

# Medical Writing

Plain Language and Readability

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Number 1  
March 2015

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## Themes of upcoming issues of *Medical Writing*

June 2015: The theme will be '**Risk Management**'. The issue will include articles on risk management strategies, writing risk management plans, and risk-benefit analysis. *The deadline for feature articles is 3 February 2015.*

September 2015: The theme will be '**The medical writing business**'. The issue will include articles on different kinds of medical writing business models (e.g. freelance, contracting, contract research organisation, and networks), along with issues related to outsourcing and medical writing management. *The deadline for feature articles is 2 May 2015.*

December 2015: The theme will be '**Writing for lay audiences**'. The issue will include articles on writing patient education materials, informed consent forms, writing for special populations, medical journalism, and websites. *The deadline for feature articles is 2 September 2015.*

If you would like to submit an article, have ideas for issue themes or articles, or would like to discuss any other issues, please write to [editor@emwa.org](mailto:editor@emwa.org).

# Plain language and readability

Stephen Gilliver

Co-Editor, *Medical Writing*



*Plain language* is writing in clear, concise language that is easy to read and understand. Whenever I hear the term plain language I am reminded of a lay summary I was once asked to edit. The stream of technical language ('self-source bias', 'effect modifiers', 'peer context',

'latent class growth modeling', 'marginal structural models', 'propensity score matching', 'co-relative control designs', 'GIS analytic techniques') made my head spin. What was the author thinking? Of course, a lay summary not written in plain language is not a lay summary. But why shouldn't plain language also apply to other kinds of medical writing?

As explained by **Alistair Reeves** in this issue of *Medical Writing*, writing in plain language does not come naturally, and it does not mean writing the way we speak or dumbing down what we write. It means using words that you expect your audience to understand and formulating sentences and paragraphs to make your text easy to understand. When writing for our peers, we assume that they know or can understand the technical terms that are a normal part of our lexicon. Even so, we can do them a favour by keeping long sentences and awkward passive constructions to a minimum. And we should never assume that only our fellow professionals will read what we write, or that our readers all have the same first language as we do.

Some medical writers, even experienced ones, argue that certain documents, such as those destined for regulatory agencies, must be written in language that is awkward and excessively technical due to supposed 'rules' or 'standards'. This is a disturbing dogma that has developed – with no rules or guidelines to justify it. Regardless, in some hands, medical English has become understandable only to the writer and a few experts. Imagine that you are forced to read documents written in such language. Why should they not be easy to understand? And if you were a regulator, wouldn't you want to avoid lost time and headaches from having to decipher bad writing?

## Editorial

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As Alistair Reeves also points out in his article, writing in *plain English* can be time consuming but can become automatic with practice. He goes into detail about what plain English means in the context of medical writing and invokes especially George Orwell's six rules for clear writing as they apply to medical writing, adding five useful rules of his own.

The failure of professionals to write in a way that ordinary people can understand led to the emergence of campaigning organisations such as Plain English Campaign, which has spent the last 35 years fighting 'gobbledygook, jargon and misleading public information'.<sup>1</sup> It also forced governments to adopt firm measures. In 1999, the UK Lord Chancellor ordered civil courts to replace archaic terms with plain language alternatives.<sup>2</sup> *Plaintiff* was replaced with *claimant* and *interrogatories* with *requests for information*, and we all now have some hope of understanding what's going on. The US Congress went one step further, signing into law the Plain Writing Act of 2010, which requires that all documents issued by federal agencies be in plain language. Writing in this issue of *MEW*, **John Parmer** and **Cynthia Baur** describe steps the US Centers for Disease Control and Prevention (CDC) has taken to comply with both the act and CDC's own plain language agenda.

The above examples are from English-speaking countries, and plain language is often used synonymously with plain English. However, other countries have similar movements. The Institute for Language and Folklore in Sweden campaigns to promote *klarspråk* (plain language) in Swedish companies, organisations, universities, and county authorities.<sup>3</sup> In 2009, the Norwegian government launched its own *klarspråk* project to make documents created for its citizens easier to read.<sup>4</sup>

Plain language is one aspect of *readability* – how easily a text can be read and understood. Readability is a multifaceted concept with visual as well as linguistic aspects. In practice, it is quite hard to define. Algorithms you can use to test the readability of your writing often do little more than judge how long your sentences and words

are and how often you use the passive voice. Their value has been widely questioned.<sup>5</sup>

Such readability tests are among the online plain English resources I review elsewhere in this issue of *MEW*. Reviews of offline resources – three recent books on plain English – fill the pages of the *In the*

*Bookstores* section. One of the books<sup>2</sup> was written by plain language campaigner **Martin Cutts**, who here contributes a feature article on patient information leaflets used in Europe. In it he highlights language and readability problems and offers helpful guidance.

