English Grammar and Style

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We have three articles in this edition. Pamela Haendler's contribution deals with the medical writer as a reviewer and quality checker. Because of their close involvement with all of the documentation on a project, the medical writers involved are often the only members of the team who have an overview across documents. This inevitably results in the medical writer – in the regulatory area at least – taking on the function of a reviewer and quality control person, ensuring consistency across documentation and compliance with guidelines. Pamela has some recommendations on how to handle this. Our first GWP article continues Debbie Jordan's deliberations on 'Writing for the Audience', this time covering regulatory documents, journal articles, and writing for the public and official websites of government agencies. This is complemented by Alistair Kidd's reflections on 'appropriate tone' in scientific and medical writing under Points of view, where he highlights the importance of pitching the level of language correctly for the expected audience.

Good Writing Practice

GWP is not a formal set of rules about how to write.[1] The aim is to highlight that the focus of all writers should always be on their readers, providing advice on practical aspects of writing to make texts easier to write and read. The aim is to keep contributions short so that a variety of topics can be covered in each issue. If you have any ideas or wish to agree or disagree with any of the advice or add new aspects, please do send in a contribution to Wendy Kingdom (info@wendy kingdom.com) or Alistair Reeves (a.reeves@ascri be.de), however long or short. Ultimately, we hope to bring everything together in an EMWA Publication.

Reference

1. Reeves A, Kingdom W. Good Writing Practice. TWS 2010;19(4):281.

Writing for the Audience (2)

Following on from part 1 of Writing for the Audience,[1] which outlined some basic principles, I would now like to develop this topic by considering the various audiences we write for and the key features of each style of writing.

Regulatory documents

Regulatory documents are structured and there are many guidance documents that specify the format. So we are often constrained by these guidelines when writing regulatory documents. However, in most cases the guidance templates are just that and are for *guidance*. They are not enshrined in law. It is better to adapt the structure so that it helps the reader rather than sticking to the letter of the template and making it hard for the reviewer to navigate through the document. When writing these documents, you need to consider that the audience is a highly educated and qualified person at the regulatory agency who is capable of reading and understanding scientific information. So be wary of 'dumbing down' the information too much, i.e. there is no need to spell out in full abbreviations such as UK and USA. Regulatory documents should be scientific and factual with no room for ambiguity or interpretation. However, they should also be easy to read so do not overcomplicate the language or use technical jargon because you think it sounds more intelligent. You should avoid large blocks of text; use bullet points and section headings to guide the reader, particularly in a study protocol. You can also help the reader by putting all of the information relating to one topic in the same place so that it can be found easily, and by putting similar topics close together.

Journal articles

A journal article should provide new information to the scientific community. Journals vary in their target audience, the degree of technical information

required, and their instructions for authors, but most are specialist journals targeted at a specific audience that is interested in a particular therapeutic area. As such, most of the readers are familiar with the medical issues in the therapeutic area, so it is not appropriate to include lengthy background information on the disease or current treatments. The focus should be on what is new, or the unmet need that is being filled by the research. People rarely read a journal from cover to cover; they skim through it, and most readers will read only the title, and if interested, the abstract. Therefore, the title and abstract should capture the reader's attention so that they want to read more. Remember that the key messages for a publication may be different from that of the clinical study report (CSR) – the CSR systematically reports the results of the study endpoints, but the purposes of a publication are to provide new information to the medical community and to add to current medical knowledge, which includes negative as well as positive information.

Writing for the public

Examples of writing for the public are the patient information leaflet for a clinical trial and the package insert for a marketed product. When writing for the public, it is important to bear in mind that the patient is usually not interested in the fact that a study is being conducted or the research in general; the patient is interested in taking something that will cure their illness, alleviate their symptoms, or reduce their risk of a serious event, such as a stroke. Therefore, you need to address the person and focus on what is important to them. Your language should address the individual who is reading the leaflet, e.g. 'you will be asked to come to the hospital three times', rather than the impersonal language used in other documents such as 'the patient will need to attend the hospital for three visits'. The patients are unlikely to be medical experts, so the language needs to be straightforward. In particular, avoid medical and technical jargon. However, you should not treat the patient like an idiot and oversimplify the information so that it becomes inaccurate or unclear. For example, stating that 'the tablets may affect your bowels' could mean that the tablets may cause diarrhoea, constipation, wind, or something else. The text also needs to present a professional image in terms of language and appearance since this is the company's only direct communication with the patient. The information should also be ordered logically, which might mean that it differs from the order of the trial conduct. For example, it might be appropriate to inform the patient that they will have blood samples taken five times during the study, rather than listing the tests to be done at each visit. It is important to remember the message that you need to convey to the patient – the patient does not need to understand how to do the study and they do not need extensive details on the disease. However, they do need to understand what will be done to them, and the risks and benefits of taking part. It is always useful to ask a lay person, who is not familiar with the study, to read a draft of the document and ask them to point out any parts that they do not understand.

