the context for your reader on the left and the 'unknown' (new) material on the right (Table 1).

In this table, the known information, the amount of material you started with, is on the left and the unknown information, how much DNA was isolated, is to the right.

Table 1: Yield of genomic DNA from different starting amounts of leaf tissue (mean ± SD)

Starting amount (mg)	Arabidopsis (μg)	Maize (μg)
40	8.33 (±1.15)	7.67 (±0.58)
100	43.33 (±2.52)	40.67 (±6.66)
150	49.83 (±1.04)	47.17 (±2.75)
250	59.67 (±7.57)	60.00 (±4.00)

In the topic position of a sentence, your reader will expect context and 'old' information. The reader needs perspective. The topic positions in a string of related sentences should be consistent to guide the reader through the paragraph or section.

A reader also expects a sentence or paragraph to be about whatever shows up first. For instance, if you are writing about the mechanism of action of antidepressants, don't begin by talking about beta blockers (unless you can make a really strong connection between the two that uses sensible transitions and related topic strings).

The 'stress' position comes at the end of a sentence, and readers will naturally remember and emphasize the information that appears in the stress position. If you start with the exciting material at the beginning of the sentence but have a so–so ending, you can lose your writing momentum.

For the most effective endings, shift the less important, less exciting information to the 'left' (or the beginning of the sentence). Also, when you edit, look at the endings of your sentences, see if you can trim them to give them more punch.

Consider the following example:

Draft Sentence: Sociobiologists are making the provocative claim that our genes largely determine our social behaviour in the way we act in situations we find around us every day.

Suggested Rewrite: Sociobiologists are making the provocative claim that our genes largely determine our social behaviour.

When you introduce a technical term for the first time – or even a familiar but important term – design the sentence so that the term appears at the end, in the stress position. Your reader is more likely to take note of the term if you do.

In English, the typical sentence order that a reader expects is: Subject–Verb–Object. So, keep these parts of the sentence as close together as possible. Avoid interrupting the subject and verb or verb and object with long phrases or unnecessary information.

Draft sentence: A critical gene that serves as a beacon and gives cells a much needed sense of direction in the chaotic days of early development has been identified by HHMI researchers.

By the time the reader makes it to the end of the sentence, she has forgotten what has been identified.

So, keep the subject (gene), verb (has been identified) as close together as possible for a stronger sentence. Better yet, remove the passive voice and use a subject–verb–object structure.

Suggested rewrite: HHMI researchers have identified a critical gene that serves as a beacon, giving cells a much needed sense of direction during early development.

Draft sentence: The neurotrophins, including nerve growth factor (NGF), brain-derived neurotrophic factor (BDNF), neurotropin-3 (NT-3) and neurotrophin-4/5 (NT-4/5) are a family of related polypeptides which regulate the survival and differentiation of discrete, and sometimes overlapping, neuronal populations.

Suggestion: The neurotrophins are a family of related polypeptides that regulate the survival and differentiation of discrete, and sometimes overlapping, neuronal populations and include nerve growth factor (NGF), brain-derived neurotrophic factor (BDNF), neurotropin-3 (NT-3) and neurotrophin-4/5 (NT-4/5).

Even better: Survival and differentiation of neuronal populations is regulated by a family of related polypeptides that includes nerve growth factor (NGF), brain-derived neurotrophic factor (BDNF), neurotropin-3 (NT-3) and neurotrophin-4/5 (NT-4/5). These polypeptides are called neurotrophins.

Now your introduced term is at the stress point of the paragraph. I would need to query the author about the meaning and importance 'discrete, and sometimes overlapping' phrase, but I think it is a separate thought and should be presented in its own sentence.

Give your reader context and perspective on new information before you introduce it. Place information where your reader expects to find it, and put information you want your reader to remember in the stress position of sentences and paragraphs. When you do these things, more people will read and remember what you write.

Summary

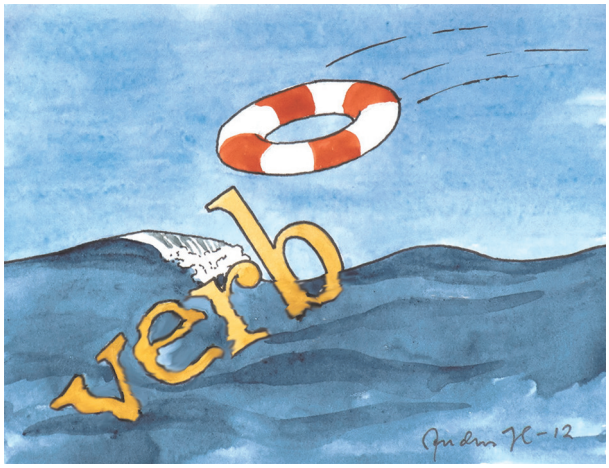
To ensure maximum clarity in your writing remember to edit for nominalised words, be precise with your language, use parallel constructs, and place information where the reader expects to find it. Although incorporating these four writing principles requires time, thought and often much editing, applying them to your writing can help you communicate complex subjects clearly and accurately.

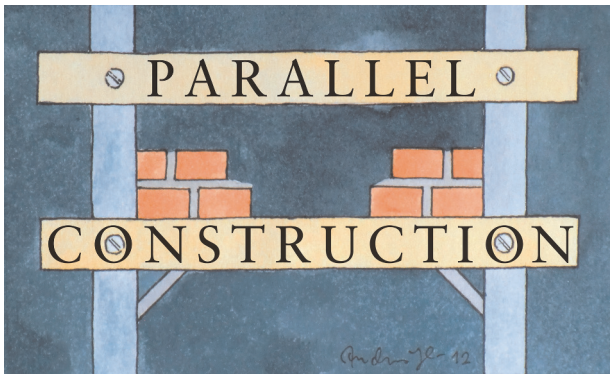
Further reading

1. Purdue Online Writing Lab, Medical Writing. Available from: http://owl.english.purdue.edu/owl/resource/732/01/.
2. Knight J. Clear as mud. Nature 2003;423:376–8.
3. Gopen GD, Swan JA. The science of science writing. Am Scientist 1990;78:550–8.
4. American Medical Writers Association. Essays for biomedical communicators. Vols. 1 and 2. 2001. Available from: http://www.amwa.org/default.asp?id=181.

Permissions

Some of the material in this article has been reprinted with permission from Promega Corporation.





Author information

Michele Arduengo received her B.A. in Biology from Wesleyan College in Macon, GA, USA, and her Ph.D. through the Biochemistry, Cell and Developmental Biology Program at Emory University in Atlanta, GA, USA. She has worked as an editor and writer in the life sciences for over 15 years and is certified by the Board of Editors in the Life Sciences (BELS). Currently, she is a writer/editor at Promega Corporation in Madison, WI, USA, where she works on technical literature, the corporate blog, and technical content for mobile applications.

What's your problem? A practical approach to scientific document design

Marina Hurley[1,2]

[1]Writing Clear Science, Melbourne, VIC, Australia
[2]Visiting Fellow, Faculty of Science, University of New South Wales, Kensington, NSW Australia

Correspondence to:

Marina Hurley,
Writing Clear Science,
P.O. Box 2373, Richmond South, Melbourne,
Victoria 3121, Australia
info@writingclearscience.com.au

Abstract

For science to be understood, assimilated, and further developed, it must be accessible through clear and concise writing. Science is about solving problems that often interlink with each other. To improve the clarity of scientific writing, every project should focus on solving a single problem and consequently every document should include a clearly articulated problem statement. The 'What's your problem?' exercise is a method for articulating a clear problem statement and then using this problem statement to guide the structure, design, and logic of the document. This exercise can be applied to the presentation of original research as a primary source document (papers, reports, dissertations) or to the interpretation or analysis of others' primary research (literature reviews, opinion pieces, magazine articles).

Keywords: Science communication, Science writing, Problem-solving

For science to be understood, assimilated, and further developed, it must be accessible through clear and concise writing. Yet accomplishing this is a struggle for many writers, especially when composing the introduction and discussion of a document. The writer must choose which details to include or exclude, how many references to cite, how to present a project within its broader topic, and how to stick to the main point. Often, there is no clear statement of what the document is about.

Words used to describe the problem: aims, hypotheses, and objectives

Traditionally, the *aim* is designated as the focus of a paper or project. Meanwhile, the *hypothesis* is often claimed to be essential. However, most documents do not refer explicitly to either. When *aim* is used, it is often presented with *objective* as '*aims and objectives*'. Yet *objective* is often used ambiguously and indiscriminately to describe tasks and targets imposed by clients and funding organizations, outcomes, aims, methods, and expected results. *Aim* is sometimes used ambiguously to describe expected results or methods.

However, a study is more than doing; it is finding out why. The goal of science is to choose or devise an appropriate method to answer pertinent questions: questions that are relevant and answerable.

The aim of a project is to solve a problem

Hall *et al.*[1] state that the most common problem for junior writers is the inability to clearly state the question that was asked, yet this remains a common problem even for established writers. Often writers are so familiar with their area of expertise that they fail to recognise that they have not clearly explained their study. Assuming that your audience is familiar with your topic is not enough. The reader should not have to rely on their experience, knowledge, or familiarity with the discipline in order to understand what the document is about. The reader also shouldn't have to rely on the title or scour the discussion to work out the focus of the study.

Problem solving is searching for explanations or reasons why something is happening. The common denominator of all science projects is the intention or desire to solve a problem, whether the problem is to answer a question, conduct an experiment, look for the cause of a symptom or phenomena, pose or test a hypothesis, or improve knowledge by gathering information. Therefore, for all scientific projects, the statement of the problem best defines the project's purpose.

DOI: 10.1179/2047480612Z.00000000042

What's your problem?

Some writers get overwhelmed trying to decide what detail to include in the background or introduction of their document, and they may discuss many problems not directly related to their project. Instead, each project should have a single aim – to solve a problem – and therefore each document should articulate a problem statement. Even large documents, such as a Ph.D. thesis, should have one central aim (see Evans 1996), with each chapter or section developing a subsidiary problem as an offshoot of the central aim.

Clear structure and design follow a clear statement of the problem. The statement of methods then stems from a clearly articulated statement of the problem. These methods explain how the problem is intended to be solved. Literature is used to validate both the importance of the problem and the choice of methods. The discussion or conclusion of the document directly addresses whether or not the problem was solved, often with recommendations on how to solve the problem on a larger scale or under different circumstances.

The 'What's your problem?' exercise

The 'What's your problem?' exercise is a method for developing a clearly articulated *problem statement*. This process is the same, irrespective of the document length or design, the topic, or the discipline. Focusing on one central problem clarifies the project aim and helps structure the document. This process may be helpful not only for scientific projects but also for many non-scientific projects.

This exercise can be used to present original research as a primary source document (papers, reports, dissertations) or to interpret or analyse the work of other primary researchers (literature reviews, opinion pieces, magazine articles).

The exercise involves answering eight questions (Q1–Q8) about one study. All questions cover the full scope of the scientific project, from statement of the problem (aim) through to discussing and assessing the results (discussion). The purpose of this exercise is two-fold:

1. *To focus your scientific thinking.* Answering the questions included in the exercise will help you concisely conceptualize all stages of the project.
2. *To produce a summary of the project or topic* that can be used as a solid foundation to further develop and finalize your document.

The process of defining 'What's your problem?' is shown in Fig. 1. The linking of Q8 with Q1 represents the continuous nature of science; answering one scientific question often generates new questions and new problems to solve.

Q1. What is the overall problem under consideration?

The first step is to make a list of the problems linked to the project. Narrow down the list to the problems that are directly relevant. Next, summarize these problems into a single paragraph that encapsulates one broad problem and includes a characterization of the main features. Ask yourself, 'What is known and what is unknown about the topic?' This paragraph will form the background to the topic. Your problem statement (Q3) will be an offshoot of this broad problem summary. If you find that you have more than one broad problem that needs solving then you may need to consider writing an additional document.

Q2. Why is this problem important?

Describing the importance of the problem helps justify the area of study and helps form the background of the document. Ask yourself how this project is important scientifically and worthwhile to society. Draw on the literature to help explain and verify the importance of the problem. However, do not rely only on literature citations to explain the importance of the problem. Although the literature is the source of knowledge about the problem, a paraphrased statement of the importance of the problem is still needed.

Q3. What problem do you aim to solve?

Focus the problem statement towards what can be addressed within the document. A clear statement of the problem should directly place the project or topic within the broader field of endeavour. For example, consider the statement, '*We aim to improve the management of patients with heart disease*'. The problem that needs to be solved, or improved upon, is the management of patients with heart disease, whereas the treatment of heart disease is the broad field encompassing the project. Details of subsidiary or related problems that cannot be adequately solved or addressed within the document can be summarised in the background (Q1 and Q2) or raised as directions for future research (Q8).

Q4. How do you aim to solve this problem?

Summarize the methods or analytical approach used in the attempt to solve the problem. This is a summary of the materials and methods and

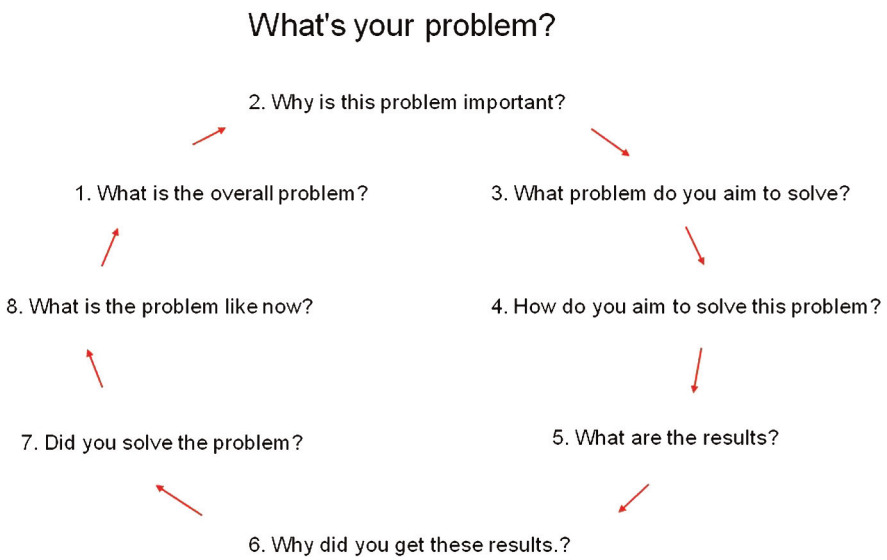


Figure 1: What is your problem?

includes the scope (time and magnitude) of the project.

Q5. What are the results?
Summarise the results. What was the consequence of the actions (methods) or analysis? What was the answer to the question(s)?

Q6. Why did you get these results?
Explain why the results were obtained. What factors explain the results? What caused these results? What was the reason for these results?

Q7. Did you solve the problem? Did you achieve your aim?
What do the results mean? Did you solve or partially solve your problem? Did you effectively answer the hypotheses or question(s)? The solution to the problem is ultimately a scientific statement that may be used to develop a conclusion, propose a hypothesis or uphold a principle or rule. Therefore, what interpretations and conclusions can you make from these results?

Q8. What is the problem like now?
The problem has now changed because of the findings (results and interpretations of the results). What are the implications of these findings? What are the recommendations? Can new principles be generated from the evidence? Can these principles be applied to other situations? What are the limitations of this study? If the results are unclear, this is still an important aspect of the project. In this case, why were the results unclear? What problems remain unsolved? What are the new problems that need solving? What are the future directions for research in this topic? What new research can now be carried out?

An example

As an example, the exercise is applied to a published article on a clinical trial with the use of direct quotes and paraphrased statements.[2]

Q1. What is the overall problem under consideration?
'*Clinical trials to test effectiveness of HIV preventative methods are increasingly being conducted in Sub-Saharan Africa where HIV incidence is high. Women at risk for HIV recruited for these trials are often at risk of pregnancy, yet are asked to avoid pregnancy whilst on investigational products, regardless of the trial phase, as safety to the unborn child is usually unknown*' (page 2).

Q2. Why is this problem important?
Women who become pregnant have their safety at risk from the study treatment. This can also reduce the efficiency of the trial. '*Being able to identify women at higher risk for pregnancy at screening may enhance participants' safety and minimises time off study product, which increases trial efficiency*' (page 2).

Q3. What problem do you aim to solve?
'*Pregnancy risk during vaccine trials is poorly characterised.*' '*…findings …suggest that pregnancy risk can be modified. It is particularly important to identify factors that can help African women avoid pregnancy in vaccine trials… Findings from this analysis may improve screening and support of women in minimising pregnancy during HIV prevention trials in sub-Saharan Africa*' (page 2).

Q4. How do you aim to solve this problem?

'*…we report pregnancy rates and outcomes during and after the vaccination period and identify factors reported at screening that were associated with incident pregnancy during this trial*' (page 2).

Q5. What are the results?

'*…pregnancy incidence was 9.6/100 women-years overall… …pregnancy was reduced among women who: enrolled at sites providing contraception on-site; entered the trial as injectable contraceptive users or as consistent condom users* (page 1). *… although the difference in pregnancy rates during and after the vaccination period was not statistically significant, there was a trend to higher rates after the vaccination period* (page 4). *Predictive factors were identified and women with two or more risk factors* (*heavy drinking and marijuana use*) *had increased pregnancy incidence* (page 8).

Q6. Why did you get these results?

Women's access to effective contraception and the requirement that the participants use at least two forms of contraception during the trial were important in reducing the risk of pregnancy. The reasons why heavy drinking and marijuana use increased the risk of pregnancy were not discussed.

Q7. Did you solve the problem? Did you achieve your aim?

Yes, pregnancy risk factors were identified. '*It is possible to screen South African women for pregnancy risk at trial entry. Providing injectable contraception for free on-site and supporting consistent condom use may reduce incident pregnancy. Screening should determine the substance use, partnering, and HIV status of both members of the couple for both pregnancy and HIV prevention*' (page 8).

Q8. What is the problem like now? What new research can now be carried out?

'*The …preliminary implications for clinical trialists are that women reporting multiple risk factors, but not heavy drinking alone, should be flagged for increased pregnancy prevention counselling, and may be especially suitable candidates for trials given their increased risk for HIV, and their need for the risk reduction packages offered within trials*' '*Factors examined were… …highly predictive of pregnancy risk. This bodes well for future trials as women can be readily screened for pregnancy using a few questions. Limitations of this analysis were the variable pregnancy prevention messages and pregnancy outcome ascertainment once the trial was interrupted*' (page 8).

Conclusion

Clear and concise writing arises from articulating one problem statement for each project. The 'What's your problem?' exercise helps you define the problem and then uses the problem statement to guide document design, structure, and logic. This exercise not only clarifies the writer's thinking, it also helps build solid structure and content for a wide variety of documents and topics.

References

1. Hall GM. The structure of a scientific paper. In: Hall GM, (ed.) How to write a paper. 3rd edn. London: BMJ Publishing Group; 2003.
2. Latka MH, Fielding K, Gray GE, Bekker L-G, Nchabeleng M, Mlisana K, *et al.* Pregnancy incidence and correlates during the HVTN 503 Phambili HIV vaccine trial conducted among South African Women. PLoS ONE 2012;7(4):1–8. e31387. doi: 10.1371/journal.pone.0031387.
3. Evans D. How to Write a Better Thesis or Report. Melbourne University Press, Victoria: 1996.

Author information

Dr Marina Hurley specializes in improving the writing skills of science professionals, across all fields and with different levels of experience. Marina has a B.Sc. and Ph.D. in Science (Zoology) specializing on the herbivores of stinging trees (Dendrocnide spp.) and established the training consultancy Writing Clear Science (www.writingclearscience.com.au) in 2005 (in Melbourne, Australia). Dr Hurley is also a Visiting Fellow at the University of New South Wales. Prior to 2005, Marina worked as a research scientist, lecturer, and academic for over 20 years.

The joys of outlining in medical writing

Robert B. Taylor

OHSU School of Medicine, USA

Correspondence to:

Robert B. Taylor, Department of Family Medicine, OHSU School of Medicine, Portland, OR USA
taylorr@ohsu.edu

Abstract

Using an outline to organize your writing project can help keep you on a straight path and avoid wandering into wastelands of irrelevance. There are various formats – the classic hierarchal model, the IMRAD system used for research reports, the disease description arrangement often found in clinical reviews, and various types of lists and categories. All help you organise your data and present it in a structured, coherent manner.

Keywords: Outline, Organise, Hierarchal, IMRAD, Pre-writing

About outlining

What is an outline – as used in the context of writing – and what is special about outlines in medical writing? Simply stated, an outline is a short, organised description of what will be contained in an article. When it comes to medical writing, there are a few types of outline that are often used, as described below.

Fig. 1 illustrates a typical outline format.

Whether it comes to writing an essay such as this one, a book chapter, or a research report, I am an unashamed advocate of outlining. To me, beginning a writing project without an outline is like driving in new territory without a road map. Outline-less writing invites one to waste time and risks dithering, with results that can threaten the coherence of your work. Using an outline is especially helpful when a writing project has multiple authors because it can be used to force all contributors to agree on the structure and direction of the project.

Title of article
XXXXX
Yyyyy
Zzzzz
Zzzzz
XXXXX
Yyyyy
Zzzzz
Zzzzz

Figure 1: Schematic example of a medical writing outline.

With that said, good writers are flexible and are willing to modify their outlines as bright, new thoughts emerge. When working on an outline, be sure that what is added, or rearranged, is consistent with the overall theme of the project.

The length and complexity of the outline are dictated by the length and complexity of the paper being planned. For a short article, such as this one, an extensive outline with multiple levels of topics is not really needed. A shorter outline, with a limited number of subheadings, will suffice. On the other hand, a more ambitious project such as a long book chapter, thesis, or even a planned book will require a more extensive outline.

Getting started

Outlining is part of 'pre-writing', the phases that should come before embarking on the first draft.[1] When planning an article, you should first think about it – a lot. Let various approaches simmer in your subconscious, until the right one declares itself. At the same time, you should be collecting data, whether you assemble your facts in piles and files or on computer.

I believe there are two special advantages to using an outline. First, as you construct the organisational scheme for your paper, the use of an outline will quickly reveal where more research is needed. Second, the outline also exposes items that are unnecessary and allows you to jettison them early, before they become unneeded distractions diluting the coherence of your presentation.

When you have located key data sources related to your topic – items that will subsequently appear in your paper and your reference list – you are ready to begin sorting the results of your search. Look through the articles and other data you have collected and see how they seem to cluster in groups. At first, you may have too many piles, but usually the small piles can be bunched into three or four general headings. Now you are ready to begin your outline.

There are two main styles of outlines: the topic outline and the sentence outline.[2] In writing a topic

DOI: 10.1179/2047480612Z.00000000044

outline, you might use a heading such as, in the example below, 'Types of medical review articles'. In a sentence outline, that entry would become, 'There are three important types of medical review articles'. For economy of words, I prefer the former style, which I have used in this article. There are, however, two advantages to the sentence style: your topic sentence in each section of the article is already drafted and the use of full sentences will reveal if you are being inconsistent in verb tenses. Whether you favour the topic or sentence style, you should use indentations to indicate levels of sub-headings.

Outline formats

There are several types of outline format, and your choice of which you use will be guided by your topic and the style of your target publication.

Hierarchal outline

The classic model is the *hierarchal outline*. This model can be applied to any type of document. For a hierarchal outline, you may choose numbers and letters, decimals, or simply indentations to identify levels of importance. Fig. 2 shows a schematic example of an outline using numbers and letters and an example using decimals.

The American Psychological Association provides some useful examples.[3] A skeletal example of a hierarchal outline for a hypothetical article on 'Writing a Review Article' might be:

Why write a review article?
Types of medical review articles
  Clinical update
  Literature review
  Systematic/evidence-based review
Where and how to have a medical review article published
  Who publishes review articles?
  Tips on submitting your work for publication

Note that in the example provided, I simply indented the lines and did not include letters, numbers, and decimals, although you can use bullets. Also, when you make a subheading, another one or more should be added; otherwise the topic merits its own heading or might just be eliminated.[3]

Example of use of numbers and letters
I. XXXXX
  A. Yyyyy
    1. Zzzzz
    2. Zzzzz
II. XXXXX

Example of use of decimals
1.0 XXXXX
  1.1 Yyyyy
    1.1.1 Zzzzz
    1.1.2 Zzzzz
2.0 XXXXX

Figure 2: Schematic examples of the use of numbers and letters, and also decimals in outlining.