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## Medical Writing – A successful team effort

*Medical Writing* is a collaborative team effort that depends on the voluntary contributions of the editorial board and the feature article contributors. Thanks to this rich collaboration, we are producing a high-quality journal that is well appreciated by our members. As Editor-in-Chief, my goal has been to produce a journal that is accessible and useful to medical writers. Based on comments I have received over the last year, we seem to be accomplishing this goal, although we always seek to improve and provide new and interesting content.

Thanks to suggestions from several non-native English-speaking readers, we have now added a new section entitled ‘Lingua Franca and Beyond’, which appears for the first time in this issue. This section, edited by Maria Koltowska-Haggstrom, will present articles and information for medical writers writing in English as a second language and in languages other than English.

I would also like to take this opportunity to thank several board members who have had to step down for various reasons. They include Gabriele Berghammer, who was Section Editor of ‘Gained in Translation’; Nancy Milligan, who was Section Editor of ‘Journal Watch’; and Shirin Ghodke, who served as Associate Editor. I thank these volunteers for their valuable contributions and for helping me make the transition from the journal’s original incarnation, *The Write Stuff*, to *Medical Writing*.

Phillip Leventhal  
Editor-in Chief

# President's Message

Julia Donnelly

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## Dear medical writers



Welcome to the first issue of medical writing in 2015 on plain language, which means that this message had better be simple and easy to read. I am a huge advocate of plain writing and, as a Publication Manager, spend much of my time

working with writers and authors to help achieve greater simplification and improved readability. Indeed, it is always welcome to receive a journal response stating that the manuscript is 'well-written'. However, writing simply is not as easy as it sounds, and I know that many writers struggle with this concept at the beginning of their careers. What to include and discount is always a dilemma but must reflect the interests and needs of the target audience. In this respect, writing simply should be practiced in whichever type of communication we are developing, from detailed reports to simple e-mails; we are all busy and no-one wants to wade through lines of superfluous text.

Another important role for a Publication Manager is keeping up-to-date with new guidelines, which impact upon the delivery of scientific publications. Recently, I had the honour to discuss the 'Five-step Authorship Framework to Improve Transparency in Disclosing Contributors to Industry-sponsored Clinical Trial' (<http://www.biomedcentral.com/1741-7015/12/197>) with Professor Ana Marušić, lead author of the research. A summary of my discussions are available on our website, but in essence, the researchers believe that current authorship guidelines are often too rigid for complex multi-centre, multi-disciplinary trials. They recommend that the difficult issue of authorship is openly discussed before publication writing begins. However, author contributions are monitored throughout the publication development to make sure that individuals who merit authorship are recognised.

I am also looking forward to working with the Good Publication Practice 3 recommendations. Although it can be difficult to keep abreast of all

the new guidelines and recommendations, they are prepared to help us all deliver high-quality publications to the highest possible standards from a transparency perspective. Don't forget to visit <http://www.equator-network.org/> for all the latest news and guidelines in a single place.

The EMWA Executive Committee has been working hard to forge new collaborations with aligned organisations. You may have seen the online link to GAPP (The Global Alliance of Publication Professionals), which has requested our help in finding articles about publication ethics or unethical practices. Our presence has also been requested at the Second International Congress on Medical Writing in Ajman, UAE and, of course, the Budapest Working Group is an expert collaboration. Such alignments give us the opportunity to broadcast EMWA to wider audiences as well as participate in new initiatives that will affect our future work. We strive to find new member benefits, which taken with our journal, conferences, growing Webinar programme and e-learning opportunities, provide exceptional value for money, within a professional network.

Our conferences in 2015 will take place in Dublin in May and the Hague in November. In the Spring conference, in addition to our full educational programme, we will host our third symposium day with the theme of 'Risk Management and Risk-benefit Evaluation – a 360° Perspective'. Our new EMWA Expert sessions will also be launched. Sitting either side of the symposium day, these have been introduced to give senior delegates an opportunity to learn about new areas and applications, as well as sharing their valuable experiences. I hope that Dublin sees record-breaking attendance and shall look forward to seeing many of you there.