Writing regulatory information to be published on official websites

Details of protocols of all clinical trials now have to be published on a public website, and there are moves to make it mandatory in Europe to publish all results of clinical trials (it is already mandatory in the USA). Most companies post the synopses from the CSRs on their own websites, but it might become a requirement to provide both a technical summary and a summary suitable for a lay person. The published information is available to patients, patient lobby groups, physicians, and opinion leaders, as well as to competitors developing similar products and the generic companies. The varied audience of these documents presents a challenge to the medical writer, since there is a delicate balance between providing enough information to be transparent, without providing company sensitive information to competitors or journalists. The requirement to provide a lay version as well as the technical CSR synopsis might help to define the audience for each document more accurately, and to avoid the current situation of trying to write a synopsis that is an accurate summary of the CSR for the regulatory authorities, but understandable to the lay person.

In summary, it is important to think about the audience for each document you write and to target the language, layout, and style appropriately. Medical writers are increasingly relied upon to have the skills and the expertise to mould their work and writing style as required, and the best way to do this is to think about the reader (the audience) and their requirements.

Reference

1. Jordan D. Good Writing Practice. Writing for the audience (1). TWS 2011;20(4):248.

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Are medical writers and editors also reviewers and quality checkers?

Despite their name, medical writers often spend as much of their time reviewing documents as writing them. However, the scope of review is seldom as well defined as the task of writing. If you are assigned to write a clinical study report, the understanding is usually that you will produce a final report, complete with in-text tables, a hyper-linked table of contents, and a list of abbreviations. A number check and technical quality check (QC) might be negotiated too, but these should be done by someone else, either in your organisation or outside of it, even if you are responsible for getting them done.

The review of documents by medical writers often leaves room for much interpretation, so a priority should be to clarify the scope of the review and the time available. I can roughly divide the texts I review into the following categories:

- Outsourced regulatory document owned by Medical Writing (e.g. CSR)
- Regulatory document owned by Medical Writing and written by colleague
- Regulatory document not owned by Medical Writing (e.g. Statistical Analysis Plan)
- Non-regulatory company document requiring official input from Medical Writing (e.g. Standard Operating Procedure [SOP])
- Presentation slides
- Publication
- Website or other text

Whatever category the text falls into, I also need to define the capacity in which I am reviewing, i.e. as a medical writer, a native English speaker, a mentor, or maybe just as a second pair of eyes. In these different capacities my role will vary, and with it the style and extent of my review. How much of the text I then permit myself to correct will depend on my role and what I feel is the extent of my responsibility.

The aspects of the review can be divided into what I consider to be formal requirements, content, consistency, and language.

Formal requirements

Any regulatory document coming out of a Medical Writing department must adhere to the formal requirements of authority guidelines and company SOPs and templates. On this level, medical writers should have the full authority to change the text and bring it in line, indeed it is their job to do so. The correct numbering of paragraphs, tables, and figures could be seen as formal requirements too, but these are often reviewed as part of a technical QC done separately.

Content

The extent to which medical writers can review the content of the text will vary enormously and it is difficult to come up with hard and fast rules about what the extent of our involvement should be. My recommendation would be only to go as far as you are able and confident to go, and to remember that most documents are the result of team work, and teams have their specialists. Medical writers can make an important contribution by asking questions of the other specialists, but any interpretation must be made with great care. We may notice points that in some way trouble us, even if we do not have the necessary scientific, statistical, or medical background to fully grasp the complexities, and this can be very helpful to authors. Note: it is quite possible to perform a detailed review of all other aspects of a text while actually understanding little of the content.