IMRAD model

When presenting research data, such as in a peer-reviewed article, the *IMRAD model* is often the prescribed method. The acronym stands for Introduction, Methods, Results and Discussion. Although not part of the IMRAD acronym, all reports of original research will need an abstract. In describing research results, I urge you to follow this general model because using your own, innovative method may invite summary rejection. Not all journals follow the IMRAD model precisely. Some use their own variations. When you begin to prepare your report of original research, consult the Instructions for Authors of your target journal, and follow the directions carefully. A very useful source of general information describing the structure of a scientific article is found in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Manuscript Preparation and Submission.[4]

Clinical review model

A *clinical review*, like the report of clinical research, also follows a predictable series of headings, although these are generally not rigidly prescribed. This type of essay may be published in a journal or as a book chapter. An outline of an article on migraine headache, for example, might be as follows:

Pathophysiology
Clinical manifestations
Diagnosis
  History and physical findings
  Diagnostic imaging
Therapy
  Lifestyle and diet
  Management of the acute headache
  Prophylactic therapy

Category and list model

Many review articles are based on *categories and lists*. Some examples of possible approaches are listed below. For each of these, I believe that the outline is suggested by the title. For an article on statins, for example, the main headings might be: (1) Current issues regarding statin use in primary prevention; (2) The case for using statins…; (3) The case against …; and (4) Conclusion.

The use of statins for primary prevention of cardiovascular disease: the cases for and against

A short history of cancer chemotherapy: from nitrogen mustard to *Gleevak*
Some myths about the use of herbal medicine in elderly patients
Three new drugs to treat depression
Four common mistakes in the evaluation of abdominal pain
Five reasons why physicians should write for the medical literature

Putting theory into practice

At this point, let me share the outline I used for this article. It was composed on paper, probably a reflection of my personal experience and habits. Today, most writers would prepare their outlines on computer.

After doing some thinking and just enough research, I began. The outline that follows eventually developed after moving some items and crossing out others, resulting in several drafts before I was satisfied. In the end, the outline helped me organize my thoughts. I used the outline items as headings in the text, although in a shorter article, I might not have included headings. Generally, I like headings because they help the reader understand what I am trying to say, and they break up the flow of words on pages.

Here is the outline of the article you are reading:

Abstract (required by the *journal*)
Introduction: About outlining
Getting started
  Prewriting: thinking, data, files, and piles
  Merits of outlines
  Outline styles
Outline formats
  Hierarchal model
  IMRAD model
  Clinical review
  Categories and lists
Putting theory into practice
  The outline for this article
  Some helpful comments
    Computer use
    Including citation prompts
    A writer's block remedy
Conclusion
References

Practical tips on outlining

Following are some additional tips that may be helpful when you begin to develop your next article outline:

- Learn the skill of using your computer for outline construction; it is much more efficient than pen and paper. On your screen, you may find it useful to use bold font for major headings.
- Consider indicating in your outline where key citations will occur. Including prompts to important referenced facts helps assure that each will be included, and that a cited statement will not show up twice in your article.
- Outlining can be a useful remedy for writer's block. If you are 'stuck,' and have tried the ploys of seeking coffee, reading your work out loud, or walking around the block, try creating an expanded outline for the section of the article that has you blocked.

Conclusion

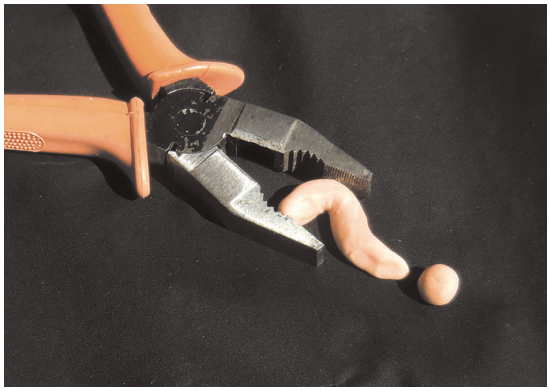
If you have never tried outlining for your writing, I urge that you do so. It imposes a discipline that many of us lack, helps you maintain your focus, and is an excellent deterrent to over-writing.[5] With a well-thought-out, comprehensive outline, your article practically writes itself. In the end, you may find that medical writing is more fun than ever.

References

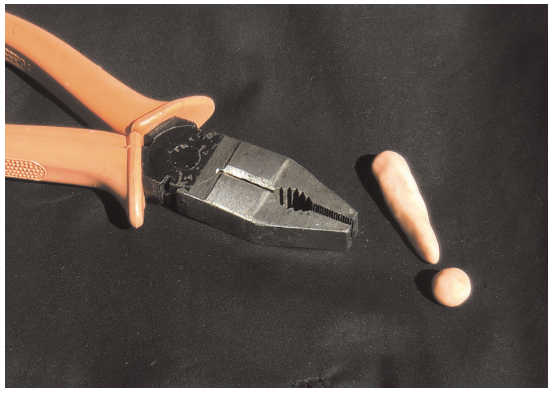
1. Taylor RB. Medical writing: a guide for clinicians, educators, and researchers, 2nd ed. New York: Springer; 2011. p. 69.
2. How to write an outline. Los Angeles College Library. Available from: http://www.lavc.edu/library/outline.htm [accessed 2012 April 27].
3. APA Outline Format Examples. Available from: http://examples.yourdictionary.com/apa-outline-format-examples.html [accessed 2012 April 20].
4. Uniform requirements for manuscripts submitted to biomedical journals: manuscript preparation and submission. Available from: http://www.icmje.org/manuscript_1prepare.html [accessed 2012 April 27].
5. Turabian KL. A manual for writers of research papers [theses and dissertations], 7th ed. Chicago: University of Chicago Press; 2002:p. 63.

Author information

Robert B. Taylor, MD is professor emeritus and former chairman of the Department of Family Medicine at the Oregon Health & Science University School of Medicine in Portland, Oregon, USA. He is the editor/author of 24 medical reference books, including six editions of *Family Medicine: Principles and Practice* and two editions of *Medical Writing: A Guide for Clinicians, Educators and Researchers*.



© Anders Holmqvist



© Anders Holmqvist

Clinical pharmacology series
Symbolism in PK reporting

The author Dan Brown is recognised for using symbols and their mystery in many of his novels. In a similar way pharmacokinetic (PK) literature is laden with it's own symbols and mystique. Unlike a Dan Brown plot, PK symbols should immediately and precisely convey their meaning to the reader.

The word symbol is derived from the Greek verb "symballein" which means "to put together and the related noun "symbolon", which means "mark", "taken" or "sign". Many PK parameters and terms raid the Greek alphabet to aid their abbreviation. For example the dosing interval is represented by tau (τ) the 19th letter of the Greek alphabet. It is commonly used thus, AUC_{τ}, to denote the area under the plasma concentration-time curve over a dosing interval.

PK processes such as elimination of drug from the body and drug uptake into body tissues can be mathematically represented using a rate constant. In chemical engineering, from which much of the mathematical basis of PK is derived, rate constants are represented by the letter, 'k'. In PK a subscript is often added to 'k' to define the associated rate. The respective rate of drug elimination from the body and rate of drug absorption are commonly given as k_{el} and k_a. Though the former may be reported as lamda$_z$ (λ_z) in order to identify that the parameter has been derived from the terminal portion of the drug concentration-time curve i.e. k_{el} is equivalent to λ_z.

Any individual who has worked for several pharma companies or who has reviewed published PK papers across several academic journals will have discovered inconsistencies in how the same PK parameter can be represented. A frequent offender of this changeability is the measure of exposure term area under the drug concentration time curve (AUC). For example, the area under the curve from time zero to infinity can be denoted in several ways: AUC, AUC_{∞}, $AUC_{0\text{-}\infty}$ and $AUC_{0\rightarrow\infty}$. All are correct in their presentation.

Unsurprisingly, several published papers have attempted to present a gold standard for the representation of PK symbols[1–4]. Unfortunately, these attempts have failed to launch a universally accepted set of symbols for PK parameters. Generally, the core symbol for a particular PK parameter tends to be similar regardless of its origin. The discrepancies occur in the denotation of the subscript as outlined above. Although many regulatory guidances concerning PK have been published by the EMA and FDA, none define appropriate symbols for PK parameters. So where does this leave the medical writer?

Essentially symbols are an integral part of PK and as explained above there is often more than one way to denote a specific PK parameter. The medical writer's task is therefore to ensure consistency of PK symbols within a project so that data can be compared across clinical studies and easily extrapolated back to pre-clinical work.

To conclude T_{max} or t_{max}? I prefer the latter, but don't let the idiosyncrasies of an individual pharmacokineticist distract you from the bigger picture.

References

1. Rowland M, Tucker G. Symbols in pharmacokinetics. Br J Clin Pharmac. 1982; 14: 7–13.
2. Manual of symbols, equations & definitions in pharmacokinetics. J Clin Pharmacol. 1982 Jul;22(7):1S–23S.
3. Clinical Pharmacokinetics preferred symbols. Clin Pharmacokinet. 1999 Jul;37(1):87–9.
4. Baggot JD. Pharmacokinetic terms: symbols and units. J Vet Pharmacol Ther. 2001 Apr;24(2):81–2.

Graham Blakey
GBPK Consulting Ltd
graham@gbpkconsulting.co.uk
www.gbpkconsulting.co.uk

Pleasing the reader by pleasing the eye—Part 1 The role of format and design in readability

Gabriele Berghammer[1], Anders Holmqvist[2]

[1]*the text clinic, Vienna, Austria*
[2]*Holmqvist AD & Bild, Lund, Sweden*

Correspondence to:

Gabriele Berghammer
gabi@the-text-clinic.com;
www.the-text-clinic.com

Abstract

Whoever writes wants to be read. Yet, even if we succeed in creating an informative, logically structured, and adequately worded text tailored to our target audience, i.e., text we consider to have an adequate level of readability, our documents may still go unread—or read with antipathy. Next to linguistic factors, therefore, there is a wide range of other aspects determining how well we understand a text, including layout, typography, or cultural adequacy. Documents people can use effectively and with ease have language, graphics, and design combine into a harmonious whole. Good design helps arouse interest and singles a text out from many others that vie for our attention. In short, good design is no luxury. This article is the first in a series of assays on the role of format and design in readability. Rather than attempting to transform writers into graphics designers, the goal is to have writers see the beauty of layout and typography and have them harmoniously blend with the content to be conveyed.

Keywords: Readability, Layout, Typography, Graphics design, Reading process

> I learned about serif and sans serif typefaces, about varying the amount of space between different letter combinations, about what makes great typography great. It was beautiful, historical, artistically subtle in a way that science can't capture, and I found it fascinating'. – Steve Jobs[1]

The more we read and write, the fonder we grow of letters and the spaces and symbols that hold them together. The ways empty page areas, typefaces, punctuation marks, and visuals are arranged on a piece of paper can be as much a part of the story as the content itself. They can make or break a message.

At least that 's what we thought. Seeing, however, that many of today's publications, particularly in the areas of technical, informational, and instructional prose, fall short of what we have come to perceive as essential aspects of our crafts, we started to ask ourselves whether, in these fast-paced times of budget constraints, format and design had become an obsolete luxury reserved for belletristic literature or art. Not long ago, one of the authors (GB) read a novel published by Bloomsbury in 2011, 'Other People's Money' by Justin Cartwright. Not only is the story a brilliant, tongue-in-cheek tragicomedy, even the paperback edition had a pleasant look and feel to it. The last page of the book confirmed that the publisher had taken care to design a book people feel drawn to. It contained a note on the typeface used, explaining that the text was set in Adobe Garamond, who had originally designed it, and when it was first used. But more on typefaces later.

What about format and design in technical documentation? Even if our reports and brochures are impeccably written – what role do layout and typography play in the readability equation? Is it important how our study reports are laid out? What does the design of our marketing brochures say about our company's philosophy and products? Does the visual appearance of a patient informed consent form or package leaflet make a difference to the reader? In a 2007 systematic review of research on the effectiveness of written information available to patients, Raynor *et al.*[2] found that most people failed to value the written medicines information they received. Also, they had concerns not only regarding the use of complex language – an aspect

DOI: 10.1179/2047480612Z.00000000045

professional medical writers tend to be sensitive to –, but also regarding the poor visual presentation of much of the available material – a frequently neglected aspect of documentation. Documents that people can use effectively and efficiently will have language, graphics, and design coalesce into one. As Raynor *et al.*[2] put it, writers must be aware that 'easy to understand text is worthless if people cannot (or cannot be bothered) to find it'.

Assessing the reading ease of written material

It was as early as the 1920s that educators started to devise methods to assess the reading ease of written material.[3] Perhaps the most effective way to assess the suitability of a piece of writing is to evaluate it in a sample of its prospective audience. Due to a lack of time or money, however, this is not always feasible. In the 1950s, therefore, readability formulae gained popularity and came to be widely used in areas such as journalism, health care, and industry.[4] Even today, more than half a century later, well-known names associated with readability testing are those of the forerunners of the métier, such as Rudolf Flesch, Robert Gunning, Edgar Dale, Harry McLaughlin, or Edward Fry. For example, Flesch, who cooperated closely with the Associated Press, and Gunning have had a tremendous influence on journalistic writing,[4] bringing the reading grade level of newspaper front-page stories down from the 16th to the 9th to 12th grade, where they have remained to this day.[3]

What is readability?

There are different ways of defining the concept. George Klare[5] defines readability as 'the ease of understanding or comprehension due to the style of writing'. Style alone, however, is hardly the only factor influencing readability. McLaughlin[6], creator of the Simplified Measure of Gobbledygook (SMOG) formula, provides a more general definition of readability as 'the degree to which a given class of people find certain reading matter compelling and comprehensible', emphasizing the dynamics between a text and a group of readers that share a set of common characteristics, such as reading skill, prior knowledge, or motivation. Dale and Chall, who developed the first version of their readability formula in 1949, define readability more broadly still as the 'sum total (including all the interactions) of all those elements within a given piece of printed material that affect the success a group of readers have with it. The success is the extent to which they understand it, read it at an optimal speed, and find it interesting'.[7]

Elements affecting readability

What, then, are the elements Dale and Chall may have had in mind? Most readability formulae are based on assessing word choice and sentence length, allowing the user to compare the readability level of a given text with a person's reading ability, or terminal educational age. These formulae have been widely shown to be important predictors of the suitability of reading material,[7] and they have a valuable role in guiding and informing the writing process. However, classical readability formulae disregard a wide range of other factors determining how well a reader will understand a text.

Among these are such seemingly mundane aspects as inadequate lighting or noise, bad eyesight, or fatigue. Other influencing factors include the reader's background knowledge, what he wants or needs to know, how much time – or motivation – he has to read and understand something, or what is interesting to a particular person at a given point in time.[6] A high-concept density,[3] common words used in an unfamiliar context, and (a lack of) cohesion or coherence between thoughts and sentences have also been found to affect readability.[8] Overall, therefore, a text with a low grade level may still not be easily understandable for one or more of these reasons. Yet, because the effect of many of these physiological and psychological variables is difficult to quantify, most readability formulae have focused on linguistic predictors of reading ease.

Classical readability formulae have another limitation: they are only applicable to running text,[3] but not to word lists, tables, or figures, which are frequent components of didactic or informative prose. Therefore, alternative tools, such as the Suitability Assessment of Materials (SAM),[3] the PMOSE/IKIRSCH document readability formula,[9] or the User-Friendliness Tool (UFT)[10] have been developed since the 1990s and include previously ignored attributes such as graphics, layout, typography, or cultural appropriateness.

Format and design had been found to influence readability much earlier. In their 1935 landmark study[11] on what makes a book readable, Gray and Leary identified 289 elements contributing to readability based on responses from a large number of individuals with an interest in adult education. They then grouped these elements into four categories, i.e. (1) content, (2) style of expression, (3) format, and (4) features of organization. Not

surprisingly, content and style ranked highest so that, if you provide readers with material that interests them and that is written in a style that matches their needs and tastes, almost 65% of the readability problem has been solved (Fig. 1). This leaves another 35% to be dealt with, i.e. formatting and textual organisation – and these aspects are what we will be focusing on.

Format and design: important aspects of readability

They say that first impressions count. Indeed, it often takes only one glance to decide whether or not we want to read a piece of printed matter. There is, admittedly, a fundamental difference between reading for pleasure and reading for business: Whereas the former is generally a voluntary activity we find inspiring, reading work-related texts can be a chore. In the first case, good design will add yet another dimension to our reading experience – as it did with Justin Cartwright's harmoniously typeset novel. In the second, good design has the potential to turn the chore into enjoyment. To make the most of the finite reading time available to us, clear letters and correct emphasis through effective layout are crucial.[12]

Good design combines form and function. It groups elements that are logically related with each other and emphasizes important textual elements.[12] Good design helps arouse interest, singles a text out from many others that compete with it for our attention, and can make a message memorable.[12] Good design, then, is no luxury.

Why should writers bother about format and design – is this not generally taken care of by experts? This was indeed the case ever since Johannes Gutenberg laid the foundation for the mass production of printed text based on movable letters in the 1440s. For more than 500 years since, a typed or handwritten text was sent to the composing room, where the typesetter – a professional with many years of training – assembled sorts into lines and lines into pages.

A 'seismic shift'[13] in our dealings with layout and type happened in 1984, the year the first Apple Macintosh personal computer hit the shelves – a machine that came with a wide choice of typefaces and marked the beginning of the era of modern desktop publishing, not least because of Steve Jobs' infatuation with anything having to do with letterforms. IBM, Microsoft, and manufacturers of home printers soon followed suit.

Steve Jobs had been enthralled by the power of typography during his stint at Reed College (Portland, Oregon). In his Stanford University commencement speech of 2005,[1] he credited his arts professor, Robert Palladino, for inspiring him to design typography into the Mac. Palladino had taken over the calligraphy programme at Reed from its founder, internationally renowned calligrapher Lloyd J. Reynolds, lover of letters and a disciple of William Morris, who taught generations of students and some of today's finest typographers. 'Letters have fascinated me ever since I found their power and beauty when I was five years old', Reynolds once wrote,[14] and for 35 years, not a single class at Reed College held more students captivated than his.[15]

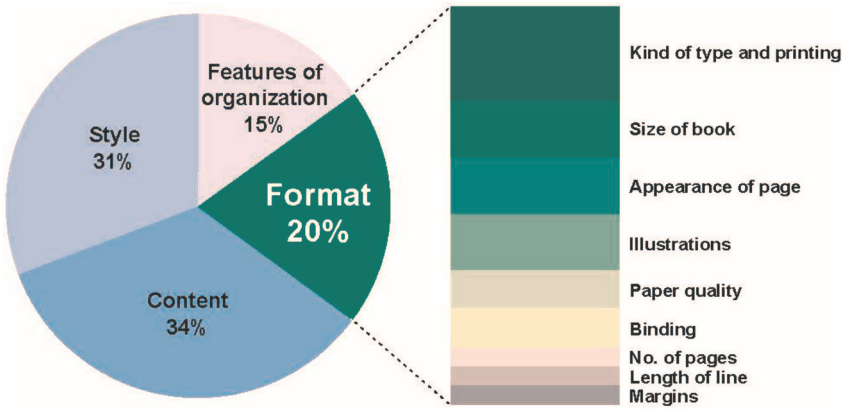
Two of Reynold's students were Chuck Bigelow and Kris Holmes, co-designers of the Lucinda family of typefaces.[16] Bigelow, who was an associate professor of computer science and art at Stanford University, once said about Reynolds:[15]

> Calligraphy has its beautiful aspects, but that is hardly where Lloyd's classes started or stopped. Lloyd saw calligraphy as the visible means of literate expression and, through that, as a gateway to the history and lore of civilization. Moreover, it is a link between one's own simple, utilitarian practice of handwriting and the accumulation of knowledge and scholarship through the ages. —Chuck Bigelow[15]

Again, more on typefaces later. We are repeatedly going to digress into the history of graphic design because we find it fascinating to see how it all started many centuries ago and how the past helps us appreciate the present. Generations of scribes, printers, and designers have spared no pains to shape and reshape the most basic components and concepts we use as writers: letters and the way they are laid out on a page.

With the freedom of desktop technology now available to most of us has come the challenge to take on many of the compositor's tasks – without, however, drawing on many years of formal training. To save the finer points of typography from getting lost, writers should understand the key concepts of layout and typography. This will not only improve the visual appearance of the templates and documents they design, it will also help them evaluate the work of graphics designers with a critical eye.

This article is the first in a series of assays on the role of format and design in readability in which we are going to look at page layout, typography,



Adapted from Gray and Leary[11]

Figure 1: Categories of readability according to Gray and Leary.[11]

and visuals in turn. The intention is not to turn writers into graphics designers. Rather, our goal is to have writers see the beauty of layout and typography and have them harmoniously blend with the content they wish to convey.

The reading process

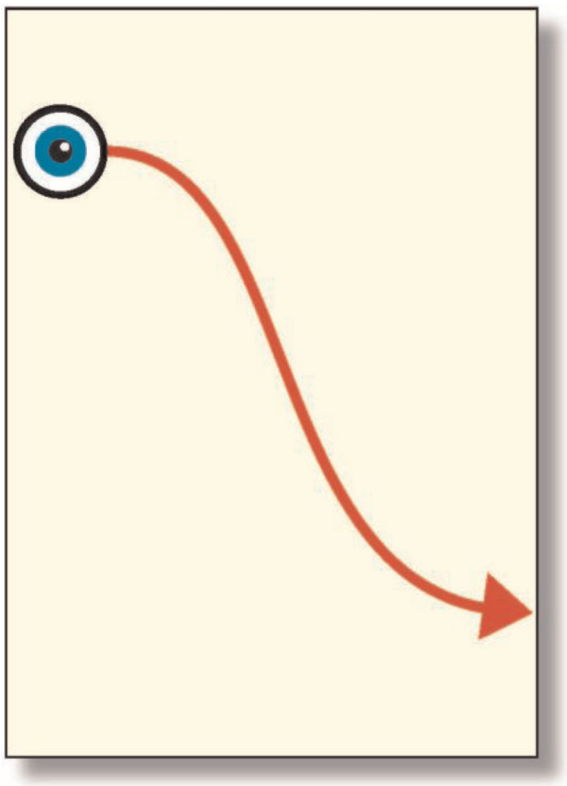
Underlying any functionally adequate layout is an understanding of how we read. A child, learning to read, thoroughly studies every single letter, then tries to combine two or three letters to form a syllable or word. Over time, words begin to form pictures in our brain and, rather than reading each of the three letters 'd-o-g' individually, the word shape 'dog' will eventually evoke the image of a fur-covered, food-loving animal. With continued training, the number of word shapes stored in our brains increases and we develop the ability to take in the meaning of groups of 3–4 words all at once.

> Letters can be grouped in myriad combinations. Words that are perceived as having meaning are those with which we have become familiar over time. They form a distinct and familiar shape. —Rob Carter[17]

In document design, three aspects of eye movement play an important role, i.e. fixation frequency, fixation pauses, and interfixation saccadic movements. The eye cannot see during interfixation movements, i.e. while in motion. It is only during fixation pauses that we are capable of extracting information from printed text. A normally skilled reader uses 3–4 fixation pauses on an average line of printed matter.

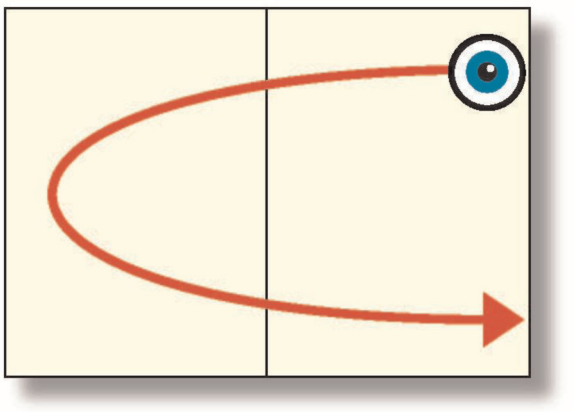
With Western European languages, most interfixation movements occur from left to right. Only some occur from right to left ('regressions'), namely when we re-read text we did not fully understand the first time round. At the end of each line, the eyes make a 'return sweep' that takes them to the beginning of the next line. Also, we generally read from top to bottom (Fig. 2).