In the meantime, if anyone has any suggestions for new educational or webinar topics or would like to volunteer as a workshop leader, webinar leader, or for any administrative role, please do not hesitate to contact Head Office or a member of the Executive Committee.

Julia Donnelly

# Time to make it shorter: Plain English in our context

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## Abstract

Plain English in medical and scientific writing is not one-size-fits-all, because audiences differ. Advice on writing plain English abounds. In 1946, George Orwell, best known as the author of *1984*, formulated a much quoted, compact set of rules for clear writing. The present article explores the relevance of his rules to medical writing, makes recommendations how to apply them, and adds further rules specific to our field of writing.

**Keywords:** Plain language, Plain English

## What is plain English?

Medical writers should always strive to write plain English, whatever the context. Plain English means that you use words that you expect your audience to understand and that you formulate sentences and paragraphs to make your text easy to understand. It also means that your text should be as concise as possible. Plain English is not a simple lowest-common-denominator language that you use all the time, nor is it all about using monosyllabic words, or writing in a way that can be understood by children.

According to plainlanguage.gov<sup>1</sup>, 'Plain language (also called Plain English) is communication your audience can understand the first time they read or hear it'. In other words, plain language means writing for your audience. Medical writers do not have as many different audiences as they may think. We produce four basic types of text in language terms: texts for regulatory purposes and medical communications texts, and within each of these, texts aimed at professional and lay readers. Scientific publications can be either regarded as medical communications documents or as a separate group, but they are subject to the same principles. Different styles of plain English are required for these groups.

## How to learn to write plain English

Few of us are natural writers, which means that writing plain English is something we have to learn with discipline and application. Moreover, the ability to write plain English has nothing to do with being a native speaker of English. In fact, I think that our non-native-speaking colleagues sometimes often have an easier time writing plain English: most people who use English as a second language are used to strict rules that have to be observed in their first language and are used to applying new rules to simplify their writing. Moreover, they have much less interference from colloquial English than native speakers.

Countless online and paper resources tell you how to write well, and most apply the same principles and have similar recommendations. Nowadays, these resources include manuals and style guides specifically for medical and scientific writing, which differ from other fields of writing and from creative writing in general.

## The history of 'plain language': Leclerc, Orwell, and Cutts

The need for clear written communication in the life sciences is not new: it was expressed by Georges Louis Leclerc, Comte de Buffon, an eminent French biologist, who wrote, in his *Discours sur le Style* in 1753 on admission to the Académie Française, '*Ceux qui écrivent comme ils parlent, quoiqu'ils parlent très bien, écrivent mal*'<sup>2</sup> (Those who write as they speak, even though they may speak well, write badly). In saying this, he was highlighting an important point: speech is different from writing and is often not plain at all. We rarely speak spontaneously using plain language or simple structures, and you cannot go back and edit speech. Thus, using plain English when writing is not achieved by emulating spoken English.

A more recent – and better known – attempt to help authors in writing clear English was George Orwell's six rules for writers, which 'one can rely on when instinct fails', published in 1946<sup>3</sup> (Box 1).

#### Box 1: George Orwell's six rules for writers

1. Never use a metaphor, simile, or other figure of speech which you are used to seeing in print.\*
2. Never use a long word where a short one will do.
3. If it is possible to cut a word out, always cut it out.
4. Never use the passive where you can use the active.
5. Never use a foreign phrase, a scientific word, or a jargon word if you can think of an everyday equivalent.
6. Break any of these rules sooner than say anything outright barbarous.

\* A simile is a figure of speech that directly compares two things using words or verbs of comparison, such as *like*, *as*, *so*, *than*, or verbs, such as *resemble*. A metaphor is a figure of speech that identifies one thing as being the same as a related other entity. A metaphor does not use any words or verbs of comparison.

*The Oxford Guide to Plain English*<sup>4</sup> by Martin Cutts – a superb resource for all writers – reproduces these rules in its introduction and comments: 'You'll find more about most of his [Orwell's] points as you read the book'. To help you write plain English, you could hardly do better than abide by Orwell's rules as far as sensible in the context of medical writing, and read *the Oxford Guide to Plain English* from cover to cover, keeping it by your side as a constant companion. Stephen Gilliver reviews the latest edition of *the Oxford Guide to Plain English* in this edition of *Medical Writing*.