Consistency

The ability to write consistently and coherently is a pre-requisite for medical writers. Equally, as reviewers we are often the ones to point out inconsistencies, and this aspect of reviewing has to be one of the most important, regardless of the type of text we are dealing with. Inconsistencies look sloppy and can lead to confusion, but ironing them out can be painstaking work that invariably takes much longer than anticipated. If you have already worked on other documents from the same project, you will have insight that the author might not have, and as well as making the text consistent in itself, you will want to compare it with other texts. Such a full review needs to be agreed up front if you are to have the time to do it thoroughly. It should be noted, however, that it really is a job worth doing, whether or not you stand to benefit personally from such harmonisation, e.g. when writing the clinical summaries. The project, whatever it is, will definitely benefit.

Language

As a native English speaker living in Germany, I am often asked to 'take a look at the English'. This in itself can be interpreted in many ways, and depending on whom the request comes from and the type of text it is, can mean anything from 'could you read this and make sure I haven't made any howling mistakes' to 'could you read this, translate the bits I couldn't, re-phrase as necessary, and while you're about it use your amazing Word skills to make this rough draft suitable for publication?'.

The language review might be the most difficult one to gauge beforehand, unless you know the quality of the work the author is likely to produce. All writers are familiar with the length of time it can sometimes take to formulate a single sentence satisfactorily, and having someone else's imperfect draft in front of you does not necessarily make the job easier.

Making language corrections is also a very sensitive issue. Authors do not usually take offence at having the SOP quoted at them – many will take pleasure in explaining the intricacies of their subject to the uninitiated, and are grateful to a nit-picker for pointing out their inconsistencies – but hardly anyone enjoys having their prose pulled apart by someone else. Reviewers need to tread carefully! Knowing when it is not appropriate to correct a text, due to the author's individual style or personal preferences, or when it is simply out of the scope of the mandate, is essential. If you start micro-editing you need to see it through to the end, and after 5 pages of an 80-page document you might realise that you have wildly underestimated the amount of work involved. If you only have half a day to review a long document, try to establish what the absolute minimum is. While you are reading through and checking consistency, get a feeling for the style. You might notice recurring mistakes in vocabulary or grammatical errors, and you could decide to correct these, even if you have no time for a full-text review. But it is wise to make the extent of your corrections clear to the author. We have all heard the complaint of '… but I had it checked by a native speaker!'.

So, if you want to avoid the pitfalls and be appreciated for your honest reviewing, stick to your own rules, which might look something like this:

- Clarify the level of review the author expects.
- Establish whether anyone else is doing an official QC or number check.
- Ensure that you can fit the expected feedback into the time you have.
- Once agreed, do not exceed the mandate.
- Do not attempt to make the text sound like your own.
- If in doubt, leave well alone.

You might then become a favourite reviewer and get more work than you actually want, but you will be accused neither of skimming nor of nit-picking.

Anyone who needs more advice on reviewing and where to draw the line on correcting other people's texts might like to read the following articles that appeared in MEW last year:

1. Gilliver S. English: should being understandable be enough? MEW 2012;21(3):248.
2. Reeves A. Lost causes (2) MEW 2012;21(4):319.
3. Kingdom W. Consistency MEW 2012;21(1):74.

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Points of view

Appropriate tone: a sprinkling of subjectivity over painstaking, objective research

Tone in writing is difficult to define, but it is generally agreed that tone reflects the author's attitude to the subject. Note that I write 'reflects'. It need not necessarily *be* the author's attitude (after all, as an author you can appear to the reader to be fully engaged – or even enthusiastic – but actually be bored by the subject and need a holiday). If we use this reflection of attitude as a working definition, then it begs the question 'what attitude is best reflected in medical writing?'.

A scientific attitude? What exactly is that? The words 'objective' and 'impartial' spring to mind. If you use a neutral, balanced tone, it may make the reader feel confident that you are not being overly biased in your conclusions. And that is surely a good thing. (Of course, this is entirely separate from any bias there may be in the choice of data presented, which is another issue altogether.) It is also important that the reader

feels that he/she is being treated as an equal and not being patronised, so words like 'obviously' have no place in scientific writing.