At the same time, the eye tends to travel from largest to smallest picture, from most to least colorful, and then to the text. Understanding this and adapting one's layout accordingly will ensure that



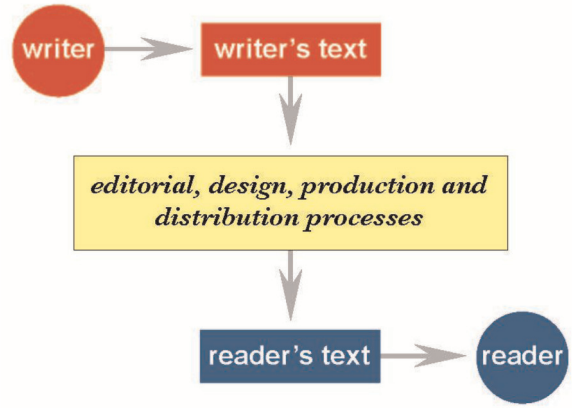
Adapted from Whitbread[12]

Figure 2: Eye flow: from left to right, from top to bottom.



Adapted from Whitbread[12]

Figure 3: Parabolic eye movement on a two-page spread.



Adapted from Waller[18]

Figure 4: Three-part communication model: writer – text – reader.

text is read rather than hidden. The goal of page design is to limit the number of backward eye movements. Thus, misplacing a particular element on a page may cause the eye to not travel back, and text in these 'fallow' areas is likely to be skipped by the reader, unless his eye is intentionally drawn back to where he left off.[12] For example, text placed above a picture is likely to be lost on the reader, whose eye will first jump to the picture and then continue reading through the bottom of the page.

On double pages, the eye generally moves parabolically from the top right-hand corner to the left and back to the bottom of the right page. This is why right-hand page advertisements in newspapers generally come at a higher cost than those on the left-hand side of a two-page spread.[12] Also, placing a picture on the right-hand page of a two-page layout may mean that the text on the left-hand side does not get read – unless there is something on the left-hand page that drags our eyes back across the spread. In magazine feature stories, the story generally starts on the right-hand page, with the left-hand page carrying a full-page illustration (Fig. 3).[12]

One way of increasing readability, then, is to present documents in such a way as to support the reading process through intuitive layout and typography.

Layout and typography defined

At this point, a brief definition of terms seems in order. Page layout is the part of graphics design that deals with arranging text and visuals on a page. Typography, on the other hand, arranges letters to make language visible. Thus, whereas layout happens on a page, typography happens within paragraphs[18] – even though an exact differentiation between the terms may not always be possible.

British information designer Robert Waller[18] sees layout and typography as one component of a three-part communication model involving the writer, the text (including all those who transform the text from a 'writer's text' into a 'reader's text'), and the reader (Fig. 4).

Thus, layout and typography play a central role in communication. In the late 1990s, Waller redesigned *The Lancet*. The brief was to make the journal, which functions not only as a peer-reviewed medical journal but also contains medical journalism, clearer to its readers. To Waller, the two-column layout was something we generally associate with journal design, whereas journalism is more frequently associated with narrower columns. Therefore, by 'using three columns … for the news sections, we were able to make a clear typographic distinction between the two types of content'.[18]

According to Waller[18], layout and typography add an additional dimension to a 'key restriction of mainstream lingustics—linearity'. Good page layout and typography support active reading, and good designers will focus on 'articulating the topic or supporting the reader'. The more complex the content, the more layout and design features can help make a text accessible – or readable.

Conclusion

Format and design is all about supporting and bringing out the message of a text, giving it its personality, and optimizing its readability. Harmonious page design is no coincidence, and, as the history of printing and typesetting illustrates, it is less a matter of personal taste than we tend to

think. Rather, layout and typography are an additional means of communication that writers have at their disposal to reach their prime goal – arousing the reader's interest and having their message hit home.

References

1. Jobs S. You've got to find what you love. Commencement address delivered on 12 June 2005. Standford University News [http://news.stanford.edu/news/2005/june15/jobs-061505.html].
2. Raynor DK, Blenkinsopp A, Knapp P, *et al.* A systematic review of quantitative and qualitative research on the role and effectiveness of written information available to patients about individual medicines. Health Technol Assess 2007;11(5).
3. Doak C, Doak L, Root J. Health literacy studies. Teaching patients with low literacy skills. 2nd ed. Available from: http://www.hsph.harvard.edu/healthliteracy/resources/doak-book/index.html. Philadelphia: J. B. Lippincott Company; 1996.
4. DuBay WH. The Principles of Readability, Available from: www.nald.ca/library/research/readab/cover.htm; 2004.
5. Klare GR. The measurement of readability. Ames, Iowa: Iowa State University Press; 1963.
6. McLaughlin GH. Proposals for british readability measures. In: Downing J, Brown AL (eds). The third international reading symposium. London: Cassell; 1968. p. 186–205.
7. Dale E, Chall JS. The concept of readability. Elementary English 1949;26:19–26.
8. Kandula S, Zeng-Treitler Q. Creating a gold standard for the readability measurement of health texts. AMIA Annu Symp Proc 2008; 353–7.
9. Mostenthal PB, Kirsch IS. A new measure for assessing document complexity: The PMOSE/IKIRSCH document readability formula. J Adolesc Adult Literacy 1998;41:638–657.
10. Arnold CL, Davis TC, Frempong JO, *et al.* Assessment of newborn screening parent education materials. Pediatrics 2006;117:S320–5.
11. Gray WS, Leary B. What makes a book readable? Chicago: University of Chicago Press; 1935.
12. Whitbread D. The design manual. University of New South Wales Press Ltd.; 2001.
13. Garfield S. Just my Type. London: Gotham; 2011.
14. Reynolds LJ. Lloyd J. Reynolds Collection. Autobiographical Notes. Available from: http://library.reed.edu/using/collections/findingaids/reynolds/ljrauto.htm; 1977.
15. Schwartz T. The Dance of the Pen. Available from: http://web.reed.edu/reed_magazine/aug2003/features/dance_of_pen/index.html. Reed Magazine; 2003.
16. Ascender Corporation. Charles Biglow. Available from: http://www.ascendercorp.com/designers/charles-bigelow/.
17. Carter R, Meggs PB, Day B. Typographic design: form and communication. John Wiley & Sons; 2011.
18. Waller R. Making connections: typography, layout and language [www.aaai.org/Papers/Symposia/Fall/1999/FS-99-04/FS99-04-002.pdf]. AAAI Technical Report FS-99-04 1999.

Author information

Gabriele Berghammer studied translation & interpreting at the University of Vienna, Austria, and the Monterey Institute of International Studies (MIIS), California. She has held various positions as a linguist in the pharmaceutical industry, most recently as medical writer in a major pharmaceutical company. Brief excursions into the software industry as a technical writer and into multilingual translation management have rounded off her documentation expertise. Since 2006, she has been running her own medical writing & translation consultancy, the text clinic.

Anders Holmqvist is an art director, illustrator and photographer from Lund, Sweden. He has extensive experience of illustrated reporting from international medical symposia, conferences and events, (DDW, EULAR, ACR, UEGW etc), and has also produced a wide range of product monographs, textbooks, booklets and newsletters, in collaboration with leading scientists and professional medical writers.

Writing visually for medical writers

Charlotte Leventhal[1], Phillip Leventhal[2]

[1]Arlington Heights, USA
[2]4Clinics, France

Correspondence to:

Phillip Leventhal,
4Clinics, Paris, France
pleventhal@4clinics.com

Abstract

Although content is obviously important for effective documents, the look of a document is also important. If you want someone to read a document, it should be pleasant to look at, and if you want the document to be used, the information should be easy to find. This can be accomplished by following the principles of 'writing visually'. These principles include making pages open and inviting to the reader, using clear text styles, and employing lists, tables, and illustrations to explain complicated processes and relationships.

Keywords: Readability, Document formatting, Tables, Lists, Diagrams, Visual elements

How long does it take you to decide to bother reading a document, website, or advertisement? Probably you need just a few seconds. If you want someone to read something, you need to make it pleasing or at least easy to look at. And if you want the document to be used, you need to make the information easy to find. You might be the William Shakespeare of medical writing, but if your document is difficult to look at, it will either not be read or it will frustrate and slow your reader.

We instinctively know a visually appealing document when we see one, but we might not be able to list the common principles. In this article, we provide a set of guidelines for making visually appealing documents, a process we call writing visually.

Make pages open and inviting

Use white space to provide relief

Blank space on the page, also known as white space, entices the reader to read a document because it keeps it from looking overwhelming. White space gives breathing room, that is, it separates ideas into manageable chunks and relieves the reader from trying to understand too much at one time. White space can also be used to highlight key information. Important areas of white space include:

- *Margins.* Margins should be one inch (2.5 cm) on all sides of the page. Smaller margins make the text look crowded. On the other hand, more is not better; larger margins can also distract the reader.
- *Spaces before and after paragraphs.* Although not customary in some European countries, always add space between paragraphs or at least indent the first line. This helps separate the different ideas and makes the text look less crowded.
- *Spaces before and after headings.* This makes headings easier to see.
- *Spaces between lines*. Double-spacing, at least in a draft document, makes text easier to read and allows hand-written editorial marks and comments to be inserted in a printed document. Double-spaced text is usually required for manuscripts submitted to journals.

Break the text into sections and subsections with section headings to make information manageable and easy to find

Breaking long documents into sections makes information more manageable. This is also a way of creating additional white space.

Indicate the content of each section with headings. Headings help the reader scan for needed information. The title and headings should be enticing and relatively short. The headings should follow a consistent format and structure throughout the document. For example, in a manuscript describing clinical trial results, you can help the reader by breaking the results into subsections on patient demographics, efficacy, and safety. In this way, the reader can immediately find the data they need.

Three heading levels are usually adequate. Change the font size and style to give the reader clues as to the heading level. The best options include ALL CAPS, **bold**, and *italics* and font sizes

DOI: 10.1179/2047480612Z.00000000046

between 16- and 12-point. Underlining may be useful in some cases, but be aware that underlined text might be confused with hyperlinks. This is easily done in Microsoft Word, where the format of the different heading levels can be quickly changed. For example, use Heading 1 for the title of the document, which you might make Arial 16-point bold. Heading 2 could then be used for section headings and could be Arial 14-point plain ALL CAPS (non-bold), and Heading 3 could be used for subheadings and could be Arial 12-point italics. An example is shown in Fig. 1.

Use short paragraphs

Long paragraphs make the text look intimidating and discourage the reader. Breaking up the text into short paragraphs is probably the most effective way of making the text easier to read. This creates white space and makes the content more manageable. Paragraphs should typically be no more than six to eight lines.

Use a ragged right margin to keep the text from looking too crowded

Margin formatting is often overlooked. Europeans often use proportional spacing (justified on both the right and left), but this can be distracting because the amount of space between each character and word vary to stretch the line to fit the given space. Proportional spacing also creates a monotonous block of text, which can tire the reader. As seen in Fig. 1, a ragged right margin (combined with white space and headings) makes the text easier to read.

Use text styles that are easy to read

Choose text styles that are easy to read on screen and on paper

To make life easier for readers, reviewers, and editors, use Times New Roman or Arial 12-point for the main text of most documents. Smaller font sizes are difficult to read. The standard font for Microsoft Word 2010 is Calibri 11-point, which, although pleasant to view on screen, can be a bit small when printed. For tables, where space is more limited, Arial 10-point is a good font and is easy enough to read.

You may wish to highlight headings by using a different text style. For example, you might use Times New Roman 12-point for the main text, Arial 16-point bold for Heading 1, Arial 12-point bold for Heading 2, and Arial 12-point italics for Heading 3. Whatever you do, be consistent and don't use too many different styles in a single document.

For emphasis, select text styles that are clear and not annoying or confusing

Bold, underlining, all caps, italics, or a combination of more than one of these can be used to emphasize key text in some documents. For example:

- Do NOT reuse the injection system.

However, TOO MUCH ALL CAPS CAN BE ANNOYING. Also, underlining can be confused in some cases with hyperlinks. And, *italics can sometimes be hard to read especially when printed.* The best way to emphasize text may be **boldface**. Generally, use emphasis techniques sparingly and reserve them mostly for headings and titles.

Avoid coloured text for most technical documents, but for documents where colours are desirable, choose colours that are easy to see and differentiate

Coloured text should be avoided in most documents. Many people do not have colour printers and, even if they do, the ink is expensive, so they generally will not print a document in colour. When printed on a black and white printer, colours may appear light grey, making the text difficult to read. Also, colour in a technical document can be annoying or look out of place.

However, for electronic documents like websites or for marketing information, colours can be useful and can help highlight key information. Keep the number of colours to no more than three or four; more may confuse and annoy the reader. Also, try to use colours that show up well both on screen and when printed. Note that the appearance of colours can differ between different computer screens, projectors, or printers, so be sure to use colours that can be easily differentiated. Finally, avoid using green and red together because many people are red–green colour-blind. A list of recommended colours for different backgrounds is shown in Table 1.

Use visual elements for quick reference

Lists, tables, and illustrations can cut through several pages of text. Like section headings, these visual elements allow the reader to quickly extract information and can help them remember it better.

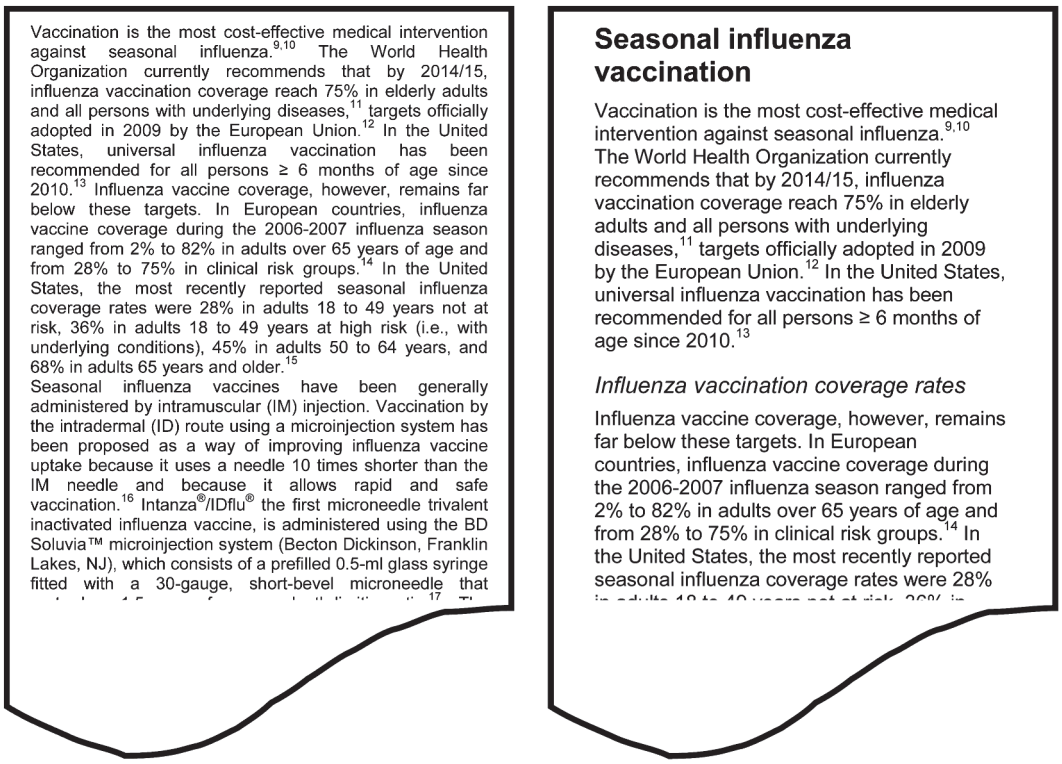


Figure 1: Comparison of a poorly formatted text and a well-formatted text. Left: the text looks crowded because of narrow margins, proportional spacing, small text, and a lack of white space. Right: the text is open, with sufficient margins, a larger text size, a ragged right margin, headings, and plenty of white space.

Organise related items in lists

Lists help readers quickly understand a series of related items. Lists also give plenty of white space and breathing room and they provide information in easily manageable chunks.

The items in a list should have consistent format and structure, and begin with a capital letter. If using full sentences, end each with a period. Keep lists short and try to limit them to roughly nine items. For longer lists, try grouping them into several shorter lists. Generally begin each list with an introductory phrase that ends with a noun describing the items, followed by a colon.

- *Numbered lists.* Use these to show sequential steps in a procedure or rankings. Use only one action per numbered step.
- *Bulleted lists*. Use these to show non-sequential items or choices. Bulleted lists help readers quickly scan a document. Each item should be independent of the others. This may keep the reader from understanding how the items fit together, so construct them carefully and avoid overusing them. For readability, it is possible that a paragraph may be more effective than a bulleted list.
- *Checklists*. Use these to track completion of required steps.

Examples of the different kinds of lists are shown in Fig. 2.

Table 1: Colour choices for text readability

Background	Use	Avoid
White	Black	Yellow
	Blue	Cyan
	Red	
Black	White	Blue
	Yellow	Red
	Green	Magenta

Organize information in tables to show how different pieces of information relate to each other

Tables are an effective way to concisely describe relationships. A well-designed table can save the reader from going through pages of text to find one fact or understand how different pieces of information relate to each other.

Tables generated by Microsoft Excel and some other software appear as grids with horizontal and vertical lines. However, vertical lines interfere with understanding relationships in the table, and too many horizontal lines can make the table difficult to look at. For manuscripts, vertical lines are generally not allowed, and horizontal lines are allowed only above and below the column headings and at

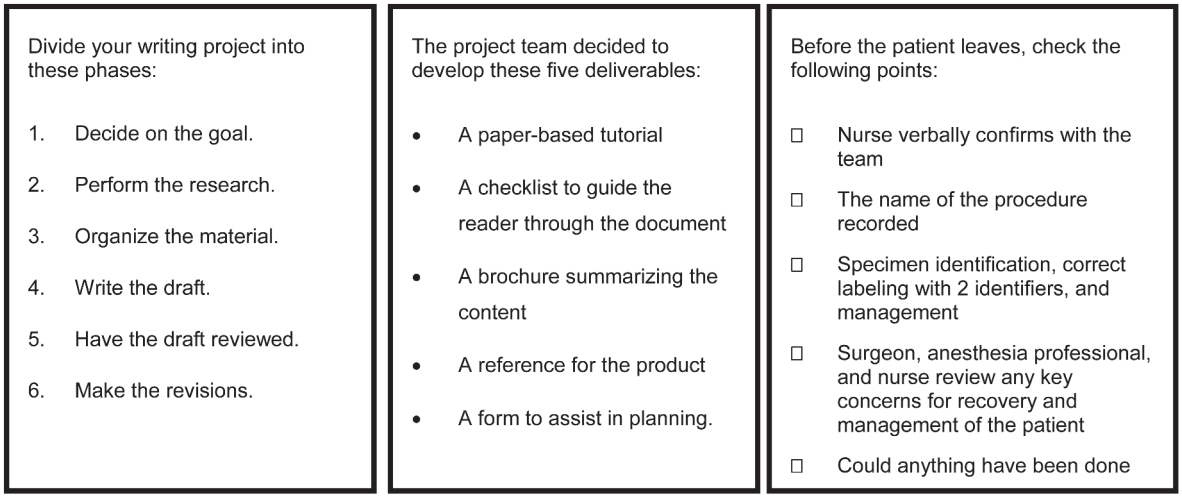


Figure 2: Lists. Left, a numbered list. These are used to show sequential steps or rankings or when a procedure must be completed in a fixed order. Middle, a bulleted list. These are used to show non-sequential items or choices, and they help readers quickly scan a document. Right, a checklist. These are used to track completion of required steps.

the end. However, vertical lines can be useful for grids as in a process table (Fig. 3).

Keep the table's description and the table close together. A short, informative title should be included before or after the table. Below the table, provide a legend adding any key information and describing all abbreviations and footnotes.

The top row or rows of the table should include column headings. Each column should have a heading. These should appear in bold, and the first letter of each heading should be capitalised. Horizontal lines should be added above and below the column headings.

Within the table, group related information together, and make each group consistent. Also, be sure that there is sufficient white space to differentiate columns. Different groups of information can be separated by inserting blank rows (to create white space) or by shading alternating sections or rows, although shading should not be used for manuscripts.

Stay within the 1-inch (2.5-cm) page margins. However, the page can be rotated from portrait to landscape format for a wider table. If you feel compelled to go outside these margins after rotating the page, your table is probably too complicated and should be split into multiple tables.

Use a font that can be easily read. To save a little room, you can use a san serif font, like Arial, which is made of simple lines as opposed to one with little bits on the ends of the lines like Times New Roman. Remember that the reader needs to be able to see the information in the table, so try to not go below 9-point for most documents. For example, Arial 10-point is a good style for table text. If you feel compelled to use smaller text, your table is probably too large and should probably be broken up into multiple smaller tables.

- *Reference tables*. These show data in a grid. A reference table usually lists a category of information in the left column. Once the reader understands how the table is organised, the reader looks at the category in the left column for the item of interest and then looks for the related information across the same row. Comparisons are made between different rows. These are used for display of data, for example, in a study report or manuscript.
- *Process tables*. These show who is responsible for doing a task in a long procedure and when. These are used, for example, in clinical study protocols.
- *Decision tables*. These help readers make decisions, and they are useful when your written explanation about a procedure is filled with if's, and's, and but's. These are used, for example, in instructions given to study investigators and trial nurses.
- *Action–response tables*. These show actions and the responses to that action, especially human actions and the related machine responses. These are used infrequently by medical writers.

Examples of reference, process, and decision tables are shown in Fig. 3.

Patient Characteristic	Group 1 N=38	Group 2 N=73
Age (y)		
Mean ± SD	65.0 ± 9.0	65.1 ± 8.7
Range	50 – 84	51 – 90
Sex, n (%)		
Female	22 (57.9)	40 (54.8)
Male	16 (42.1)	33 (45.2)
Ethnicity, n (%)		
African-American	0 (0.0)	1 (1.4)
Native American	0 (0.0)	0 (0.0)
Arabic/North African	0 (0.0)	0 (0.0)
White/Caucasian	38 (100.0)	72 (98.6)

Task / Visit	1	2	3
Week	0	4	8
Collect informed consent	X		
Confirm that patient conforms to entry criteria	X		
Assign subject identification number	X		
Patient provides demographic information	X		
Physical examination	X	X	X
Collect medical history	X		
Collect available clinical data	X	X	X
Collect concomitant medication data	X	X	X

IF the patient's score is...	Option 1	Option 2	Option 3
Under 60	YES		
60		YES	
Over 60			YES
THEN...			
Complete form 2	X	X	
Call the physician		X	X

Figure 3: Reference, process, and decision tables. Top left, a reference table. These are used to show results, for example, in a study report or manuscript. Top right, a process table. These are used to show who is responsible for each task and when, for example, in a study protocol. Bottom left, a decision table. These help readers make decisions and are used, for example, in instructions given to study investigators and trial nurses.

Use illustrations to describe complex processes

Illustrations are line drawings meant to describe complex processes. Carefully thought-out illustrations show the reader what they need to know without making them wade through pages of written text. However, be sure that the illustration is needed; simple illustrations sometimes are better left as text. For example, a flow chart describing a long process with no decision points might be better presented as a numbered list.

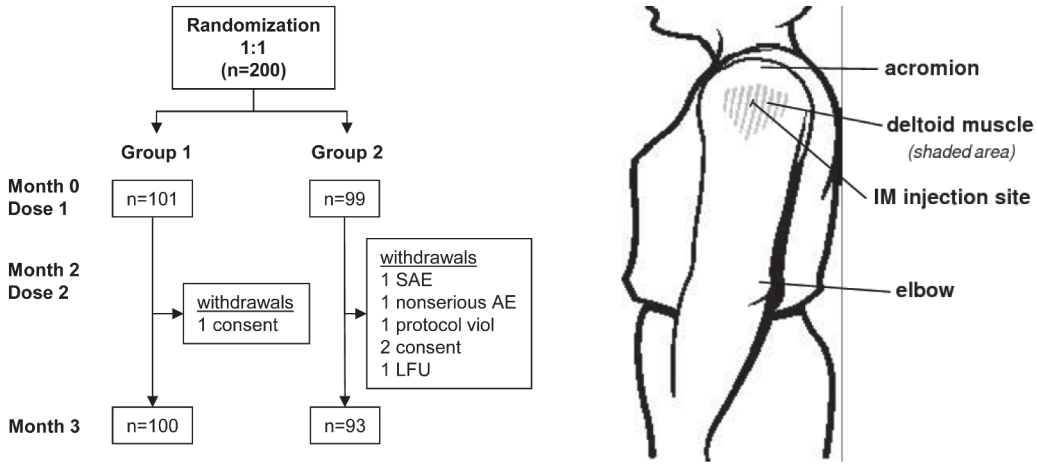


Figure 4: Flowcharts and diagrams. Left, an example of a CONSORT flow diagram, which is a type of flow chart. Flow charts describe workflow in complicated processes and procedures and may be used in place of or in addition to process tables. Right, an example of a simple diagram (public domain image). Diagrams are effective for helping the reader rapidly comprehend complicated equipment or procedures.

Illustrations should be clear and big enough to be easily read on screen and when printed. If you are providing illustrations for a journal, magazine, or flier, check the proofs to ensure that the copy editor did not make them too small or too big.

The illustration should include an explanation so that the reader does not have to refer back to the text. Keep the explanation and the illustration close together except in manuscripts where figure legends are generally listed on a separate page at the end of the text.

- *Flowcharts.* These are used to describe workflow in complicated processes and procedures and may be used in place of or in addition to process tables. Flowcharts allow readers to grasp essential steps quickly and easily, especially when the process involves decision-making. The flowchart should present the workflow from top to bottom, then from left to right, using arrows and lines to connect different steps. For long procedures, present one concept per flowchart, then continue to the next flowchart. To tie several flowcharts together, you can use an overview flowchart.
- *Diagrams.* These are effective for helping the reader rapidly comprehend complicated equipment or procedures.
- *Report or form samples.* Inserting a sample can help the reader understand how to complete a report or form. Be sure to replace actual data, such as names, addresses, social security numbers with fictitious information.

Examples of a flowchart and a diagram are shown in Fig. 4.

Conclusion

Although content is obviously important for effective documents, the look of a document is also important. If you want someone to read and use a document, it should follow the principles of writing visually, including making pages open and inviting to the reader, using clear text styles, and employing lists, tables, and illustrations to explain complicated processes and relationships.

Bibliography

- Hibbard C. Improving the appearance of your technical document. 2012 [cited 2012 June 10]. Available from: http://www.cypressmedia.net/articles/article/15/improving_the_appearance_of_your_technical_document.
- Horton W. Illustrating Computer User Documentation, 1991, Available from: http://www.horton.com/icdbook.htm.
- Make it visually appealing. 2011 [cited 2012 June 10]. Available from: http://www.nedarc.org/tutorials/utilizingData/adoptGoodCommPrinciples/makeItVisuallyAppealing.html
- Pabst C. How to make your writing more visually appealing. 2007 [cited 2012 June 10]. Available from: http://www.igniteliving.com/the-lighter-side/how-to-make-your-writing-more-visually-appealing/.

Author information

Charlotte Leventhal is a retired technical writer living in Arlington Heights, Illinois, USA. Her son, Phillip Leventhal is a medical writer at 4Clinics in Paris, France and is Editor-in-Chief of *Medical Writing*.

Quality control: getting the best out of your review

Nicola Haycock

Senior Medical Writer, PRA International, UK

Correspondence to:

Nicola Haycock,
Senior Medical Writer,
PRA International,
Reading, Berkshire, UK
HaycockNicola@praintl.com, www.praintl.com

Abstract

In medical writing, quality control (QC) means ensuring that a document's content, style, and format are of high quality. This does not just 'happen' but is the result of a systemic QC review. These reviews are critical because mistakes can cause the reader to question the validity of the content and may lead to errors in interpretation. QC guidance documents may be available in-house or from a client, but if not available, they can be created by combining existing guidelines and checklists. A good QC review takes time but is well worth the effort.

Keywords: Quality control, Checklist, Time

We all hear about quality control (QC), but what does it really mean? A check for typos on a rough first draft? A quick skim of a near-final document before it's finished? Neither! QC is checking a document to ensure the best possible quality of the output. It is an integral part of the production of a document rather than a one-off step in the progress from first to final draft.

Clearly, a final document should not contain errors. However, QC should be done before your reviewers even see the *first* draft. Indeed, QC is critical for making sure that every version is of the highest quality. Your reviewers are your customers, regardless of whether they are within your own company or external, and a high-quality document instills confidence that they are working with an accomplished medical writer. A poor-quality document, on the other hand, can jeopardize the chance of repeat work and may even limit your job prospects.

Who should perform the QC review?

Ideally, the QC review should be performed by somebody other than the author of the document. A fresh pair of eyes can spot errors that an author may have overlooked. Most commonly, a QC reviewer will be another medical writer within the same company. This reviewer can have less, equal, or greater experience than the author. For writers working alone, without a colleague to perform a QC review, the author may have to perform self-QC, but the principles are still the same.

Whoever is doing the QC, training on how to perform a good review is always beneficial. If QC training is not available at your place of work, you can obtain it through courses such as the Editing and Proofreading Essentials workshops (Parts 1 and 2) that are part of the Foundation Level of the EMWA Professional Development Programme. Other courses, some of which are available on line, are offered by various professional organizations such as the Society for Editors and Proofreaders (http://www.sfep.org) and the DIA (http://www.diahome.org). If you are a new medical writer or a new QC reviewer, a QC training course will give you a good start, but even an experienced medical writer can learn something new in a training course.

If a document has already undergone a review and needs subsequent QC on a later version, a review by the same person who performed the first QC review can be beneficial because they will already be familiar with the document. Some companies employ people whose main role is to perform QC reviews, which is a wonderful asset if available.

The tools of the trade – what you need to perform a QC review

Most pharmaceutical companies and contract research organisations will have their own standards for producing documents. These will be described in company-specific templates, style guides, and authoring instructions. Standard operating procedures describing the QC review process may also be available. To ensure that the quality and level of detail of a review are consistent, a QC checklist may be available. A detailed QC checklist is an important tool. It will help you cover all of the aspects of a review and will let you keep track

DOI: 10.1179/2047480612Z.00000000047

Table 1: Documents to be supplied to QC reviewer

✓ QC checklist
✓ Document template
✓ Signature page (if not part of checklist)
✓ Style guide (covering text styles, punctuation, abbreviations, capitalization, number and date formats, etc.)
✓ Source documents (data tables, protocol, protocol summary, statistical analysis plan, clinical study reports, etc., depending on the document to be reviewed)
✓ Authoring instructions (covering use of company-specific authoring toolbars, document formatting, cross-referencing, in-text table format)
✓ Standard operating procedure for QC
✓ Last but not least, the document(s) to be reviewed!

of what you've checked and what's left to do. This, in turn, will help you manage your time.

The QC guidelines should be taken into account when the author is writing the document, and likewise, should be passed on to the QC reviewer. Also, the QC reviewer will invariably need the source documents (e.g. protocol or data) to verify the content of the document. A signature page should also be included as part of or separate from the QC checklist to document that the review has taken place. If you are acting as the QC reviewer, make sure that you have received as many of these documents as possible before starting your review because they will ensure maximum thoroughness. When timelines are tight, the document author may forget to provide all of the necessary documents you need, but don't hesitate to ask them to dig out the guidelines and checklist. Typical documents needed by a QC reviewer are listed in Table 1.

No QC checklist? Create your own!

Ideally, you will already have a QC checklist to work with, but if you don't, why not create your own? You can create a QC checklist specific to each type of document you review, for example, separate checklists for protocols, clinical study reports, and manuscripts. You can also create a generic checklist that contains the kind of items that should be checked in any document.

Begin constructing your checklist with a brainstorming session. Think about document formatting, style, correct use of grammar and punctuation, consistency of text and information/data in the synopsis, main body of the document, conclusions … the list goes on. The main topics that should be included in a QC checklist are shown in Table 2.

Table 2: Main topics of a QC review with examples

- Formatting
  - Styles
  - Page layout
  - Pagination
  - Headers and footers
- Consistency
  - Synopsis/summary/conclusions versus the main body of the document
  - Text and message throughout the main body of the document
  - Tabular data quoted in text
  - Specifically for protocols, the schedule of assessments table versus the text (a common one for consistency errors!)
- Tables
  - Formatting and layout
  - Consistency in style of tables throughout document
  - Clarity of presentation
  - Caption style
  - Electronic cross-references
  - Sources (correctly cited and content matches source)
- References
  - Correct citations
  - Format of in-text citations and reference list
  - Completeness of reference list
- General
  - Accuracy versus source documents/data
  - Spelling and grammar
  - Sentence construction
  - Abbreviations
  - Table of contents

In constructing your checklist, take advantage of and combine together any guidelines or checklists you already have. Useful resources include style guides such as the AMA Manual of Style,[1] and for reporting trials and manuscripts, the CONSORT[2] guidelines and the ICMJE guidelines.[3]

Include tick boxes where the QC reviewer can check off that each item in the list has been checked. Also, include a comment box where the QC reviewer can explain why an item is not checked and in which specific findings can be described. A general comments section either at the start or end of the list is also useful, for example, for explaining that only certain parts of the document have been reviewed. In addition, include a section to state the version number and date of the reviewed document together with its title, project code, or any other identifiers, and a space to sign and date the form to record that the QC has been completed. You may also want to include space for the author to sign to document implementation of the comments or to allow the author to respond to comments. An example checklist is shown in Fig. 1.

Document title:		
Document version number and date:		
Study identifier/protocol number (if applicable):		
Document type (e.g. protocol, clinical study report etc.):		
General notes for review (guidance from author to reviewer or notes from reviewer to author):		
Item	**Checked**	**Comments (including reason if not addressed)**
Formatting		
Header and footer appears on every page	Yes ☐ No ☐ N/A ☐	
Header and footer information is correct on every page	Yes ☐ No ☐ N/A ☐	
...		
Name of reviewer: Signature: The comments have been addressed: Name of author:	Title: Date of review: Signature and date:	

Figure 1: An example QC checklist.

Keep your QC checklist as a living document, adding to it every time you spot something that you think will be relevant to check on future documents. You may well find your list growing, but you can always refine it to make it comprehensive but concise.

You may be involved in creating company style guides during your career. A good rule of thumb for these documents is to avoid complicated style instructions such as detailed grammar rules, so that even people who are not medical writers or who are not native English speakers can follow the guidelines.

Getting started on the QC review

Once you have all of the things you need to start your QC, it may be very tempting to dive straight in. Although QC reviews are often performed in a relatively short time due to tight timelines, take a few moments to take stock at the start of the review. This can pay dividends in the end. Make sure that you know how much you need to do and the amount of time you have to do it. Check with your author to see if any part of the document has had its QC review already and therefore doesn't need to be checked again. For example, the non-data-driven sections of a clinical study report are often reviewed before the results section of the report is written. Also, check if all of the items on the QC checklist apply to your review because your document may have already been reviewed using the checklist and therefore not everything needs to be checked again. Clarify whether the QC review is being split between you and another reviewer.

If the timelines are very tight, the author may want two QC reviewers to work in parallel on different parts of the checklist or even on different parts of the document. If it seems that there is too much work to finish in the time allotted for the review, you may suggest at the start that another reviewer is brought on board; it's better to ask this at the start than to find yourself in a fix as your deadline approaches. You can also agree on the priority areas in case you are running out of time. Take care to look through the whole QC checklist before you start because it is easy to misjudge how much time each item will take. For example, you may find yourself speeding through the easy items, such as consistency of headers and footers or use of page breaks, and it can feel great to make such rapid progress through your checklist, but you may suddenly be slowed by an item that requires checking the entire document against its source. Reviewing your checklist before you get started can give you a better feel for how long it will take to complete and therefore which items you want to do first.

Make the most of your time

In practice, the QC probably has to fit around your other work. Try to put the other priorities aside and find some peace and quiet so that you can give close attention to the QC review. Consider

even taking a deep breath and switching off your email, if you can get away with it! Remember to take breaks to maintain your focus over long reviews as tiredness can lead to missing small mistakes. In case you have limited time, you can suggest providing comments to the author in stages if they are keen to start on revisions.

Finishing off

When you return your reviewed copy of the document and checklist to the author, ensure that your edits are clear and easy to understand. Giving a brief explanation of certain edits can also be valuable. For example, if you suggest that some text should be removed from a summary section of a document but that it should be retained in the main part of the document, explain this so that the author does not remove the text throughout the document. You can also justify stylistic changes by referring to the style guide to make it clear that you are not basing your edits on your own preferences. The QC review of a document can be a useful tool for learning (both for the author and the reviewer), so a small number of explanations with the comments can be helpful.

Conclusion

More than just a quick read-through, QC reviews are comprehensive and detailed exercises that can also be learning experiences. As a reader, we all expect high-quality documents, but this requires an organized review process. As well as QC guidance documents, a good QC checklist will contribute towards a review that is performed well and will improve the standard of the reviewed document.

References

1. Iverson C, Christiansen S, Flanagin A, *et al.* AMA manual of style: a guide for authors and editors. 10th ed. New York: Oxford University Press; 2007.
2. Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomized trials. Open Med 2010;4(1):60–8.
3. ICMJE guidelines [document on the internet]. 2010 [cited 2012 Jun 23]. Available from: http://www.icmje.org/.

Further reading

Wrede PC. The business of writing: quality control [document available on the internet]. 2012 [cited 2012 Jun 23]. Available from: http://pcwrede.com/blog/the-business-of-writing-quality-control/.

Author information

Nicola Haycock is a Senior Medical Writer at PRA International and lives in Wokingham, England. She gained industry experience in contract research organisations, starting in clinical operations, before specialising in medical writing.

Pharmaceutical medical writing competencies: Comparing self-perception with employers' expectations

Sabrina Heisel-Stoehr, Thomas M. Schindler

Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

Correspondence to:

Thomas M. Schindler
Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach an der Riss, Germany
thomas.schindler@boehringer-ingelheim.de

Abstract

In the recently published 'Pharmaceutical Medical Writing Competency Model', a group of medical writers describes the knowledge, skills, and behaviours they considered essential for successful medical writers. Thus, this model represents a list of essential job requirements from within the medical writing profession. Using the job postings of the EMWA website (in total 146 adverts from 2009 to 2011), we investigated whether the competencies listed in the model are in line with the expectations of the employers of medical writers. In these adverts, we found that familiarity with the techniques of scientific writing and editing, a science background, the ability to comprehend scientific concepts, and the capability to author quality documents were the most frequently mentioned requirements. Generally, the Competency Model matched well with the requirements mentioned in the job adverts. However, certain essential attributes were rarely mentioned in job adverts; examples include proficiency in statistics and knowledge about publication guidelines. With regard to social skills, job adverts tended to ask for more general skills than those described by the Competency Model. The Competency Model distinguishes between publication and regulatory writers, and this distinction was reflected in the attributes mentioned in the job postings with adverts for regulatory medical writers listing a broader skill set than did those for publication medical writers.

Keywords: Competency model, Medical writing, Regulatory writing, Publication writing, Qualifications, Job market requirements

Introduction

The 'Pharmaceutical Medical Writing Competency Model', published in 2011 was developed by an international committee of 22 medical writers with diverse backgrounds and experience.[1] The group aimed to '… help define what makes a medical writer different from other professionals involved in the development of therapeutic products'.[2] Hence the Competency Model is a form of 'wish list' developed for use by the profession and others. The Competency Model has two parts: the first part describes nine work functions of medical writers and outlines benchmark activities that should be mastered and the second part identifies the knowledge, skills, and behaviours that are required for medical writers. In the print version, the items in the Competency Model are described in considerable detail (some nine pages in total). The authors define competency as 'the ability of an individual to perform a specific role successfully …'[1] The model has been used in hiring and training medical writers and in reviewing their performance.[2,3]

We were interested to establish whether the 'self-prescribed'competencies, listed in the second part of the model, concur with the expectations of the employers of medical writers. To identify what employers want from medical writers we used the job postings of the EMWA website in the years 2009–2011. We worked on the assumptions that the requirements listed in the job postings are chosen carefully to attract the most suitable candidates, and that they had undergone considerable scrutiny because they convey the values and self-perception of the company. Job adverts also help to position a company within its competitive environment. We further assumed that the costs of job adverts (although low in the case of EMWA) generally encourage advertisers to be selective in the requirements presented.

The length constraints that commonly apply to job adverts may also be a limitation of our comparative

DOI: 10.1179/2047480612Z.00000000049

approach since they preclude the level of detail that was applied in the Competency Model. Also the wording of the requirements of the position advertised is usually more general than the items that are used in the model. Therefore we had to devise rules to ensure that the wording in the job adverts is appropriately linked to items in the Competency Model (see the Methods section). Our analysis concentrated on the section of the Competency Model covering 'Knowledge, skills, abilities and other characteristics' because job adverts usually list these attributes while they rarely give details of work functions and critical behaviours.

"Posting" refers to the display on the website and "advert" denotes an individual job offer. One posting could comprise several adverts and one advert could offer several positions.

Methods

Categorizing job adverts

Upon request, the EMWA web team provided us with copies of the job adverts posted from 2009 to 2011 as pdf files. One posting from 2009 was excluded because it lacked relevant content and three from 2011 were excluded because of technical problems (e.g. non-functional links) or lack of relevant content. According to the predominant tasks mentioned, all adverts were categorized as targeting either 'regulatory medical writers' or 'publication medical writers'. In about 90% of cases this categorization was straightforward. If, however, the description of the tasks did not indicate the nature of the position advertised, the professional focus of the company was used to guide the allocation, e.g. if the posting of a medical communications company was unclear in this respect the position was assumed to be for a publication writer. The listed order of requirements was assumed to reflect their priority for the employer.

Mapping job adverts to the Competency Model

We limited our evaluation to the second main part of the Competency Model covering technical knowledge, technical skills and abilities, and behavioural skills for technical contribution. As the original descriptions of the behavioural skills (all writers: 17 items) in the model are often lengthy they were condensed into 15 keywords for tabular presentation. Some items in the model are for all medical writers and there are additional separate lists for regulatory writers and for publication writers. All items were transferred to a Microsoft Excel file.

Each job posting was initially read by the two authors. To limit potential bias in allocating the items in the job adverts to the categories of the Competency Model, mapping rules were devised prior to a second thorough reading of the postings. The individual items mentioned in job adverts were 'coded' and subsequently entered into the appropriate Competency Model categories in an Excel file. SHS read and analysed all job postings, TMS categorized a sample of 15 job postings (ca. 10%). In most cases, the items mentioned in the adverts could be directly assigned to Competency Model categories. Unclear categorizations were discussed and agreed between the authors. Absolute numbers and frequencies were calculated for the total number of jobs advertised as well as for the number of regulatory writing and publication writing positions.

When a job advert asked for relevant experience in scientific or medical writing this was allocated to the category 'techniques of scientific writing and editing'. If a qualification in life science or medicine was requested, this was entered as 'science'. Whenever knowledge of life sciences or clinical research was required, this was mapped into the category 'ability to comprehend scientific concepts'. Only if the words 'statistics' or 'statistical [knowledge, competence, etc]' were used in an advert, was this requirement entered. However, no advert contained text that could be construed as making reference to statistics without mentioning the word. When the ability to analyse data was asked for, this was entered as 'ability to comprehend statistical concepts'.

If working within a matrix environment or according to standard operating procedures (SOPs) was explicitly mentioned, this was entered as knowledge of 'company policies'. The categories knowledge of 'regulatory guidelines', 'regulatory authorities', and 'publication guidelines' were only ticked if these were explicitly requested in the text. Knowledge of 'publication planning software' was assumed when the use of publication planning tools was asked for. The category 'rewrite existing documents' was ticked when rewriting was explicitly mentioned and also when updating of SOPs was on the list of responsibilities. The model term 'build positive and productive relationships' was renamed to 'networking' and entries were made whenever the establishment of relationships with clients, team members, collaborators, or opinion leaders was mentioned. The abilities 'to globally share work' and 'to effectively work in multicultural teams' were combined to 'intercultural competence'.

In parallel with the above analyses, the job adverts were screened for terms alluding to soft skills that were not mentioned in the model using these same terms such as 'communication skills' and 'interpersonal skills'.

Observations

From 2009 to 2011, 61 different companies used the EMWA website to place 118 job postings. This included medical communications agencies, large pharmaceutical and biopharmaceutical companies, biotechnology companies, contract research organizations (CROs), and recruiting agencies. Over the 3 years, 152 positions were advertised and 146 could be included in the analysis. Exactly half of the positions were for regulatory medical writers and half for publication medical writers (Table 1). Overall, 83% of adverts specified the need for a scientific background or knowledge of life sciences or clinical research. A total of 68% expected a university degree (B.Sc./M.Sc. or M.D./Ph.D.) in life sciences or medicine; 39% of adverts preferred or required a Ph.D. This is in line with previous analyses of the EMWA website job postings.[4] Assuming that items were listed in adverts in order of importance, we found that the first requirement mentioned was a scientific degree in 49% of adverts or relevant work experience in 30%. The second requirement mentioned was relevant work experience in 38% of job adverts, followed by language skills in 21%. The second item mentioned showed greater diversity than the first one (e.g. knowledge of ICH, management skills).

Table 1: Medical writing job postings on the EMWA homepage from 2009 to 2011

	2009	2010	2011	Total
Number of companies with at least one job posting	25	27	34	61
Number of job postings[#]	37	36	45	118
Number of positions advertised*	48	46	58	152
Number of non-analysable job adverts	3	0	3	6
Number of analysed job adverts	45	46	55	146
Number of positions for regulatory medical writers**	17	24	32	73
Number of positions for publication medical writer	28	22	23	73

[#]Job postings could include several adverts.
*The number of positions advertised is not easily determined as some postings offered several positions. In these instances, two positions were assumed.
**A total of 30 job adverts (2009: 10; 2010: 8; 2011: 12) described items for both regulatory and publication writing activities. However they were categorized as regulatory medical writer adverts because of the dominance of regulatory writing aspects.

Technical knowledge

Most job adverts (84%) required the medical writer to have mastered the techniques of scientific writing and editing (Table 2); this requirement was more frequent in adverts for publication writers (93%) than for regulatory writers (75%). A science background was specified in 68% of adverts and the preponderance of this requirement was higher for regulatory writers (78%) than for publication writers (58%). More than one-third (38%) of all adverts asked for knowledge of software and systems including document management programs, word processing software, or reference management software. Again, the frequency of this requirement was higher in job adverts for regulatory writers (49%) than in those for publication writers (26%). A quarter of the adverts required the ability to train or mentor less experienced writers or to instruct external writers. The other items in the 'technical knowledge' section of the Competency Model (statistics, company policies, industry guidelines, knowledge about the functional roles of team members, and publishing standards) were only rarely asked for (<10% of all adverts). While job adverts for regulatory writers specified the requirement for knowledge about regulatory guidelines (53%) and authorities (27%), knowledge about international guidelines was substantially less frequently required in adverts for publication writers (1%).

Technical skills and abilities

The majority of adverts wanted medical writers who are able to comprehend scientific concepts (83%). About 45% of the job adverts asked for the ability to 'author quality documents', which denotes the writing of compelling, clear, concise, and correct texts. Project management skills were also in high demand (38%) and this includes the management of deliverables, timelines, responsibilities as well as communication planning and meeting organization. One-third of the job adverts required editing skills such as formatting, proof-reading, micro-editing, and macro-editing.