Let's take this idea of reflecting a neutral, balanced attitude one step further. How do we achieve it? Avoidance of strong language, humour, and contractions will obviously bring the reader closer to accepting my credentials as a serious scientist, but is it all about choice of words? Can I command respect in other ways? The grammar must of course be up to scratch for the author(s) to be taken seriously. How much abstraction you use and how you handle strings of nouns may also play a part. And then there is the issue of voice. Nowadays, the lack of single-author papers has led to a changeover to the active voice. It is much more comfortable to write 'we' than to write 'I'. I believe that using a good balance between active and passive voice is smart because in a subtle way it reflects the same all-pervading balanced attitude to the subject that should be apparent throughout the document.

You can also affect the tone of a document if your work with tenses isn't quite right. In my experience, one crucial consideration in this context is figure legends (captions). These often require far more work in this respect than the authors are prepared to give to them.

Let us now consider choice of words. How important is it? If you are faced with two or more synonyms for exactly the same thing, how do you make the choice? This is surely the most difficult part of handling tone in a scientific document, as it is so subjective. Those who read my contribution in the December issue about the use of 'seems' and 'appears' got a taste of what I mean here. Some feedback from other medical writers was entirely in line with my own ideas, and some of the feedback – often from people with a linguistic background – indicated that there was a clear difference of opinion.

Consider the phrases 'we think that…' and 'we believe that…' in the Discussion section of a scientific paper. Most native English speakers would say that 'think' is too informal here and that in the right context 'believe' would be quite acceptable. But the difference in meaning is difficult to explain, as both words have a range of meanings and they certainly overlap. So why would we prefer 'believe'? I can continue with other synonym pairs: *nearly* and *almost*, *maybe* and *perhaps*, *too* and *also*, *big* and *large*. Is it because we use the first of the pair more in everyday conversation?

What about words that help us with arguments, such as 'therefore', 'thus', and 'hence'? I hear some of you cringe – '*hence*'? This word belongs more and more to the past, but fields that rely wholly on logic (such as mathematics) actively use it and they will probably retain it. Where do you stand on use of the words 'thus' and 'hence'? Are they too stuffy? Perhaps you still use 'thus' but have shifted your way of using it so that it no longer starts a sentence? Or perhaps you *only* use it at the start of a sentence?

Have you thought about when you use 'approximately' and when you use 'about'? Some people would say that 'around' is too informal for scientific writing. Where do you stand on this issue?

We all have our own opinions and biases. It would be difficult to find two individuals working in medical writing who have exactly the same range of preferences and behaviour patterns concerning choice of words. Fortunately there are trends in these preferences, though, and we should perhaps value these trends more than we do. They are all that we have. There are no definitive guidelines on scientific tone, and perhaps that is a good thing. Some authors of recent books on writing in biomedical research don't even mention the concept of tone (perhaps because they assume that it is intuitive). They do say, though, that you should use the simplest word that expresses your meaning, which will certainly help eradicate the use of pompous tone, and quite rightly ('showed' rather than 'exhibited', for example). This is often used by insecure newcomers to medical writing, either consciously or subconsciously, for the sake of impressing.

A related issue: apart from choice of words, we must consider choice of phrases. Some books refer to *empty phrases* or even *dead wood*: material that stands in the way of the direct message. Do you like the phrase 'in order to', for example, when you can simply use 'to'? But does this really affect the tone? I am not sure, unless the whole document is dogged by empty, time-wasting phrases such as 'displays the presence of', 'is often subject to', 'in close proximity to', 'it has recently been found that' and so on. In such cases, the reader will quickly develop a negative attitude to the tone of the author(s)!

We must also be prepared to adapt to developments in tone in scientific writing: for example, the extinction of some terms and the ever-increasing use of others (such as 'impact', which I have personally avoided until now because I feel that, whether it is used as a noun or a verb, it always looks like an exaggeration).

If the choice of words and phrases to give appropriate scientific tone is so subjective and perhaps even controversial, isn't this a very serious consideration when trying to publish what might amount to years of scientific work, which has cost many thousands – if not millions – of euros? When so many people entrust us with work which has serious consequences for them and perhaps even for society as a whole, it feels good to have EMWA and *Medical Writing*, a line of communication and bouncing board that actually works.

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Answers to Medical Writing Jumble #8:
GROSS, WOUND, BLOCK, MARKET
'The entomologist spent more time in the library than in field work because he was a BOOKWORM'.