The ability to interpret and communicate clinical and numerical data was requested in 42% of job adverts for regulatory writers but only in 7% of those for publication writers. Similarly, the abilities to comprehend statistical concepts (regulatory writers 29% vs. publication writers 5%) and to report and summarize information (regulatory writers 33% vs. publication writers 1%) were required predominantly in adverts for regulatory writers. In contrast, the ability to layout posters and slides was more frequently mentioned in adverts for publication writers (27%) than in those for regulatory writers (13%).

Table 2: Representation of the technical knowledge and technical skills and abilities categories from the Competency Model[1] in EMWA website medical writing job adverts for 2009–2011

	Regulatory medical writers	Publication medical writers	All medical writers
Number of positions advertised	73	73	146
Technical knowledge			
All medical writers			
Techniques of scientific writing/editing	75%	93%	84%
Science	78%	58%	68%
Software and systems	49%	26%	38%
Training/mentoring	26%	26%	26%
Statistics	12%	0	6%
Company policies	3%	3%	3%
Industry guidelines	0	3%	1%
Functional roles of team members	0	0	0
Publishing standards	0	0	0
Regulatory medical writers			
Regulatory guidelines (e.g. ICH M2, M4)	53%	0	27%
Regulatory authorities	27%	0	14%
Standardization initiatives (CDISC, CDASH)	0	0	0
Publication medical writers			
Publication coordination	3%	23%	13%
Publication planning software	0	15%	8%
Publication guidelines (e.g. GPP, ICMJE)	1%	1%	1%
Reporting guidelines (e.g. CONSORT)	0	0	0
Technical skills and abilities			
All medical writers			
Comprehend scientific concepts	92%	74%	83%
Author quality documents	41%	48%	45%
Project management	36%	41%	38%
Document editing	26%	36%	31%
Interpret clinical/numerical data	42%	7%	26%
Quality control	23%	29%	26%
Review documents	30%	16%	23%
Layout slides/posters	13%	27%	20%
Report/summarize information	33%	1%	17%
Comprehend statistical concepts	29%	5%	16%
Conduct effective literature search	7%	3%	5%
Transcription	10%	0	5%
Rewriting existing documents	5%	1%	3%
Information management	3%	0	1%
Interview for information	1%	0	1%
Publishing	0	0	0
Regulatory medical writers			
Prepare regulatory documents	79%	0	40%
Prepare communication strategy	15%	0	8%
Prepare publishing ready documents	7%	0	3%
Publication medical writers			
Prepare publication documents	41%	53%	47%
Prepare publication plan	3%	18%	10%
Meet journal guidelines	1%	0	1%

The difference between the technical knowledge item 'statistics' (6% of all adverts) and the ability 'to comprehend statistical concepts' (16% of all adverts) seems likely to be attributable to a distinction between the need for a formal background in statistics and an ability to understand statistical concepts. As expected, regulatory writers were required to prepare regulatory documents (79%) while publication writers were not (0%). Conversely, publication medical writers should prepare publications (53%), although this is also requested in a fairly high percentage of postings for regulatory writers (41%).

Soft skills

In addition to the technical knowledge and abilities, the Competency Model provides a list of necessary behavioural skills (Table 3). The ability

to build positive and productive relationships with clients, team members, collaborators, or opinion leaders (networking skills) as well as strong leadership and team working skills were the most frequently requested soft skills for all types of medical writers. About 20% of the job adverts mentioned an exceptional eye for detail, organizational skills, or time management in their profiles. These skills are, however, more frequently asked for in job adverts for regulatory writers than in those for publication writers. Likewise, the ability to 'multitask' and to 'manage conflicts' are more prevalent requirements in adverts for regulatory writing jobs. All other soft skills such as proactive attitude, flexibility, and creating solutions were mentioned in less than 10% of all adverts.

Intercultural competence was almost never mentioned as a requirement. Compared with the Competency Model, job adverts tend to use more general terms for behavioural skills (Table 4). The most prevalent social skills listed in adverts were communication skills, interpersonal skills, and the ability to work independently. All of these were asked for more frequently in adverts for regulatory writers than for publication writers.

Most frequently listed requirements

Based on our analysis of the adverts, the most frequently (≥20%) required skills and competencies for all medical writers were (in order from higher to lower frequencies):

Technical knowledge

- knowledge of the techniques of scientific writing and editing
- having a science background
- familiarity with software and systems
- ability to train and mentor

Technical skills and abilities

- comprehend scientific concepts
- author quality documents
- perform project management
- edit documents
- interpret clinical and numerical data
- perform quality control
- review documents
- layout slides and posters

Table 3: Representation of the behavioural skills from the Competency Model in EMWA website medical writing job adverts for 2009–2011

	Regulatory medical writers	Publication medical writers	All medical writers
Number of positions advertised	73	73	146
Networking (5)	56%	56%	56%
Leadership and team working skills (12)	62%	36%	49%
Detail oriented (3)	27%	22%	25%
Time management (2)	30%	12%	21%
Organized (1)	33%	7%	20%
Multitasking (4)	15%	3%	9%
Commercially astute actions (14)	7%	10%	8%
Conflict management (8,9)	10%	3%	6%
Proactive attitude (13)	7%	5%	6%
Flexibility (10)	7%	4%	5%
Create solutions/resolve problems (11)	8%	3%	5%
Intercultural competence (16,17)	3%	3%	3%
Work ethic (15)	4%	1%	3%
Learning agility (7)	1%	4%	3%
Effective decisions (6)	0	0	0

The Competency Model uses the term 'Behavioural Skills for Technical Contribution'; however, as no other skill sets are mentioned we interpreted this as the overall skill set. The numbering (order) of these skills in the Competency Model is given in parentheses.

Table 4: Social skills as mentioned in EMWA website medical writing job adverts for 2009–2011

	Regulatory medical writers	Publication medical writers	All medical writers
Number positions advertised	73	73	146
Communication skills	47%	15%	34%
Interpersonal skills	22%	1%	12%
Ability to work independently	18%	0	10%

Behavioural skills

- being able to network
- having leadership and team working skills
- being detail-oriented
- having effective time management
- being organized

This 'condensed' list may constitute the blueprint for an 'ideal' medical writing candidate.

Discussion

Given the spatial constraints of job postings, we found that the technical aspects of the 'Knowledge, skills, abilities and other characteristics' section of the Competency Model matches well with what employers of medical writers want. This conclusion rests on two assumptions, namely that the categorization of job adverts as for regulatory writers or for publication writers was straightforward and that the mapping of items in the job adverts onto the categories in the Competency Model did not distort their content. The categorization of a job advert was simple and unambiguous with almost no differences between the two assessors. Mapping the items listed in the job postings to those in the Competency Model was more challenging. We tried to address this potential source of bias by defining rules for individual items. Nevertheless, even the most stringent application of rules inevitably involves some degree of subjectivity and interpretation.

Certain essential aspects in the Competency Model are or only rarely seen in job postings. Most medical writers work with data and should therefore be familiar with the methods of data analysis and data interpretation, i.e. they should have a certain statistical competence. However, knowledge of statistics was infrequently asked for (all writers 6%; regulatory writers 12%; publication writers 0%) as well as the ability to understand statistical concepts (all writers 16%, regulatory writers 29%, publication writers 5%).

In only 1% of adverts was the writer required to know international publication guidelines. This is in stark contrast with the multitude of international initiatives surrounding the writing of scientific publications such as the GPP, CONSORT, STARD, MOOSE, STROBE, and PRISMA guidelines. This is the more puzzling as these guidelines often have a direct impact on the way publications have to be written. Also, job adverts rarely ask for knowledge about standardization initiatives (e.g. CDISC), the ability to conduct literature searches, management of information, the ability to interview for information, or knowledge about publishing standards.

With regard to social skills, adverts for medical writers indicate that they should be able to network, to lead and to work in a team, to be organized and detail oriented, and to employ good time management. Other social skills were less in demand. Job postings tended to ask for more general social skills than those provided by the Competency Model. Requirements for intercultural competence, for strong work ethics, for the agility to learn, and for effective decision making were only rarely expressed. This is surprising because it is hard to see how a medical writer, who often works in a multinational and multicultural teams, can be successful without cultural sensitivity.[5] Likewise, how can a medical writer function without the willingness to behave ethically, i.e. ensuring appropriate copyright permissions and acknowledgements, and safeguarding against plagiarism or falsification?

As indicated in the Competency Model our analysis also shows that the skill sets required from regulatory medical writers and publication medical writers are distinct. In many instances, the adverts for regulatory writers asked for more skills and a more varied background than did those for publication writers. For example, regulatory writing adverts more often required a science background, the abilities to interpret scientific data to understand statistical concepts, and to report and summarize information. None of the 73 adverts targeting publication writers asked for a knowledge of reporting guidelines and knowledge in statistics was only rarely required. Surprisingly, not even the ability to devise a publication plan was in high demand in postings for publication medical writers.

The need for highly skilled medical writers in the regulatory field might be a result of the increasing complexity of documentation required by the regulatory authorities.[6,7] Our analysis suggests that for hiring purposes a more condensed list of competencies might be more useful than that provided in the fully fledged Competency Model.

Acknowledgements

We would like to thank the Shanida Nataraja, Melanie Foster, and Mark Allen from the EMWA web team for providing us with copies of the job adverts and our editor Margaret Gray for the excellent editing of our manuscript.

References

1. Clemow D, the Drug Information Association Medical Writing Special Interest Area Community

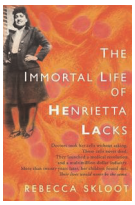
Competency Model Working Group. Pharmaceutical medical writing competency model. AMWA J 2011; 26(2):62–70.
2. Woolley K, Clemow D. Development and practical use of an international medical writer competency model. DIA Global Forum 2010;2(3):8–11.
3. Clemow D. Pharmaceutical medical writing competency model: practical applications. AMWA J 2011; 26(3):106–10.
4. Schindler TM. Reflections on stability? A 3-year analysis of the EMWA website job postings. Write Stuff 2010; 19(4):272–4.
5. Ely J, Lew R, Woolley K. Manners and more! Importance of cultural sensitivity when medical writers work with authors from the Asia-Pacific region. DIA Global Forum 2010;2(4):20–5.
6. Korieth K. Demand for medical writing continues to rise. CenterWatch Monthly 2008;15(12):1–13.
7. Witherell G. The importance of medical writers to the success of clinical and regulatory documents. Monitor (Assoc Clin Res Professionals) 2012;16(1):45–8.

Author information

Dr Sabrina Heisel-Stoehr studied human biology and molecular biology at Saarland University, Germany. She received her Ph.D. in human genetics and pursued her postdoctoral research at the German Cancer Research Centre (DKFZ) in Heidelberg. She has 6 years of experience in oncology and cell biology. Most recently, she gained an advanced training degree in clinical research at the mibeg-Institute Medicine in Cologne, before becoming a medical writer at Boehringer Ingelheim Pharma GmbH & Co. KG.

Dr Thomas Schindler studied biology and German language and linguistics at the University of Freiburg, Germany and the University of Sussex, UK. He received his Ph.D. in molecular plant physiology from the University of Freiburg and completed a post-doc at the John Innes Institute in Norwich, UK. He then became an editor in the Popular Science Department of Birkhäuser Publishers in Basel, Switzerland, working on book projects in biology, geography, mathematics, physics, and astronomy. Thereafter he entered the field of medical writing and became a medical writer at a CRO. He then worked for many years as Senior Manager Medical Writing at Fujisawa GmbH where he was responsible for scientific publications along with the writing of regulatory documents. Thereafter he moved to Boehringer Ingelheim Pharma GmbH & Co. KG where he heads the European Medical Writing Group, which is currently focused on writing regulatory documents.

In the Bookstores



The Immortal Life of Henrietta Lacks
by Rebecca Skloot;
Pan Books, 2010.
ISBN: 978-0-330-53344-7.
7.99 GBP. 431 pages.

A personal view incorporating the insights of a UK-based book group

Henrietta Lacks was a 31-year-old African American who died in 1951 from cervical cancer. Her biopsied cancer cells were taken without her permission, propagated seemingly forever after and shared by research laboratories across the world. The resulting immortal HeLa cell line is an integral, multimillion-dollar constituent of the scientific and medical research industry from which Henrietta's family has failed to materially benefit. Her story is rooted in the institutionalised racism of the 1950s and 60s, unthinkable today. Skloot personalises the cell line that so many of us are familiar with, using gritty and sometimes depressing insights into the life of the real person behind it.

I suggested that my book group, based in Newcastle Upon Tyne, UK, read Skloot's book late in 2011. We are an eclectic mix of high-achieving women with a rough balance of arts and science/medicine backgrounds. Our system, by which the member hosting the book club for a given month, chooses the book in advance, ensures endless variety. Meetings can become quite lively as we thrash out often polarised views.

First, it was interesting to observe how the group handled the science. Although written with clarity for intelligent individuals with or without an in-depth understanding of science or medicine, it is clear that a significant proportion of readers, based on our small dip sample, tend to filter out or switch off altogether when science is discussed at more than a fairly basic level.

HeLa, the group universally grasped, led to the birth of virology, but quite why the cell line was so scientifically important was less well understood. In brief, although cancerous, HeLa cells exhibit many of the characteristics of normal healthy cells, communicating with one another, producing proteins, generating energy, dividing, expressing genes, and exhibiting susceptibility to infection, particularly viral infection. Their immortality, and ability to reproduce aggressively means that once infected they churn out proteins, bacteria, viruses, etc. in copious quantities, and indefinitely. This key scientific information, although well-communicated, evoked a degree of skim reading in some quarters.

The HeLa research phenomenon was better understood. HeLa became general scientific property through uncontrolled sharing between laboratories in the 1950s, and remains a ubiquitous laboratory cell line today. Its early widespread dissemination heralded an exponential increase in cell culture experimentation, and significantly extended the boundaries in protein, hormone, bacterial, and especially viral research. HeLa disproportionately contributed to scientific and medical discovery and innovation – that was undisputed.

Second, we spoke as one regarding Henrietta's treatment by the establishment, and in particular, the ethical issues surrounding privacy and consent, or rather the lack of both. Shocking deficits in both areas in the 1950s meant that informed consent for use of Henrietta's tissue was never sought or obtained, and that her privacy, once the provenance of the HeLa cell line became widely known, was not protected.

A review of the privacy and consenting requirements of today to investigate how Henrietta would have fared on this side of the Atlantic (arguably more relevant to European-based medical writers) in the new millennium is interesting. With specific reference to the UK in 2012, there is little absolute clarity on either matter. The Human Tissue (HT) Act of 2008 resulted in the UK's Human Tissue Authority revising its codes of practice in September 2009 (http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm/). These are now codified into UK law. Under the HT Act, 'data about the tissue does not have to be permanently or irrevocably unlinked, and may be pseudonymised where, for example, a system of coding is used'. The HT Act also states that consent from the living is needed for storage and use of tissue research in connection with disorders, or the functioning, of the human body, but tissue may be stored or used without consent, provided the material is used for a specific research project with ethical approval. In addition, consent is not needed for storage and use

DOI: 10.1179/2047480612Z.00000000054

of tissue for 'education or training relating to human health (including training for research into disorders, or the functioning, of the human body)'.

It is clear that loopholes for exploitation exist. It seems that in reality, we may not actually be better off in terms of privacy and consenting today in the UK than in the USA in the 1950s. That revelation came as a shock to the group, who mostly believed we are now part of a more informed and just society.

Third, Henrietta and her family made no monetary gain from the scientific use of her cells. Commercialization of tissue and associated research was and is the inevitable result of our insatiable appetite for new drugs and diagnostic tests. Who should own the tissue once removed from an individual is an indefatigable argument. Material benefit for donors is unlikely to ever happen, despite the huge gains by institutions and companies.

In discussing all these issues, the group clearly read the book on two different levels. The science and medicine easily comprehended by some was brought to life by Henrietta's personal story, and complemented by stirring ethical issues. For others, the focus was the tragedy of a strong and much-loved matriarchal woman and her family's grief and incomprehension at what had unfairly befallen them all. The science for this latter contingent presented something of a distraction!

As a regulatory medical writer, with an audience of industry insiders, medical and scientific experts, this insight serves to remind that occasional forays into writing for a lay audience should be approached with a fresh perspective and great care. The versatile medical writer should never underestimate the breadth of the intended audience!

Editor's note: The *Immortal Life of Henrietta Lacks* has previously been reviewed from a different perspective by Anne McDonough in *The Write Stuff* 2010;19(3):219–20.

Reviewed by Sam Hamilton
sam@samhamiltonmwservices.co.uk

Are you addicted to busyness?

Busyness is in vogue. Have you ever asked someone to do something and received the reply that they are too busy to entertain the idea, even when you invite them to join you for a social drink? Might you have given such a reply to someone yourself?

Tim Krieder, writing in *The New York Times*[1], has noticed that it is not people who work back-to-back shifts or commute to three minimum-wage jobs by bus who tell you they are busy. They are simply exhausted. Busyness is something else; a boast disguised as a complaint. The people who complain about being too busy are usually those who have brought it upon themselves with extra voluntary work or out of office activities. Busyness is a societal disease which we impose on each other. It is rooted in ambition or a dread of emptiness. We feel guilty when we are not working or doing something to promote our work. As Krieder nicely remarks, "The Puritans turned work into a virtue, evidently forgetting that God invented it as a punishment". He thinks life is too short to be busy and should you suffer from this disorder he has some intriguing universal cures, e.g. that work is divorced from income with each citizen receiving a guaranteed wage.

Reference

1. The 'Busy' Trap. Krieder T. *The New York Times*. Available at: http://opinionator.blogs.nytimes.com/2012/06/30/the-busy-trap/

Elise Langdon-Neuner
editor@emwa.org

Journal Watch

Section Editor:

Sara Hughes,
Dianthus Medical Limited
shughes@dianthus.co.uk

Improving the credibility of reporting industry-sponsored research

Reports of ghostwriting, guest authorship, selective or biased disclosure of research results, and inaccurate or incomplete reporting of potential conflicts of interest have damaged the credibility of industry-sponsored clinical research.[1] For example, an analysis of the financial conflicts of interest of members of the American Psychiatric Association who are responsible for updating the Diagnostic and Statistical Manual of Mental Disorders (DSM) showed that nearly 70% of those responsible for version 5 of the DSM had financial relationships with pharmaceutical companies.[2,3] This has raised concerns that so many experts responsible for defining mental health conditions and treatments have financial ties to pharmaceutical companies.[2,3]

Pharmaceutical companies are trying to improve this by using recommendations from groups such as the International Committee of Medical Journal Editors (ICMJE), the Good Publication Practice guidelines, the Committee on Publication Ethics, the EQUATOR (Enhancing the QUAlity and Transparency Of health Resources) Network, and the Medical Publishing Insights and Practices (MPIP).[1] Even though important improvements have been made, a negative view of industry-sponsored research remains. In 2010, the MPIP convened a debate with journal editors and industry representatives to resolve this issue. Mansi *et al.*[1] report the 10 recommendations suggested for improving the quality and transparency of industry-sponsored clinical research reporting; these recommendations would also improve the reporting of other clinical research publications, regardless of how they were funded. The findings are summarized below.

Recommendation 1: Ensure clinical studies and publications address clinically important questions

Credibility is compromised when clinical research is intended for marketing purposes rather than advancing scientific and medical knowledge. Sponsors could enhance transparency and credibility by better explaining the rationale behind the research and to ensure that research is designed to answer important clinical and scientific questions.[1]

Recommendation 2: Make public all results, including negative or unfavourable ones, in a timely fashion, while avoiding redundancy

Many industry sponsors have committed to disclosing the results of all clinical studies through trial registries. The ability to cross-reference trial registries, results databases, and all related publications informs the scientific community whether studies are completed or are under way and discourages selective reporting.[1]

Dissemination of negative, confirmatory, or inconclusive results can be challenging, but they can be very valuable in the progress of science and can prevent redundancy. They could be published in journals dedicated to these studies (perhaps in open-access format), abridged article formats more suitable to them, and/or specific reviewing mechanisms focused on scientific validity as opposed to 'impact'. Many of these potential solutions are currently being explored and developed by journals and publishers.[1]

Recommendation 3: Improve understanding and disclosure of authors' potential conflicts of interest

The processes for disclosing authors' potential conflicts of interest have recently improved. Journal editors and sponsors should support the use of the updated ICMJE Conflict of Interest Reporting Form. A centralized, publicly accessible disclosure database may also be a possibility in the future.[1]

Even though the processes have improved, the *PloS Medicine* Editors have raised the question as to whether or not disclosure worsens bias. They acknowledge that disclosure is preferable to non-disclosure but they also report that it may be a limited strategy in mitigating bias.[2] Disclosure shifts 'secret bias' to 'open bias'; a reader may be blinded by the amount of information provided; and that by disclosing a conflict of interest, it may be viewed that a person no longer needs to

DOI: 10.1179/2047480612Z.00000000055

manage their conflict.[3] Loewenstein *et al.*[4] have demonstrated that patients think that doctors would not intentionally mislead them and they tend to not discount advice even when they know there is a conflict of interest.

Recommendation 4: Educate authors on how to develop quality manuscripts and meet journal expectations

Researchers may lack formal writing training or knowledge of reporting guidelines, for example the Consolidated Standards of Reporting Trials (CONSORT) requirements, which affects the quality of manuscripts. To address this, best practice guides could be widely disseminated to industry and academic authors. For example, the MPIP's Authors Submission Toolkit can help authors navigate the manuscript development and submission process, and EQUATOR's author resource library can provide guidance on research reporting.[1]

Recommendation 5: Improve disclosure of authorship contributions and writing assistance and continue education on best publication practices to end ghostwriting and guest authorship

Research sponsors have improved their credibility by recognising the positive role that professional writers can play in manuscript development, acknowledging them appropriately as authors or contributors (in accordance with ICMJE guidelines) and disclosing their names, affiliations, and potential conflicts of interest. Everyone must work towards zero tolerance of ghostwriting and guest authorship.[1]

Recommendation 6: Report adverse event data more transparently and in a more clinically meaningful manner

The commonly used phrases of 'no clinically significant adverse events' and 'no unexpected adverse events' lack clinical relevance, particularly regarding rare adverse events that may be important for agents used over a long period in large populations. Everyone would benefit from more uniform reporting guidelines that clearly specify the type and format of adverse event data to be reported. In addition, journals may need to revisit their manuscript length policies if they wish this information to be present in the main document. Authors should also be made aware of the need to balance the strength of adverse event claims versus the features and limitations of trial design.[1]

Recommendation 7: Provide access to more complete protocol information

Some journals request submission of a clinical study protocol and some also publish them online to provide greater transparency to readers. However, making protocols publicly available raises issues that require further discussion, for example protection of intellectual property. Also, protocols are often amended as a trial progresses and public disclosure of multiple versions may cause confusion.[1]

Recommendation 8: Transparently report statistical methods used in analysis

Statistical methods are assessed as part of the peer review process for many journals. Sponsors should ensure that authors provide adequate information about the chosen methods based on the prespecified study design, and how they were applied to the final data set. The issue of statistical analysis reporting warrants further discussion to explore how journals can develop policies that raise standards for all clinical publications, independent of the financial support or authorship.[1]

Recommendation 9: Ensure authors can access complete study data, know how to do so, and can attest to this

Authors need to be able to explain important details of study design and analysis or prove their access to raw data.[1]

Recommendation 10: Support the sharing of prior reviews from other journals

The MPIP's Authors' Submission Toolkit suggests that when submitting a rejected manuscript to another journal, a copy of the previous manuscript and reviewers' comments could be provided to show that suggestions have been incorporated. Some journals already encourage the sharing of previous reviews as it improves transparency, avoids duplication, and increases the quality of subsequent submissions.[1]

References

1. Mansi BA, Clark J, David FS, Gesell TM, Glasser S, Gonzalez J, *et al.* Ten recommendations for closing the credibility gap in reporting industry-sponsored clinical research: a joint journal and pharmaceutical industry perspective. Mayo Clin Proc May 2012;87(5): 424–9.
2. The PloS Medicine Editors. Does conflict of interest disclosure worsen bias? Plos Med 2012;9(4):e1001210. doi: i10.1371/journal.pmed.1001210.
3. Cosgrove L, Krimsky S. A comparison of DSM-IV and DSM-5 panel members financial

association with industry: A pernicious problem persists. Plos Med 2012;9:e1001190. doi:i10.137/journal.pmed.1001190.

4. Loewenstein G, Sah S, Cain DM. The unintended consequences of conflict of interest disclosure. JAMA 2012; 307:669–70.

Sara Hughes
Dianthus Medical Limited
shughes@dianthus.co.uk

Journal round-up

While working on a paper for a colleague, I stumbled across the following information in the Instructions to Authors provided by the journal *Hypertension*[1]:

'Recent Advances in Hypertension. These articles are intended to highlight, provide further perspective, and enhance the overall significance of recent studies published in *Hypertension* that contribute to our understanding of hypertension and related areas. … References should generally be restricted to those published in *Hypertension* during the last 2–3 years'.

The requirement that the references be limited to articles published in *Hypertension* struck me as strange since many of the most highly cited studies on hypertension are published in general medical journals. Of the 25 most frequently cited articles published since 2010 whose titles include the word 'hypertension', eight were published in *JAMA*, *The Lancet*, or the *New England Journal of Medicine*; only one was published in *Hypertension* (data from Web of Science, Thomson Reuters; information correct as of 18 July 2012).

Perhaps this is merely some kind of exercise in vanity, a way of bigging up *Hypertension* and its contribution to the medical literature. One thing's for sure though: it does the journal's impact factor no harm at all.

According to a set of international standards for editors agreed upon at the Second World Conference on Research Integrity, held in Singapore in 2010, 'Editors should not attempt to inappropriately influence their journal's ranking … it is inappropriate to demand that references to that journal's articles are included except for genuine scholarly reasons'.[2]

Whatever *Hypertension*'s reasons for insisting on the referencing of its own articles, they certainly do not appear to be scholarly.

***

My exploration of the *Hypertension* website led me to a staggering case of image recycling/manipulation involving multiple articles published in leading journals including *Circulation*, *Kidney International*, and *Hypertension*.[3–5]

The articles, which come from a single lab in Japan, feature industrial-scale reuse of immunofluorescence and histology images, and Western and Northern blot bands. A number of the journals involved (*Hypertension* included) have published Expressions of Concern. Retractions will surely follow.

How many more such cases will come to light over the coming years?

***

While doing a spot of research on plagiarism (a favourite topic of mine), I came across a promising looking source in *Journal of Visual Communication in Medicine*.[6] When I attempted to access it, however, I was informed that access for 24 hours would set me back US$86.00. This is the highest such fee I have ever come across. To put it into perspective, an annual individual subscription to *Medical Writing* costs US$85.00.[3] (Individual *Medical Writing* articles cost US$48.00 plus tax.)

To the relief of my bank manager, I will not be paying to find out what wisdom the *J Vis Commun Med* article contains. Luckily, excellent resources on ethical aspects of writing are available free of charge.[7]

***

How refreshing it was to read an editorial in the *Journal of Clinical Oncology*[8] which questioned and indeed criticized the research methodology of recent trials – trials reported in none other than the *Journal of Clinical Oncology*.

The editorial highlighted the following issues with different trials:

1. reliance on significance test results for hazard ratios when choosing the optimum treatment regimen;
2. use of a design that was inappropriate to address a trial's stated goals; and
3. selection of an inadequate primary outcome.

Identifying ways of improving trial designs and data interpretation can only be a good thing. Good work, guys!

References

1. Hypertension. Instruction to authors, article types. Available from: http://hyper.ahajournals.org/site/misc/ifora.xhtml#articles [accessed 2012 July 17].
2. Kleinert S, Wager E. Responsible research publication: international standards for editors. A position statement developed at the 2nd World Conference on Research Integrity, Singapore, July 22–24, 2010. In: Mayer T, Steneck N (eds.) Promoting research integrity in a global environment. Singapore: Imperial College Press/World Scientific Publishing; 2011. p. 317–28.
3. Matsubara Lab in Japan: breathtaking reuse of Western and Northern blot bands. Abnormal Science Blog. Available from: http://abnormalscienceblog.wordpress.com/2011/11/27/matsubara-lab-in-japan-breathtaking-reuse-of-western-and-northern-blot-bands/#more-1026 [accessed 2012 July 18].
4. Matsubara Lab in Japan: breathtaking reuse of histological images and fragments (part 2). Abnormal Science Blog. Available from: http://abnormalscienceblog.wordpress.com/2011/11/30/matsubara-lab-in-japan-breathtaking-reuse-of-histological-images-and-fragments-part-2 [accessed 2012 July 18].
5. Matsubara Lab in Japan: anything goes? (part 3). Abnormal Science Blog. Available from: http://abnormalscienceblog.wordpress.com/2011/12/14/matsubara-lab-in-japan-anything-goes-part-3 [accessed 2012 July 18].
6. Bryson D. Using research papers: citations, referencing and plagiarism. J Vis Commun Med 2012;35(2):82–4.
7. Roig M. Avoiding plagiarism, self-plagiarism, and other questionable writing practices: a guide to ethical writing. Available from: http://ori.hhs.gov/sites/default/files/plagiarism.pdf [accessed 2012 July 18].
8. Levine MN, Juergens R. Method to our madness or madness in our methods? Pitfalls in trial methodology. J Clin Oncol 2012;30(17):2025–7.

Stephen Gilliver
Science Editor
Center for Primary Health Care Research
Sweden
stephen.gilliver@med.lu.se

The Webscout

Section Editor:

Webscout Editor
Karin Eichele,
Novartis Pharma GmbH,
Nuernberg, Germany
karin.eichele@novartis.com

Writing matters

Writing matters – anything that matters in writing, or any writing that matters? I tend to interpret it the second way, but I asked Google what it thinks. It responded with some nice-to-read, worth-reading, and helpful sites. I found that, like us medical writers, many people care a lot about words and language. Here is a selection of my discoveries.

http://www.dailywritingtips.com/

This is a blog by a small team of writers, who strongly believe in writing as being essential for success, irrespective of the profession. This especially holds true for the increasing importance of blogs and social networks. Daily Writing Tips gives tips for writing clear and proper English, including daily tips on grammar, spelling, punctuation, and vocabulary. The blog is structured into categories, so you can easily access topics you are interested in. And after having gone through all of these articles, you can test your knowledge in the tests and quizzes section. Enjoy this blog.

http://www.nald.ca/library/learning/writmatt/cover.htm

'Have something to say, and say it as clearly as you can. That is the only secret of style'. This citation by Matthew Arnold, British poet and cultural critic, is the beginning of this handbook on how to get your message across. And indeed, that's all good writing is about. If only it were that easy! This handbook follows the ideas of the plain language movement and also covers matters of editing, proofreading, and layout. With about 90 pages, it is of course not a complete reference, but basic ideas are pleasingly and descriptively presented.

http://www.rlf.org.uk/fellowshipscheme/documents/RLFwritingmatters_000.pdf

Writing matters is a report by the Royal Literary Fund on the importance of good writing in higher education and the current gaps. It was written in the context of the Royal Literary Fund Fellowship Scheme, which was designed to help students develop their writing skills with the assistance of professional writers. During the first years of this fellowship project, the tutors perceived a great deficit in students' writing skills. They found a gap between school writing and academic writing, and they found that the complexity and conventions of writing in academia trouble students. They add that good writing helps to convey a message and that persuasive writing is essential not only in science but also in business. The study also found that employers often criticise employees' lack of writing skills. Finally, the authors strongly feel that universities should reinforce writing education.

http://www.nwp.org/cs/public/print/doc/about.csp

The *National Writing Project* (NWP) is a network dedicated to education and helps teachers improve writing and learning at schools, colleges, and universities. It is a US-based project driven by enthusiastic writing teachers and intended for teachers with a special focus on writing in the 21st century, specifically, writing in an online environment. The resources section is warmly recommended, even for non-teaching writers, especially the online resources on digital literacy on http://digitalis.nwp.org/. NWP Digital collects ideas and reflects teaching and writing in an interconnected world.

http://www.rhetcomp.gsu.edu/~bgu/8121/Reading-Porter.pdf

Once upon a time – can you remember practicing handwriting at school? I found this 'cyberwriter's tale' on the influences of technology on writing. It is written with a good sense of humour – you will like it and it will probably make you laugh every now and then.

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

Karin Eichele
Novartis Pharma GmbH, Germany
karin.eichele@novartis.com

DOI: 10.1179/2047480612Z.00000000056

Manuscript Writing

Section Editor:

Phillip Leventhal
pleventhal@4clinics.com

Help, I can't shorten my abstract! Oh yes you can! (Part 1 of 2)

Abstracts are perhaps the most important part of a manuscript because they are often the only part that is read and used as an information source. They are also used by readers (consciously or not) to decide whether to read the full article, and editors often use the abstract to determine whether they will send out a manuscript for peer review. The abstract therefore serves not only as an essential information source but also as an advertisement for your manuscript and for you and the other authors.

This is why abstracts need to be complete, concise, and interesting. This is complicated by the strict length and format limitations for abstracts. Typically, 200–250 words are allowed (even less sometimes for a conference abstract). Also, more and more journals are requiring structured abstracts, which can add to the required content. To make matters worse, or at least more complicated, the CONSORT guidelines for abstracts (http://www.consort-statement.org/extensions/data/abstracts/) insist on including information that further increases the word count. Add to that the demands of marketing and legal departments, and squeezing everything everybody wants into the abstract becomes a delicate and complicated balancing act. An abstract is certainly not something that can be dashed off at the last minute.

So, what's a medical writer or editor to do? One thing that must not be done is to exceed the word limit. And, for structured abstracts, yes, that word limit includes the headings. On-line manuscript submission systems will not allow you to surpass the word limit, and editors will otherwise reject a manuscript with an abstract that is too long.

This is the first of two articles that shows you how to shorten your abstract. This first article describes how to shorten abstracts by eliminating unnecessary content and using plain language. The second article will describe how to use linguistic devices to reduce the word count. The accent of these two articles is on preparing informational and descriptive abstracts for publications, but these considerations also apply to conference abstracts.

Include the information needed to support your main conclusion

Generally, the majority of an abstract should be the methods and results section. Avoid wasting space in the abstract with long background, objective, or conclusion sections. In some cases, as in an unstructured abstract, the background information can be deleted; if readers want to know about the background of the study, they can read the introduction in the main text. A good rule of thumb is that the abstract should be about 10–20% background, 30% methods, 40% results, and 10–20% conclusions.

Work backward from the conclusion. Keep in mind that the abstract must be able to stand alone without reference to the text. Therefore, present the key message or messages in the conclusion and the results to support those messages. Get to the point: *What is essential?* Eliminate anything that is not essential. Then, include the methods that were used to obtain these results, but do not to go into detail. For example:

- *Antibody concentrations were measured on day 28 by enzyme-linked immunosorbent assay* is sufficient without giving any more details of the assay.
- You can also say *Adverse events were recorded up to day 56* and not go into more detail about the recording of relatedness to the treatment, intensity, or the analysis of laboratory measures.
- *The samples were fixed in formaldehyde, dehydrated, and analysed by scanning electron microscopy* can be replaced with *Samples were examined by scanning electron microscopy*.

Sometimes, a writer will be pressured by the authors or the marketing department to squeeze some non-essential messages into the abstract. Explain to them

DOI: 10.1179/2047480612Z.00000000057

Table 1: Common unnecessary words used in abstracts and their replacements

Replace	With
A bigger/higher/larger or lower/smaller + amount/degree/number	More/less
A decreased/increased number	Fewer/more
A higher/lower rate	Faster/slower
A total of seven	Seven
Above the normal range	Elevated
All of	All
Are/was/were able	Can/could
As a result of	Because of
At all times	Always or delete
At regular intervals	Regularly
At the same time that	While
Based on the fact that	Because, based on
Both of these	Both
Bring about	Cause
By means of	Using
Classified into groups	Classified
Compare and contrast	Compare
Connecting words: therefore, thus, however, moreover, consequently, nevertheless, hence	Delete when possible
Considered to be	Delete
Despite the fact that	Although
During the course of	During, while
First(ly), second(ly), finally/etc.	Delete
For the purpose of	To
Found to be	Is
Give cause to	Justify
Great/large majority	Most/many
Had an effect on	Influenced
Has been found to be/is found to be	Was/is
Has the ability to/is able to	Can
In a considerable proportion of	In many
In conclusion, in summary	Delete when possible
In excess of	Higher than
In no case(s)	Never
In order to	To
In spite of	Despite
In the absence of	Without
In the range of	About
Is an important factor in	Delete
Is currently	Is
Is seen as	Is
Known to	Delete
Known to participate in	Participates in
Male/female children	Boys/girls
Male/female subjects	Men/women
Mix together	Mix
On the basis of	Based on, because
Outside the normal range	Abnormal
Past experience/history	Experience/history
Plays an important role	Contributes to or delete
Prior to	Before
Seem to be	Seem
Subsequent to	After
The fact that	Because, that or delete
The majority of	Most/many
The minority of	Few
Time interval	Interval
Time period, period of time	Period
Time schedule	Schedule
Under/over the age of	Younger/older than
Using a combination of	By combining
Very, extremely	Delete
Virtually	Delete
Whether or not	Whether
Widely/commonly held/believed/thought/considered that	Delete
With the exception	Except (for)

that the reader can always read the main text for these additional messages, and remind them that the abstract absolutely cannot go over the word limit. (This may be different for abstracts written for a conference, where marketing considerations may take precedence and statements elsewhere in the abstract must be sacrificed.)

Finally, use the CONSORT Extension for Abstracts (http://www.consort-statement.org/extensions/data/abstracts/) as a guideline for what should be included in the abstract, but remember that it is a guideline and not a law; do your best to squeeze everything on their list into the abstract, but, in the end, use your own judgment about what needs to be included.

Avoid repetition

If you mention some detail in the title, methods section, or in the objective, do not say it again. For example:

- If your title says: *…XXX: A randomized, parallel-group, placebo-controlled study*, you do not need to repeat it in the methods.
- If you say that the antibody concentration was measured by enzyme-linked immunoassay in the methods section, you do not need to say in the results that *The enzyme-linked immunoassay showed that antibody concentrations were … .* Simply say *Antibody concentrations were….*
- If you say in the method that *Adults 18 to 55 years of age were immunized …* it is not necessary to say in the objective *The study was intended to*

assess the effects of the vaccine in adults 18 to 55 years of age.

Eliminate unnecessary words

Table 1 lists some common unnecessary words used in abstracts (indeed in all our texts) and their replacements.

Avoid meaningless or useless expressions and preliminaries

Wherever possible, cut out words and expressions that add nothing. Examples:

- *Previous studies of healthy aging have shown a strong relation between WML and cognitive decline* can be replaced with *WML strongly correlates with cognitive decline in aging healthy adults*.
- Delete *In this paper, we discuss*… . This kind of meaningless preamble often appears in academic papers but should be avoided.
- *The objective of this study was to examine*… can be replaced with *We examined*… or *This study examined*… .
- Sentences that start with phrases explaining that a certain fact is well-known or well-accepted can and should be avoided. Just say what is. For example, the following can all be deleted: *It is well known that*… , *Many studies have shown that*… , *and Several lines of evidence indicate that*…
- You can generally eliminate known, as in… *patients with known asthma were included*.
- Instead of *We were able to show that*… just say *We showed that*… , but the latter is usually redundant anyway, as it is usually used to introduce a result, and only the result should be given: *We were able to show that mean systolic blood pressure was decreased by 22 ± 11 mm Hg*… is only saying *Mean systolic blood pressure decreased by 22 ± 11 mm Hg*… .

Avoid sentences that start with 'it is/was' or 'there are/were'

You can almost always rephrase sentences that start in this way, and they are best avoided, not only in abstracts, but also in any text. They almost always end up creating a complex and wordy sentence. Examples:

- *It is known that oestrogen is a steroid hormone*… can be replaced with *Oestrogen is a steroid hormone*… .
- *There were 10 patients who had severe adverse events in the treated group* can be replaced with *10 (or Ten) patients in the treated group had severe adverse events*.
- *Under ibuprofen, there was a much earlier onset of pain relief than under*… can be replaced with *Pain relief occurred much earlier under ibuprofen than*… .
- *There was an improvement in the patient's condition on day 4* can be replaced with *The patient's condition improved on day 4*.

Eliminate 'show/reveal/demonstrate/found' in describing results

Examples:

- *Showed an increase* and *were found to increase* can be replaced with *increased*.
- *The analysis revealed an improvement in clinical response* can be replaced with *The clinical response improved*.

Avoid unnecessary negative results

Including some negative results may be essential, but others can be omitted without changing the conclusions. Example:

- Delete *Rates of adverse events were similar in the subjects receiving the vaccine and subjects receiving placebo*. This is unnecessary information. For an abstract, the important information may be only treatment-related serious adverse events.

When describing things that you did not do or negative results, use constructions without 'not'

Examples:

- *Patients with diabetes mellitus were excluded* instead of… *not included*.
- *Resuscitation failed in 20 patients* instead of… *did not succeed*… or… *was not successful*… .

Avoid multiple hedges

Multiple hedges, also known as multiple qualifications, are often used to avoid saying that you are sure of something and are often included under pressure from legal departments or because scientists are often taught to leave the door open to future changes in perspective or evidence that

contradicts a conclusion. Do your best to reduce these. Example:

- *These **preliminary** results suggest the **possibility** that the drug **might** be effective at reducing the incidence of the disease in **some** populations, **although further studies are needed to confirm this*** can be replaced with *'These results suggest that the drug will reduce the incidence of the disease*.

Do not include references

References are generally not allowed and should be avoided in abstracts for manuscripts.

When giving demographic results for which there are only two alternatives (e.g. men/women, smoker/non-smoker), give the results for only one.

Example:

- *240 patients were enrolled. 56.3% were women; 27.9% were smokers*.

Use shorter words when the permitted abstract length is given in characters and not words

Whereas journals usually specify the permitted abstract length in words, you may find that the instructions for conference abstracts stipulate a maximum number of characters. This means that the length of words is important, in addition to the different ways of shortening word count. You should therefore write the abstract first concentrating on conciseness and not on using short words, then go through it to see where you can use a shorter word. Don't worry if it initially seems too simple to you. We are too used to hearing polysyllabic words where one or two syllables are good enough. But if you really feel that you have gone too far or think you may have oversimplified or not captured the meaning you want, check things out with a colleague.

Examples:

- *use* instead of *utilize*
- *see* instead of *encounter*
- *do* instead of *perform*, *execute* or *conduct*
- *before* instead of *prior to*
- *stop* instead of *terminate*
- *halved* instead of *divided into two equal parts*

The list is, of course, endless. You can put the Word Thesaurus (CTRL + SHIFT + 7) to good use here.

Bibliography

Lang TA. How to write, publish, and present in the health sciences: a guide for clinicians and laboratory researchers. Philadelphia: American College of Physicians; 2008.

Graf J. Handbook of biomedical research: the journal article abstract [document on the internet]. 2008 [cited 2012 May 10]. Available from: http://ctl.hanyang.ac.kr/writing.

Blank GK. Wordiness, wordiness, wordiness list [document on the internet]. 2012 [cited 2012 May 10]. Available from: http://web.uvic.ca/~gkblank/wordiness.html.

Ohri M, Dawes K. Successful abstract writing: an essential skill for medical writers. Write Stuff 2009;18(1):27–8.

Phillip Leventhal (*pleventhal@4clinics.com*) and
Alistair Reeves (*a.reeves@ascribe.de*)

Evidence is growing that articles receive more citations when they are made available on the Web through self-archiving or Open Access repositories. Authors who transfer their copyright can always place a version of their manuscript on a publically accessible website. But there is often confusion about what version of an article can be deposited, where it can be deposited, and whether any conditions are attached to that deposit. Useful summaries of publishers' and journals' policies on self-archiving in Open Access repositories are available in the searchable database, RoMEO (http://www.sherpa.ac.uk/romeo/). The site can be searched with the journal title or publisher name. RoMEO is run by Nottingham University in the UK and funded by JISC, which is the UK's expert on information and digital technologies for education and research.

Regulatory Writing

Section Editor:

Greg Morley,
Freelance and Contract
Medical Writer,
Spain
greg.morley@
docuservicio.com

The EMA, the FDA, and Health Canada head to head

A recent issue of the *New England Journal of Medicine* carried an article comparing the regulatory review times of novel therapeutics by three different regulatory agencies (FDA, EMA, and Health Canada).[1] In the comparison, the FDA appears to come out rather well, with significantly shorter review times (303 days for the first review) than the other two agencies (both with review times over 350 days for the first review). The article (which seems to be written by people sympathetic to the FDA cause) should be seen in the context of the upcoming renewal of the Prescription Drug User Fee Act, which originally came into force in 1992 to allow the FDA to charge fees for reviewing drug applications. The revenue generated from these fees is dedicated to providing sufficient resources for the review processes. At each 5-year renewal, stakeholders get to voice their opinions about whether they are getting value for their fees.

A recurrent criticism of the FDA has been that the review cycles take too long, and so review times is one of the focuses of the upcoming renewal. The findings, as the authors point out, would seem to contradict this criticism. There are some caveats when interpreting these data. For instance, the FDA was more likely to require more than one review cycle than the EMA. But even when this was taken into account, the overall review times were still shorter. Another caveat would be that some of the applications for novel therapeutics in the European Union would follow a mutual recognition procedure rather than a centralised one, and these applications may well be the smaller ones that are faster to review. In addition, the analysis only includes successful applications (information about unapproved publications is not publicly available) and focuses only on novel therapeutics. Manufacturers of generics, for example, have been complaining of a backlog in the review of their applications.

Short review times are desirable (for the pharmaceutical companies because they enjoy longer market exclusivity and for the patients because they can benefit earlier from new treatments), but they should not be attained at the expense of thoroughness, particularly concerning safety; after all, the primary remit of regulatory agencies is to protect patients. The quality of a regulatory review from a safety perspective is harder to assess. One way would be to look at label changes and drug withdrawals, though as far as I am aware, there have been no attempts at such an evaluation.

In any case, I don't think that the EMA comes out that badly from the comparison, even if we only take into account review time as a limited metric of efficiency. The organisational setup of the pan-European EMA is, by necessity, more complex than the more homogeneous FDA, so a somewhat longer review time could be expected (which is not to say that there is no room for improvement).

References

1. Downing NS, Aminawung A, Shah ND, *et al.* Regulatory review of novel therapeutics – comparison of three regulatory agencies. N Engl J Med 2012 May 16. [Epub ahead of print] PMID: 22591257.

Greg Morley
Freelance and Contract Medical Writer, Spain
greg.morley@docuservicio.com

DOI: 10.1179/2047480612Z.00000000058

Resolving conflicts – 'soft skills' that a regulatory writer needs

In a previous column, I talked about the importance of review cycles, and also about how inefficient they can be. In particular, the column talked about how some reviewers inappropriately focus on certain details while failing to address high-level failings. Another essential aspect of a successful review cycle is of course the resolution of comments. Most regulatory documents receive input from different departments (or functions to use pharma jargon). Often though, these functions have different, and sometimes conflicting, priorities, and these may come through in the comments on a draft regulatory document. If a comment from one function is resolved, a conflict with another function may be generated.

And sometimes medical writers can find themselves caught in the crossfire. I would hesitate to draw an analogy with the UN peacekeeping forces or marital guidance counsellors, but nevertheless, some situations can require plenty of tact (perhaps this is one reason why women – who as a generalisation can be said to be more inclusive in their approach to problem solving – are strongly represented in medical writing). Any tips for handling such situations will no doubt sound like some staid advice column, but here goes.

First, organize a teleconference (or a face-to-face meeting if possible; I generally work offsite though so this is not an option). Teleconferences can be the most interminably dull things, but they have some advantages. For one thing, I find that people are more prepared to compromise when talking on the phone rather than using email. Email depersonalises things and people find it easier to pick an argument with an anonymous string of words on a computer screen. (I say anonymous because in large companies, often team members don't know one another in person.) While you still might not be able to put a face to the voice on the phone, the level of human interaction is higher.

Also, after a couple of hours on the call, when fatigue is starting to set in, and the end of the scheduled slot is approaching, people may soften their views. Email exchanges, on the other hand, are open-ended, and people can come back to them with renewed vigour after lunch, or the next day, or whenever. Email does have the advantage though that you have something in writing. After a teleconference is over, it is therefore useful that you jot down some minutes, even if they are very high level, summarising what was decided. This summary should be distributed to the participants to provide a written record of the meeting and avoid revisionist interpretations of any decisions made.

Next, as in any negotiation, I think it is important to show a spirit of compromise. Most people will be keen to move on, so if you are able to offer them something, they will usually be prepared to budge from their entrenched position. It is also helpful to save your time and energies for things that really matter. For instance, if someone insists on hyphenating a certain compound noun, then you could probably safety let that go. Another matter would be if someone insists on omitting a certain piece of information that in your opinion is important (based on your interpretation of applicable guidance, for example). Deciding what is important and what is a distraction is where experience comes in. Experience is also helpful because as you get more expert so you will be more likely to command respect. This in turn will make it easier to browbeat dissenters within the team.

In short, soft skills can be important for resolving conflicts in review rounds, and some people are inherently more gifted in this respect than others. The good news for those of us born with less developed skills is that they can be acquired to a certain extent through experience.

Greg Morley
Freelance and Contract Medical Writer, Spain
greg.morley@docuservicio.com

English Grammar and Style

Good Writing Practice

Section Editors:

Wendy Kingdom (info@wendykingdom.com) and Alistair Reeves (a.reeves@ascribe.de)

Lost causes and moving with the times (1)

As an editor, I have been battling against verbosity, redundant modifiers, and 'buzz' words for many years. New terms and turns of phrase or new meanings for words pop up all the time. Many of them have come with the information technology age and many of them stick, whether we like it or not. Some of them really do fill a gap, like 'to enable' meaning 'switching something on' or 'make something functional'. Some are supposed to sound good because they are polysyllabic but don't, like '*leveraging* someone's help'; and some are evidence of sloppy and indiscriminate use of words. Others come into use because a term has been so devalued by overuse that it no longer sounds right unless used with a modifier (e.g. *absolutely* essential).

Some authors lap up snappy new terminology and use it with alacrity. Some don't mind perpetuating their own bad habits and those of others (we all have them). Others resist and insist on using terminology that may sound outdated, rejecting new formulations as casualisms or even as incorrect. And we all have our personal preferences and bugbears. Over the years, I have learned to give in gracefully and use newly coined terms and phrases or new grammatical locutions when I feel that defending even a simple phrase is no longer worth the effort or the time it takes. Sometimes it just becomes plain silly to insist on a certain formulation. In short, when it becomes a lost cause.

A good example is 'different to'. 'Different from' is so firmly ingrained in my mind that this is what I spontaneously write and say, and I don't think this will change. Until about the end of the 1980s, I used to correct 'different to' to 'different from'. Around that time I started listening and looking out for 'to' or 'from' used after 'different'. I empirically established that 'different to' is what is now current – in British English, at least. It had reached the point where people rarely said 'different from' any more – or they mixed the two, and it didn't matter. So I decided to give in. That means that I stopped changing 'to' to 'from' in texts I edit because it was getting silly to do so and was basically a waste of time.

A further example is 'to report on'. In the Good Old Days (i.e. before about 1980!), everybody said 'We 'report on' the results of our study in …'. After about 1980, people started just 'reporting' things, not 'reporting on' them. This spread like wildfire. As far as I was concerned, 'report' without the 'on' and with a direct object meant 'to notify', as in 'report him to the authorities', so the 'on' was definitely needed if you meant 'tell the reader about our findings'. Hoping I could stem the tide, I dutifully added 'ons' all over the place. It reached the point where people were correcting my 'report on' back to just 'report', and after a couple of years of that, I decided to give in and just write 'report'. It still niggles every time, but I managed to move on.

For many years, I dutifully insisted on 'approximately' until I finally realized that 'about' means exactly the same thing and is so much shorter. I still haven't managed the transition to 'around' because it still sounds too informal to me. But who knows what the next few years will bring?

You also have to ask yourself: is it a tragedy if I write something like '*completely* resolved' or leave this when editing a text? The word 'completely' is actually unnecessary here, because 'resolved' means 'completely resolved'. People write 'completely resolved' to differentiate clearly from 'partially resolved'. I usually try once to change this sort of thing (e.g. *advance* planning, is *currently*, throughout the *entire* study) and then give in gracefully when challenged. I will not allow green *in colour*, however.

I still haven't given up on removing 'time' from *time* interval, *time* period and *time* schedule, because all three are only ever time concepts, and I still don't permit 'interval' to be used instead of 'period' (*The treatment interval was followed by an observation period of* …). But I gave up long ago on *variable* and *parameter* (parameter won) and compared *to* or *with*. In our context, the difference between *to* and *with* here is purely academic – whatever you use, the reader understands the same.

The measure of when to give in is: *will the reader misunderstand what is meant and is the word or term appropriate to my audience*? This is the important thing in any text. If the whole world is now saying 'prior to' – and it is – rather than the much simpler 'before' (and 'prior to' can *always* be replaced by 'before', I assure you), should I waste my time

DOI: 10.1179/2047480612Z.00000000059

changing it in someone else's text? I have resolved only ever to write 'before' myself, but I no longer 'correct' this in texts from other authors. Some claim that 'prior to' is 'more scientific' and therefore must be used. I hope you agree that it is not.

There are lost causes that are regrettable. One is the misuse of the apostrophe. We will be looking at these in future issues.

(contributed by Alistair Reeves, a.reeves@ascribe.de)

Paragraphing on web pages (1)

Writing web pages is a specialist activity and different conventions are followed from those used in writing on the traditional paper page, not only for paragraphing. The whole concept of the 'page' is different (in fact, there is no 'page'), and all sorts of visual effects can be used. The 'page' size has to be adaptable to an iPhone screen or a very large monitor. However, a recent alarming tendency in paragraphing can be seen increasingly on news and newspaper websites, and not on serious blogs or text specifically written for websites. Paragraphing seems to have been abandoned here completely, and each article – which was probably properly paragraphed in its paper version – is broken down into an endless string of single sentences with space between each. This is now so widespread that it cannot be changed. I assume that the aim is to make the text easier to read. But the very people who should know how to present text fail miserably on this score with me. The effect is a totally disjointed text that is difficult to read, and it certainly does not make me want to read on. (*contributed by Alistair Reeves, a.reeves@ascribe.de*)

Abbreviations (3)

We have described previously the generally accepted rule for using abbreviations and have given examples of when it might be appropriate not to follow the rule.[1–3] Abbreviations can be very helpful in improving the flow of text, particularly when they result in an acronym, e.g. Aids, or MedDRA.

Abbreviations can also be disruptive. If an abbreviation is inserted into a sentence, the reader has to backtrack and commit the term to memory. If there is only one other reference to the abbreviation in the document, and it occurs several paragraphs after the first reference, the reader may well have forgotten what it stands for and will have to go back through the text to look for it, or go to the list of abbreviations. Therefore, if you are going to invest in disrupting the flow of the text by inserting an abbreviation, you should make it worth the readers' while and abbreviate a term that is used enough times for them to learn what it stands for, or that they probably already recognize. The term should also be long enough for the expanded term to be disruptive, e.g. beclometasone dipropionate (BDP), so that the abbreviation benefits the reader. Note also that you should use the indefinite article that is appropriate for how you would speak: **a** scientific development plan; **an** SDP. 'A SDP' disrupts the flow of the text because we read the abbreviated term as 'ess dee pee'. If we read it as 'scientific development plan', the only reason for using abbreviations would be to reduce word count.

Take care that an abbreviation is not more commonly known by another term. A memorable example of this is a company that abbreviated the study endpoint, pre-defined event, to PDE. This can be a little confusing to someone who is familiar with phosphodiesterase (PDE) inhibitors. However, in this example, the drug was actually a PDE inhibitor with the result that the protocol was incomprehensible. The website http://www.globalrph.com/abbrev.htm is very useful for looking up medical abbreviations and illustrates nicely the many different medical terms that can be expanded from the same abbreviation. An example taken at random is VTE, which can stand for venous thromboembolism, ventricular tachycardia event, or vicarious trial and error. The third of these terms is uncommon but the first and second are equally valid in the context of cardiology.

There are no good reasons for using abbreviations for prescriptions in a regulatory document. We are not writing prescriptions in the pharmaceutical industry. We do not shroud our protocols in mysticism so that patients will believe they have been prescribed a cure. We need to give clear instructions about what to do and when to do it. Just as it is irrelevant whether we happen to know what e.g. and i.e. stand for, it is irrelevant whether or not we know that t.i.d. stands for *ter in die*, or that we could have used t.d.s (*ter die sumendus*). What matters is that we know what it means. What is even more important is that other people understand it to mean what we think it means. Do you know that QD means four times daily or that it means once daily? How you translate QD will depend on which country you work in and what you have been told (if you haven't looked it up for yourself). There are no good reasons for using the abbreviation QD in a protocol. There is one very good reason for never using QD in any document other than a prescription, i.e. a four times overdose waiting to happen. If typing 'once daily' or just 'daily' upsets you, set the autocorrect to do it for

you. Using prescription abbreviations in regulatory documents can also lead to sloppy use of language such as ‘bd dosage’ and the even more annoying American English jargon ‘q12’ for twice daily – horrible!

There are no prizes for the person who uses the highest number of abbreviations in their documents. As a guide, writers should ask themselves:

1. Does this abbreviation improve the readability of the text?
2. Is this abbreviation commonly known to mean something else?
3. Can this abbreviation be misunderstood?

If the answer to either Question 1 or 2 is 'no' and the answer to the Question 3 is 'yes', do not use the abbreviation.

(*contributed by Wendy Kingdom, info@wendykingdom.com*)

References

1. Kingdom W. Good writing practice: abbreviations (1). TWS 2011;20(1):48.
2. Reeves A. Good writing practice: abbreviations (2). TWS 2011;20(2):118.
3. Kingdom W. Good writing practice: consistency. Med Writing 2012;21(1):74–75.

Points of View

Microsoft Word malapropisms

Malapropism is the misuse of a word through confusion with another word that sounds similar, especially when the effect is ridiculous.

The most famous perpetrator of malapropisms was Mrs Malaprop in Sheridan’s play *The Rivals* (1775) - and, as you see, this is where their name comes from. Sheridan based this on the French term *mal à propos* (something inappropriately said). Mrs Malaprop’s most famous malapropism fits well with Susanne’s topic: “She is as headstrong as an allegory on the banks of the Nile”.

Writing texts about veterinary medicinal products, I usually have a lot of fun with Word’s spelling suggestions:

Parasitology – not a core competence of word …

I wrote …	Word suggested …	Comment
Ostertagia	ottertail	*Ostertagia* is one of the principal stomach worms of sheep. I do not think that ottertails are a big problem in sheep farming. Although a swallowed ottertail might also block a sheep’s intestines …
Strongyles	strangles	Even the large strongyles of horses (nematode worms of the family Strongylidae) usually do not get so large that they could strangle you!
Ixodes	exodus	*Ixodes* is a very common tick species but usually does not lead to exodus of infected people or animals
Unengorged	unengaged	Female ticks (attached e.g. to a dog) that have not fed from blood are unengorged. Whether they might be engaged to a male tick or not, I do not know
Pyrantel	pirate	Pyrantel is an athelmintic substance used in veterinary medicinal products. I doubt that pirates have the same effect on intestinal nematodes. However, it might be worth a try to find out whether they could scare away the poor worms

Names – always worth a laugh …

I wrote …	Word suggested …	Comment
Lauth	laugh	Word obviously thinks that my last name is a laugh (which it is indeed in GB as it is pronounced like ‘Lager loud’)
Daiva	Diva	Whether my Lithuanian colleague, whose first name is ‘Daiva’, is a Diva, I cannot comment on!
Florfenicol	Florence	Florfenical is an active substance in veterinary medicinal products (antibiotic); however, it was neither named after my colleague Florence nor after the capital city of the Italian region of Tuscany

Biochemistry – not only students fail…

Pegylated	Paginated	PEGylation is the process of covalent attachment of polyethylene glycol (PEG) polymer chains to another molecule, e.g. a protein. I believe that pagination is neither a standard technique in biotechnology nor that it would have the same effect
DEET	Diet	*N,N*-Diethyl-meta-toluamide, is a very common active ingredient in insect repellents. However, I would not regard it as a constituent of the human diet

Susanne Goebel-Lauth
susanne.goebel@gmx.de

English: should being understandable be enough?

In a lecture timed to coincide with the official opening of the Centre for Global Englishes at my alma mater, the University of Southampton,[1] the centre's director, Professor Jennifer Jenkins, argued for the acceptance of *foreign* Englishes by UK universities.

Speaking to *Times Higher Education*,[1] she clarifies her position by claiming that universities' insistence that all students adhere to the rules of British English is at odds with their desire to be seen as international institutions.

Professor Jenkins goes on to suggest that English tests for prospective international students need do no more than determine whether the students' language skills are adequate for them to successfully complete their proposed course. Mastery of the Queen's English (The *standard* form of English spoken in England)? Comprehension in subjects unrelated to the proposed study area? Inessential.

She further points out that forging a successful academic career depends on conforming to the language norms of British or American academics. (One way to achieve this is to shell out large sums of cash on copy-editing services.)

My experiences as an editor and a peer reviewer have convinced me that the biggest threat to comprehension in scientific manuscripts is non-native English speakers attempting to use language that they don't properly understand. That is to say, trying to adopt the language used by native English-speaking researchers.

Time to reassess our priorities?

The *Journal of English as a Lingua Franca*,[2] a new peer review periodical co-launched by Professor Jenkins, stipulates that manuscripts be 'written in an English which is intelligible to a wide international academic audience', but that 'need not conform to native English norms'.

The majority of the world's English speakers use English as a lingua franca, where the primary goal is being understood rather than achieving linguistic perfection. I can't tell you the number of times I have read the word 'evidences', used as a plural noun, in manuscripts written by non-native English speakers. While grammatically incorrect from a UK perspective, does it impede comprehension? No.

According to Jenkins,[3] a far bigger problem is the failure of native English speakers to adapt their style of speech when communicating with non-native speakers.

So, just how important is strict adherence to language ideals? Is the idiomatic language in this article appropriate for a readership made up of EMWA members from around Europe and beyond? What do you think?

References

1. Reisz M. A word of advices: let speakers of Englishes do it their way, UK told. Times Higher Education, 17 May 2012. Available from: http://www.timeshighereducation.co.uk/story.asp?sectioncode=26&storycode=419935&c=1&goback=%2Egde_1822758_member_117530306 [Accessed 3 July 2012].
2. Journal of English as a Lingua Franca. Available from: http://www.degruyter.com/view/j/jelf [Accessed 3 July 2012].
3. Jenkins J. Lashed by the mother tongue. Times Higher Education, 7 September 2007. Available from: http://www.timeshighereducation.co.uk/story.asp?storycode=310394 [Accessed 5 July 2012].

Stephen Gilliver
Center for Primary Health Care Research
Malmö, Sweden
stephen.gilliver@med.lu.se

Queen's English Society 2 giv up?

'The Queen's English Society is neither a museum nor is it a preservation Society'. That's what its website says.[1] So what is it?

Founded in 1972, the QES exists to 'promote the maintenance, knowledge, understanding, development, and appreciation of the English language as used both in speech and writing' and to 'educate the public in its correct and elegant usage'.[1] It is particularly concerned that children be given the opportunity to learn English properly and actively campaigns for improvements in English education in the UK.

Now, according to the society's former chairman Rhea Williams, it is no more. After a call for nominations to the society's management committee that met with zero response, Williams apparently informed the society's membership that the QES 'will no longer exist'.[2]

Not so, according to QES president Bernard Lamb, who does see a future for the society.[2] However, an attendance of 22 at its recent annual meeting suggests that unwillingness to join the management committee is not the only problem the society faces.

So what are its other problems? A general lack of interest? A belief that nothing can be done to halt or reverse the perceived erosion of English standards? Or a lack of awareness of the society's very existence? I'd certainly never heard of it until now and I consider myself to be an obsessive language enthusiast.

In fact, its problems don't end there. The society has been the focus of a good deal of hostility in blogs and the press, with a number of commentators[3–5] deriding its decision to establish an academy of *proper* English[6] and questioning its authority. The defiant welcoming message on its website, which labels its detractors 'a strange group of people, often quite well educated themselves, but [who] appear to be against others who strive to achieve', suggests an organization that feels under attack.

The QES's plight contrasts sharply with the reverence afforded the Swedish Academy,[7] a language preservation society in my adopted home country that is widely known (to the extent that it has been the subject of questions on popular daily quiz show *Vem vet mest?*), if similarly ineffective.

References

1. The Queen's English Society. Available from: http://www.queens-english-society.com [Accessed 3 July 2012].
2. Smith L. Queen's English Society says enuf is enough, innit? Guardian.co.uk. Available from: http://www.guardian.co.uk/education/2012/jun/04/queens-english-society-enuf-innit?INTCMP=SRCH [Accessed 3 July 2012].
3. McIntyre JE. Speak proper, or else. The Baltimore Sun. Available from: http://weblogs.baltimoresun.com/news/mcintyre/blog/2010/06/speak_proper_or_else.html [Accessed 3 July 2012].
4. Mitchell D. Snakes are evil, but save your venom for the self-appointed language police. The Observer. Available from: http://www.guardian.co.uk/commentisfree/2010/jun/13/david-mitchell-comment-is-free [Accessed 3 July 2012].
5. Carey S. The Queen's English Society deplores your impurities. Sentence first. Available from: http://stancarey.wordpress.com/2010/06/11/the-queens-english-society-deplores-your-impurities [Accessed 3 July 2012].
6. The QES Academy of Contemporary English. Available from: http://www.academy-contemporary-english.org.uk [Accessed 3 July 2012].
7. The Swedish Academy. Available from: http://www.svenskaakademien.se/en. [Accessed 3 July 2012].

Stephen Gilliver
Center for Primary Health Care Research
Malmö, Sweden
stephen.gilliver@med.lu.se

Should noun modifiers be singular or plural?

Noun modifiers or abbributive nouns are common in medical writing and often come in stacks. Here is an example in a title of a research proposal given on the University of California, Santa Cruz website: 'A high-efficiency multiple voltage retinal prosthesis research platform'. Note that all the nouns are singular. But, it could equally read 'A high-efficiency multiple voltages retinals prostheses research platform'. There are no rules as to whether the nouns should be singular or plural.

While subediting at the *Guardian* Andy Bodie noticed 'credit rating agency' and 'credit ratings agency' in the same paragraph.[1] He quotes *The Chicago Manual of Style*, which states 'Sometimes

an abbributive becomes conventional in the singular (toy store) and sometimes in the plural (ladies room).' We choose which to use by ear and there is little logic behind the evolution of commonly used pairs, with some exceptions. He gives the examples of 'arms race' and 'Antiques Roadshow', which can hardly be interchanged with 'arm race' and 'Antique Roadshow'. Some old terms which seem to be plurals have emerged from the genitive tense and are not plurals, e.g. batsman, swordsman. Apostrophes are not used because in the 17th century when they originated apostrophes were not used to denote a possessive but rather to indicate missing letters. Andy suggests that we should stick to the singular when a new term emerges, unless like the 'arm race' and 'Antique Roadshow' examples there are very good reasons to use the plural.

Reference

1. Bodie A. Don't forget your teethbrush. Available from: http://www.guardian.co.uk/media/mind-your-language/2012/jul/05/mind-your-language-nouns.

Elise Langdon-Neuner
editor@emwa.org

'Patient-centred care' mockery

New words have entered the vocabulary of medicine. Old words that had been used for three centuries are being replaced by words borrowed from commerce. Mercenary doctors who were once rebuked by society are encouraged to view patients in materialistic terms by the use of the new vocabulary. Patients are now called 'customers' or 'consumers'. Doctors and nurses have become 'providers'. However, the medical doctors Pamela Hartzband and Jeromes Groopman point out in an article in *The New England Journal of Medicine* that the terms are not synonymous.[1] 'Patient' comes from the Latin word *patiens,* which means suffering or bearing an affliction, 'doctor' from *docere*, which means to teach, and 'nurse' from *nutria,* meaning to nurture. The two doctors believe that the change in language has deleterious consequences because the words we use set expectations and change behaviour and relationships. The designations consumer/customer and provider reflect a relationship of buying and selling for money and not a humanistic one. Healthcare workers are downgraded from their professional status when they are merely seen generically as providers rather than experts with individual skills. They are no longer teachers, nurturers etc. who help patients understand their illness. A doctor ceases to be recognized as an expert or teacher with specialist knowledge.

Further language changes which they attack include 'clinical judgement' giving way to 'evidence-based practice', even though decisions in the clinic have always been guided by an examination of the available evidence. Hartzband and Groopman contend that although clinical judgement is cast as subjective, unreliable and unscientific judgement based on data is equally so because the same data can produce different subjective judgements. Cut-offs in medical guidelines are not objective but reflect the preferences of those who write the recommendations.

The outcome is predicted to be a new generation of healthcare workers who lack a focus on humanism and caring – a stupidity which is not good news for any of us.

Reference

1. Hartzband P, Groopman J. The new language of medicine. NEJM 2011;365:1372–3.

Elise Langdon-Neuner
editor@emwa.org

Out On Our Own

Section Editors:
OOOO Editors
Raquel Billiones
Zurich, Switzerland
medical.writing@billiones.biz

Sam Hamilton
Newcastle upon Tyne, UK
sam@samhamiltonmwservices.co.uk

Editorial

Another summer has come and gone. In this issue of OOOO, we are happy to feature Paul Woolley's novel approach of comparing employment and freelancing. I am sure many of us can identify with some of the points he raises.

We thank Debbie Jordan for sharing with us her *Out of Hours* hairy adventure for a worthy cause, plus a useful addition to a medical writer's *Tool Box* – a website offering a quick way of locating instructions for authors' for over 6000 journals in the field of health and life sciences.

And once again, Anu and Anders bring us an entertaining word jumble. Finally, a quick reminder that you should join the EMWA group on LinkedIn if you haven't already done so. This is our means of keeping in touch and updating you on important issues in 'real time'. Our next stop is Berlin at the November 2012 EMWA meeting this autumn. We hope to see old and new members alike at the Freelance Business Forum.

A leap into the unknown .....

As many of you know, I have been a freelance medical writer for many years (13 years I think at the last count) and I have been actively involved in EMWA for most of those years, including several years spent on the EMWA committee. I teach several workshops at the EMWA conferences and also contribute regularly to the journal. Outside of work I play squash and I help out at my local Scout group. However, on 29th February 2012, I decided to do something completely different and I volunteered to take part in a charity skydive (and for those of you that know me – yes my 'volunteering' to do this did come after a few large glasses of wine!).

The reason I volunteered to do this is I have a very dear friend called Julie who has muscular dystrophy (MD). Although multiple sclerosis (MS) is well known, MD is less well known and more funding is needed to research into this debilitating condition that causes progressive muscle wasting. The Muscular Dystrophy Campaign wanted to organize a tandem skydive on the extra leap year day this year (February 29) to raise money for research

DOI: 10.1179/2047480612Z.00000000060

and to raise awareness of this condition, so when I learnt about it I decided to volunteer. It was only after putting my name down that the fear set in – not helped by my kids laughing their heads off at the thought of their mum, who is afraid of heights and won't go on a rollercoaster, jumping out of a plane!

On the jump day it was cloudy and foggy, and part of me was hoping it would all be called off! However, we headed to the airfield and hung around for most of the morning before we were given the go ahead to do the skydive (my knees started to go very wobbly at this point). We were kitted out in our jumpsuits, our MD t-shirts, strange pointy hats and goggles and then walked out to the plane. The plane took off and went up to 12 000 feet, where we were strapped very tightly to our tandem partners before being moved to the doorway to do the jump. From this point on I must confess I had my eyes closed, and only opened then again when we had tumbled out of the plane and were freefalling at 120 mph through bright blue skies and sunshine towards the grey clouds below. At 5000 feet the parachute opened and then we gently glided to earth – although my landing wasn't as graceful as I was hoping it would be!

Overall it was an amazing experience and I am glad I overcame my fears and did it and in doing so raised a lot of money for a very worthwhile cause. But would I do it again? I may be mad – but I am not completely insane!!!

If anyone would like to donate to the Muscular Dystrophy Campaign to support my skydive then my JustGiving webpage is www.justgiving.com/DebbieJordan64. Thank you. Debbie Jordan.

Debbie Jordan
mail@debbiejordan.co.uk

Medical Writing Jumble # 4

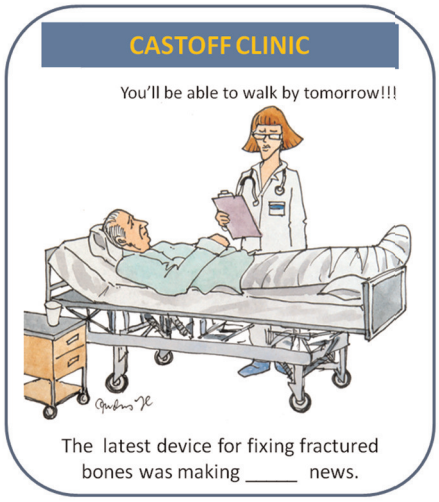
1. Rearrange the jumbled letters to get a meaningful word related to medical writing.
2. Next, take the circled letters from each word and make two new words that will answer the riddle in the cartoon. Hint: The answer is probably a pun.
3. Use British English.

SATREB ◯◯□□□□

RAGED ◯□◯□□

TIKANE ◯□□□◯□

SUREN ◯□□□□



Answer: □□□□□□□□ NEWS

by Anuradha Alahari | Illustration: Anders Holmqvist

See page 256 for the answers.

Do it yourself (?)

Editor's introduction: We asked long-standing EMWA member Paul Woolley to reflect on a decade of freelancing as a scientific and medical writer. He agreed to do this, but added that, like many medical writers, he prefers to see results presented in tabular form. The table that he gave us compares medical writing in a pharma company or a CRO with that of a home-based self-employed writer, with the caveats that not every 'employee' point applies with equal weight to pharma and CRO life, and that the trend towards employees' working from (or even at) home can blur the distinction in some respects. It is probably a coincidence that the number of points he addresses almost equals the number of weeks in the freelancer's working year.

paul.woolley@p-soft.de

	Being an employee medical writer …		Being a self-employed medical writer …
1.	Your timetable is at least partly imposed.	<	You can divide up & plan your own time.
2.	You rarely have control over work overload.	≪	You decide how much or how little work you do (but do you really decide this? – see next point).
3.	Just sometimes, you can keep overtime in check.	>	You probably cannot afford to say "no" to a client, in case he finds someone else and never approaches you again.
4.	Work is work and time off is time off. (But you probably take your work problems home with you anyway.)	=	If you work at home, you basically never leave the office.
5.	Work is work and time off is time off. So home chores don't intrude at work.	≪	With your office at home, you can easily and quickly switch from work duties to home duties and back – if convenient, several times daily (see, however, no. 39).
6.	A substantial percentage of your time is devoted to work-related meetings, etc.	<	A substantial percentage of your time is devoted to providing your own technical support, administration, book-keeping, etc.
7.	Fixed (minimum) working hours.	≪	Free choice of hours, as long as the job gets done.
8.	You have very little influence on how many projects you are working on concomitantly.	≪	You can choose, or at least steer, how many projects you are working on concomitantly.
9.	When peaks of activity occur, they are usually less busy (you can get a stand-in), but the peaks are more stressful (lots of people involved, telephone calls, urgent mails, etc.).	<	Peaks of activity are busier (you cannot delegate or arrange stand-ins), but they are less stressful (you control every minute, can disconnect the 'phone' etc.).
10.	You are sometimes under pressure from your boss to work long additional hours (unpaid).	≪	You are sometimes under pressure from your clients to work long additional hours (paid).
11.	Therefore …You have to learn to say "no" to your boss (difficult).	>	Therefore …You have to learn to say "no" to your clients (very difficult; not usually done).
12.	You are subject to political pressures from the company hierarchy.	≪	You are your own boss – no political pressures.
13.	You sometimes get exasperated by your colleagues.	=	You sometimes miss having colleagues.
14.	Projects can often be much of a muchness.	≪	There is a great difference in atmosphere and challenge from one project to another.
15.	You contribute to your working environment, but it is basically determined by others. (You may even end up in an open-plan office!)	<	You are guaranteed a happy working environment, though perhaps lacking agreeable contributions from others.

Continued

Continued

	Being an employee medical writer …		Being a self-employed medical writer …
16.	Generally, you have to work with the clients that your line manager tells you to work with, even if they are not always so pleasant … *(continued below)*	<	You can decide which clients to drop (but you probably don't – see no. 3) … *(continued below)*
17.	… and the line manager frequently gives your colleagues the clients that are good to work with.	≪	… and which ones to cultivate.
18.	In negotiating with clients, you can appeal to the rules or SOPs of your company if it suits you.	>	You cannot appeal to the rules of your company, and if you have any personal SOPs you have to justify them each time in arduous negotiation.
19.	You have the back-up of experienced client-relations experts.	>	You are your own client-relations expert and need to have – or to develop quickly – excellent assessment of a client's needs and tastes.
20.	… an organization not to try pulling a fast one on him, and is therefore easier to deal with. (For the beginning of the above sentence, see opposite.)	≪	The client is more likely to trust an individual than …
21.	It is not unknown for companies to out-source virtually impossible tasks to CROs because someone would lose face within the company if they tried the job themselves and messed it up. In the event of success the CRO gets the credit; in the event of failure the medical writer gets the blame.	≪	It is not unknown for companies to out-source virtually impossible tasks to freelancers because someone would lose face within the company if they tried the job themselves and messed it up. If the freelancer keeps a cool head and a good relationship to the client he can always pick up some credit.
22.	You are rarely told exactly what the client wants or needs; you have to extort this information from someone, which is difficult: you cannot approach your colleagues as they do not know, and you cannot approach the client because it would be letting the side down.	≪	You talk directly to the client, with no middle-men, and can find out fairly quickly what the client wants, what he needs, and whether these are the same thing. (If you can point out convincingly that they are not, you will become flavour of the month, or even longer.)
23.	Sometimes, there is someone to replace you when you are off sick. More often, you have to pretend that there is.	<	There is no-one to replace you when you are off sick. However, clients usually understand this.
24.	Someone else does your employment paperwork.	≫	You take responsibility for all paperwork, taxes, etc. … leading to much loss of sleep or the engaging of a costly professional.
25.	… ditto insurances.	≫	… ditto insurances.
26.	… ditto IT servicing.	≫	… ditto IT servicing.
27.	… ditto business development.	≪	… ditto business development.
28.	You may have to walk or cycle to work each day, which consumes time but provides much-needed exercise.	≫	Working at home, you get much too little exercise and probably need to discipline yourself to get any at all.
29.	You may have to drive to work each day, which consumes petrol and does not even provide much-needed exercise.	≪	You consume no petrol and save the planet.
30.	There is free, though not always very select, coffee at work – perhaps even a subsidized canteen.	=	The quality and price of comestibles at work are of your own choosing, as are the resources put (by you) into their procurement.

Continued

Continued

	Being an employee medical writer …		Being a self-employed medical writer …
31.	You can often legitimately use office facilities for private purposes, saving time.	=	You can often legitimately use home-office facilities for private purposes, saving money.
32.	You can store your textbooks and similar junk in your office.	>	You must store all your textbooks at home; also records, archives, etc., which take up a surprising amount of space.
33.	You cannot store personal effects (in noticeable amounts) in your office.	<	You can put excess space to good use and may even get tax back on it.
34.	You can check difficult questions with colleagues who are expert in other fields, e.g. statistics or specialized areas of medicine.	≫	Having no colleagues to check with, you have to use connections (which is difficult for confidentiality reasons), to ask the client (which is often less of a problem than it sounds) or quickly to become your own expert.
35.	With luck, you may be sent on training courses that will cost you nothing and where you may even learn something.	≫	If you have time for training courses, then you cannot afford them; if you can afford training courses, then you have no time for them.
36.	You can be trained up on the job.	≫	You cannot be trained up on the job by others (except sometimes in good collaborations with clients).
37.	*Singles:* You are tempted to turn your workplace into an ersatz family. (This applies especially if you become romantically involved with a colleague.)	=	*Singles:* You require discipline to maintain basic personal contacts.
38.	*Paireds:* You are tempted to turn your workplace into an escape from the family. (This applies especially if you become romantically involved with a colleague.)	=	*Paireds:* Monogamy is guaranteed, at least on your part.
39.	*Parents:* You can get away from the kids.	≫	*Parents:* You have to stake out territory.
40.	As a medical writer, you sometimes have to cover up for sub-standard work by colleagues in other departments. (Reason: The company, or your business unit, has to pretend to be perfect, and you are the "front man".)	<	You never have to, and never can, cover up for bad work; it is clear which mistakes are yours and which are not. (However, most clients are willing to accept a small slip now and again in the interests of an honest relationship.)
41.	All your good work can be rendered valueless by other people's policy decisions, in the making of which you were usually not consulted and which often reveal an astounding ignorance of the actual situation.	≪	Vital policy decisions can be taken in the bath-tub. They are made against the background of all necessary information, by a competent and suitably qualified person.
42.	Occasional positive feedback after good work done.	<	Frequent positive feedback after good work done.
43.	Occasional jealousy and back-stabbing after good work done.	≪	Does not apply.
44.	You can afford to have a bad day now and again.	≫	You need a clear head at all times.
45.	If you work fast, then it is of no value to you: your employer bags the profit and you rarely get much credit. (Assumption: Fixed-price contracts, as is usual with CROs.)	≪	If you work fast, then (i) you save time, (ii) your client saves money and gives you credit for it, (iii) the client returns. (Assumption: Time and materials costing, as is to be recommended for freelancers.)

Continued

Continued

	Being an employee medical writer …		Being a self-employed medical writer …
46.	If you work long hours, then it is of no value to you; your employer bags the profit and you rarely get much credit. (Assumption: Overtime unpaid, as is usual with employee medical writers.)	≪	If you work long hours, then (i) you earn more proportionately, as your costs are fixed, (ii) your client gets a quick result and gives you credit for it, (iii) the client returns. (Assumption: Time & materials costing, as is to be recommended for freelancers.)
47.	Job security is uncertain – you can revert from "100% employed" to "100% unemployed" at any time, and you have no control over this.	<	Job security is uncertain – you have to fish for contracts. However, changes are not of an all-or-none nature, and can to some extent be counteracted by adjusting acquisition effort.
48.	You are subject to performance management and reviews, goal-setting, improvement targets, and time spent on all these; moreover, you know that you are earning the money which remunerates those who devote their time to such things.	≪	Does not apply.
49.	You are expected to contribute to "operational excellence", "internal and external customer satisfaction", "innovation", "people/team development", and the like.	≪	You just get on with the job.
50.	Your performance effort is directed at least partly towards increasing your company's shareholder value.	≪	Your performance effort is directed entirely towards doing the best possible work.
51.	Holidays	≫	Does not apply – well, hardly.

The tool box

The Raymon H. Mulford health science library

The Raymon H. Mulford Health Science Library (http://mulford.meduohio.edu/instr/) is run by the University of Toledo and is a free website that provides links to 'Instructions for Authors' for over 6000 journals in the health and life sciences area. It provides alphabetical lists of the journals and once you click on the journal name it takes you straight to the guidelines that the journal issues for manuscripts intended for submission, so it is a quick way of locating these instructions rather than drilling down from the journals home page. There is also a very useful keywords search that allows you to find out what journals are published in a certain area – for example if you type in 'cardiology' you then get a list of 32 journals that publish cardiology articles, ranging from the obvious *American Journal of Cardiology* through to the less obvious *Annals of Noninvasive Electrocardiology*. The website provides links to author guidelines such as the Committee on Publication Ethics (COPE) guidelines and the European Association of Science Editors (EASE) guidelines, as well as copyright policies, conflict of interest policies and reporting standards (ASSERT and CONSORT statements), and other useful documents related to manuscript publication. The owners of the website are very keen to add new journals to make their database as comprehensive as possible, so any new additions can be sent to gerald.natal@utoledo.edu.

Shared by Debbie Jordan (mail@debbiejordan.co.uk, www.debbiejordan.co.uk).

Answers to Medical Writing Jumble #4:
BREAST, GRADE, INTAKE, NURSE
The latest device for fixing fractured bones was making BREAKING news.

Gained in Translation

Section Editor:

Gabriele Berghammer,
the text clinic, Vienna
Austria
gabi@the-text-clinic.com
www.the-text-clinic.com

Science at the multilingual crossroads

With *Medical Writing*'s third issue, this seems to be a good time to recall why this journal features a section on multilingual aspects – and why this section is called what it's called.

Medical writing, particularly the regulatory side of it, is an essentially English-language affair. Yet, in a Europe with some 30 official languages, transfer between and among them is a challenge. This section is about such challenges. At the same time, looking at the world through a bi- or multilingual lens multiplies our perceptions of it. Translation may involve an extra effort, but it's one that is not expended in vain. And this is what this section is also about.

In this issue, Monika Schöll shares some thoughts on what life is like working as a translator at university hospital in Germany. Then there's a brief piece on the different meanings of meaning and the frequent lack of equivalence in meaning between words in different languages.

Gabriele Berghammer
gabi@the-text-clinic.com

Working as a medical editor and translator in a university environment in Germany

I often get surprised looks when telling people at EMWA meetings that I work as a full-time medical editor and translator at a German university hospital, because, to my knowledge, such a position is the only one in Germany. So you may be wondering how I got there and what I actually do.

My career change from bilingual assistant to medical editor and translator started, more or less by coincidence, in the early 1990s. With several linguistic qualifications under my belt as well as a few years of working experience in England, I started to work as a personal assistant to the head of one of the departments at the university hospital in my home town in Southern Germany. To familiarise myself with the terminology of my new field of activity, I started to read medical publications, first in German, then in English. Medical articles written by the department's resident doctors needed the boss's approval before submission for publication. I had my first go at editing a medical publication when a research paper that passed my desk showed an obvious and typical German grammar mistake, i.e. use of the past tense instead of present perfect, in the title. I tactfully pointed out the error to the author and, as a consequence, was asked to correct the entire paper. Soon I was editing most of the department's medical publications written in English. Admittedly, at that time, my knowledge of scientific writing in English was rather limited, so that at first I concentrated on correct spelling, grammar and syntax. However, with lots of enthusiasm and dedication as well as the help of an American linguist friend, my experience grew and I was asked to also work on papers from other departments. After 10 years of editing and translating medical manuscripts in addition to my rather demanding job as a personal assistant, I started to wonder about a complete change of career. Knowing that I would stand little chance of getting accepted at a university hospital without a degree to my name, I completed a Bachelor of Arts degree at the Open University at Milton Keynes. After many back and forth discussions, much persistence on my part and tremendous support from my previous boss, I was offered a full-time position as a medical editor and translator at the Centre for Clinical Trials (*Zentrum für Klinische Studien, ZKS*) in Regensburg in 2006. The ZKS provides study support to clinicians and sponsors with regard to the design, implementation, evaluation and publication of clinical research projects according to national and international quality standards. The ZKS also supports

DOI: 10.1179/2047480612Z.00000000061

local researchers in non-commercial investigator-initiated trials; in such trials, publications are usually written by the investigators themselves. Depending on the English language skills of the respective researcher, the manuscript may be given to me for editing or translation.

Getting established was no easy matter and I got rather mixed reactions, mainly because I was neither a native speaker nor a physician, but also because an official editing and translation service was generally unknown within German university hospitals. Furthermore, some scientists tend to acknowledge the need for linguistic revision only when their manuscript has been rejected or returned on linguistic grounds by the editor of a medical journal. Understandably, having one's manuscript corrected is a somewhat sensitive matter for every author. Thus, my position has required not only linguistic but also diplomatic skills.

To introduce this new editing and translation service, I developed a short manual on how to write a scientific paper, which included the most frequent sources of linguistic errors, particularly for German native speakers. This manual, which was sent to all university hospital departments involved in conducting clinical trials, led to a request by one of the departments to give a 4-hour course on scientific writing. Having never done anything like that before, I did plenty of research and also included many examples from manuscripts I had corrected over the years. Typical errors included the wrong use of tenses, confusion of adverbs and adjectives, long sentences with the verb placed at the end, long paragraphs in passive voice, unnecessary words, excessive nominalisation and – my favourite – dangling participles and modifiers, such as in 'Tissue was harvested by an experienced surgeon under general anaesthesia' or 'This article has been checked by a native American English speaker'.

My first lecture in front of professors and doctors was a rather nerve-wracking experience. Despite that, the course was well received and word got around, so that my services as well as the need for them became more and more accepted within the university hospital. For time and cost reasons, I mainly edit research articles for publication in medical journals, with the occasional full translation thrown in. So far, I have edited and translated for many departments, such as the departments of dermatology, cardiology, cardio-thoracic surgery, haematology and internal oncology, cranio- and maxillo-facial surgery, orthopaedics and prosthetic dentistry.

It was whilst undertaking research for the scientific writing course that I learned about EMWA. Searching the net for similar courses, I came across Christine Moeller's Medical Writing Course in Copenhagen. Christine's advice on how to design such a course was extremely helpful, and it was she who told me about EMWA. I can genuinely say that becoming a member has tremendously helped me in my work. Attending the language courses during the conferences and autumn meetings have further strengthened my writing skills; what I enjoy most, however, is meeting with people doing a similar job, as it does get a bit lonely having no one to talk to professionally. But above all, EMWA workshops sets quality standards, particularly concerning questions of style. Thus, if an author questions any of my corrections, I can refer to my association with EMWA, which gives a much more professional impression than simply saying that I based my corrections on personal intuition alone.

The Centre for Clinical Trials I work for is also a member of a network of Coordinating Centres for Clinical Trials (*Netzwerk der Koordinierungszentren für Klinische Studien – KKS-Netzwerk*) throughout Germany, which, amongst other services, offers a wide range of training programmes for research personnel. The fact that English has become the primary language for clinical research does not pose so much of a problem to principal investigators; study assistants, however, may not have practised their English skills since their school days. English communication as well as medical and study-specific terminology can often be a major obstacle to doing their jobs properly, and having to deal with a, let's say, 80-page study protocol written in English may result in despair and even panic attacks. In 2008, therefore, I was asked to develop a job-specific 2-hour English course for study assistants as part of their further education programme. Having fallen into most linguistic and cultural traps myself over the years – particularly double meanings, false friends and a typical German straight-down-to-business no-time-for-small-talk attitude –, I developed a course that not only included study-specific medical English but also covered general situations such as introducing oneself at meetings, verbal and written communication and the typical problem areas for German native speakers. Here, too, the need for improved English language skills has increasingly become acknowledged, and the 2-hour course has meanwhile been extended into an interactive 1-day tutorial.

My set-up in an academic environment is probably a bit different from that of most other EMWA members, who mainly work for pharmaceutical

companies and non-profit organisations or run their own businesses. Yet, the problems related to our job are the same: Working in isolation and under tight deadlines or getting appropriately acknowledged. The biggest challenge for me, however, has been the flowing transition between editing or translating and re-writing a manuscript. Editing a manuscript can be a very delicate business because, sometimes, highly scientific manuscripts would benefit from being, at least partly, re-written for better readability but this suggestion is difficult to convey to any client. Usually, the overall comprehensibility of a manuscript can be improved by correcting, rearranging and shortening sentences as well as by rectifying unnecessarily complicated sentence structures. In the case of incomprehensible sentences, I tend to add a comment asking for specification – an approach appreciated by most authors. However, the problem of incomprehensibility can also occur in original language texts. In such cases, I find translating more difficult than editing because of the translators' code of practice: As literal as possible and as free as necessary. When editing, I feel free to just take sentences and even paragraphs apart and put them back together in a logical order. In the case of translations, I feel more obliged to stay close to the original. Again, adding a comment to problematic text passages has proven useful. Over the years, experience has shown that clients are not overly concerned about free translations but tend to be grateful for easy-to-read manuscripts. However, the question remains: When does editing or translating end and rewriting start? This problem, which is intensified by the fact that a manuscript must be made comprehensible in a billable period of time, will remain a constant challenge to all of us.

Monika Schöll
Monika.Schoell@ukr.de

Concepts from the linguistic crossroads

Words and their lexical meaning

Every word has a 'lexical meaning', i.e., the meaning of the word considered in isolation from the sentence containing it and irrespective of its grammatical meaning. There's different types of lexical meaning – propositional, expressive, presupposed, and evoked –,[2,3] each posing specific challenges during translation.

For example, the **propositional meaning** of the word 'liver' is that of a 'large gland of a dark-red colour situated in the right upper part of the abdomen'. Another propositional meaning of 'liver' is a type of food which, in some cultures, is eaten baked, fried, or made into liver pâté, liver sausage, or chopped liver. The propositional meaning of the word 'bloody' describes something containing blood, such as in 'bloody diarrhoea' or 'bloody mucus'. Translations considered inaccurate are generally those that use a target-language expression whose propositional meaning does not match the propositional meaning of the source-language expression.[2]

Expressive meaning, on the other hand, relates to feelings, opinions, or attitudes of the speaker. Let's take 'chopped liver' – whose propositional meaning is that of a traditional spread in Jewish cuisine. Yet, 'chopped liver' takes on a rather emotional meaning in the idiom 'What am I, chopped liver?', signifying disappointment at being cold-shouldered socially. This expressive meaning of the phrase, some think, derives from the fact that chopped liver is not quite everyone's favourite dish, while others hold that it comes from chopped liver being served as a side dish. The word 'bloody', in addition to its propositional meaning, also has an expressive side to it, such as in 'This is bloody brilliant.' or 'It's so foggy, I can't see a bloody thing.', where it is used as an intensifier which, rather than adding meaning, adds emotion to an utterance.

cross·road *noun* ˈkro\s-ˌrōd *also* -ˈrōd\
a: the place of intersection of two or more roads
b: (1) a small community located at such a crossroads *(2)* a central meeting place
c: a crucial point especially where a decision must be made[1]

Presupposed meaning is the result of restrictions on which word we expect to see in connection with other words. A *collocational restriction* is totally arbitrary and has to do with usage in a given language. For example, whereas in English we 'brush' our teeth, we 'clean' them in German.[2] Also, in English we 'go and see' a doctor, whereas in German, we 'visit'. *Selectional restrictions* have to do with the propositional meaning of a word. For example, the word 'elderly' is only used to describe persons but

not objects, whereas the word 'old' can be used for both persons and inanimate objects or abstract concepts. Also, we generally refer to men as being 'handsome' and to women as being 'pretty'.

Finally, **evoked meaning** derives from differences between language varieties or registers. *Language varieties* are used by specific groups of speakers that share geographical, temporal, or social affiliations. For example, whereas the intensifier 'bloody' is rather commonly used in British English, Americans tend to use the word 'damn' instead. Also, while Vienna sausages are referred to as 'Wiener Würstel' in Germany, the Austrian equivalent is 'Frankfurter Würstel.' *Register* is a variety of language considered appropriate in a specific social setting or situation. For example, a mother asking her teenage daughter to tidy up her room is unlikely to phrase her request along the lines of 'May I kindly ask you to get your room in order'. Similarly, whereas a physician speaking with a colleague may use the terms 'haemorrhagic diarrhoea' and 'haemoptysis', he may choose to refer to these symptoms as 'watery bloody stool' or 'coughing up blood' when talking with a patient.

Generally, there are no clear-cut borders between these different types of meaning, and drawing them may seem like a purely academic exercise. However, consciously or unconsciously, translators make numerous decisions not only as to the choice of target-language words with a propositional meaning equivalent to that of the source-language word (sometimes by far the easier part of translation), but also regarding words with an expressive, presupposed, or evoked meaning, carefully weighing the different components of meaning in the source language before transferring a word into the target language. More often than not, there are no true equivalents between target and source, which is when the true challenge in translation begins.

References

1. Webster's International Dictionary [www.merriam-webster.com/].
2. Baker M. in other words. a coursebook on translation. London, New York: Routledge; 2010.
3. Cruse DA. Lexical semantics. Cambridge: Cambridge University Press; 1986.

Gabriele Berghammer
gabi@the-text-clinic.com