### Applying Orwell's rules

Orwell's rules were not written with registration documentation about drugs and medical devices or medical communications in mind. Nor were they written by a writer who was bound by tight and often unrealistic deadlines, with a boss or client breathing down his neck not understanding why 'it is taking so much time'. Orwell's writing was also principally in the humanities and consisted largely of novels, essays, and journal contributions.

Let's take a look at Orwell's rules and see which can be applied to medical writing.

*Never use a metaphor, simile, or other figure of speech which you are used to seeing in print*

Orwell objected to the use of clichés and expected authors to be inventive and original. If you are involved solely in regulatory writing, however, you don't need to be inventive or original. Even if you tried, it would probably be counterproductive because regulatory texts are not literature. If you work in medical communications, in advertising for example, you can follow Orwell's advice, but keep it simple while being as original and inventive as you can. Dull advertising is dreadful. I used to work for a large German pharmaceutical company who developed an advertising campaign for a treatment for refractory epilepsy. The principal slogan was: *A ray of hope for your therapy-resistant patients*. *A ray of hope?* A cliché, and quite the opposite of attention-grabbing. Simple modification of this to *More than a ray of hope for your therapy-resistant patients* put this slogan into a different league.

*Never use a long word where a short one will do*

This could be adapted to read 'Never use a long word or phrase where a short word will do'. Plain writing means replacing long words and phrases with short ones. This means deleting text and eliminating polysyllabic words. For example, *notwithstanding* can be replaced with *despite*, *contralateral* with *other*, *perform* or *execute* with *do*, *therapeutic armamentarium* with *treatments available*, and *upon-with on* – I have yet to find an instance in our field of writing where *upon* is better than *on*. This is also the case for the incorrect use of polysyllabic words, such as *symptomatology* (symptoms), *localisation* (site), *methodology* (methods), and *represents* (is). Using simpler words and phrases is rewarding for the reader and for you because it makes your writing easier to read. I could have said *render* instead of *make* in the last sentence, but *render* has two syllables, so why use it?

Replacing wordy phrases with single words is another way of simplifying and writing in plain English. Eliminating wordy phrases not only reduces the word count, but also simplifies sentence structure and places less stress on the reader.

Why not make the following replacements?

- Outside the normal range → abnormal
- Period of time → period
- In a regular fashion → regularly
- In consideration/view of the fact that → because
- Is indicative of → shows
- Were found to be → were

- To come to an agreement → agree
- Except in a small number of cases/in all but a few cases → almost always
- Is in need of → needs

*If it is possible to cut a word out, always cut it out*

This is my favourite of Orwell's rules. This includes deleting superfluous qualifiers, such as removing *advance* from *advance planning*, *absolutely* from *absolutely essential* or *investigative* from *investigative research*. It also includes deletion of entire phrases, such as *in conclusion/summary it can be said that*, the perennial *randomised clinical trials are required to confirm our results*, and *in order* followed by an infinitive, which can always be deleted.

Unfortunately, many terms with superfluous qualifiers have become fixed phrases, where the original single word has been devalued so much that many people feel that the superfluous qualifier is indispensable, such as *completely* resolved, *time* schedule, predict *in advance*, and even the syllable *pre* in *predefined*, *preprogrammed* and *preplanned*. Do your best to eliminate superfluous modifiers; it is not, however, worth fighting with an author who prefers to see *link* qualified by *together*, even though it is not needed.

### A word on rules 2 and 3

These rules are not natural and *take time to learn*. And learning them doesn't happen overnight – it is gradual. You have to work on texts for years before most of what these rules decree becomes instinctive as you write.

Blaise Pascal is well known for saying '*Je n'ai fait celle-ci (a letter) plus longue que parce que je n'ai pas eu le loisir de la faire plus courte*',<sup>5</sup> which in essence means 'I would have written a shorter letter, but I did not have the time'. And this is the difference between Orwell's writing and ours. He had leisure and we rarely do. A first draft, even when written by an experienced writer, rarely fulfils Orwell's rules and is rarely in the plain English advocated by Martin Cutts in *the Oxford Guide to Plain English*. Even a second draft will not follow all the rules. Refining a text is laborious and time consuming. You must ensure you have this time when preparing a manuscript for publication, a patient information sheet, or a website, but you rarely have this luxury when writing a clinical study protocol or report, or a response to a request from the authorities. If you consistently train yourself, little by little, to observe these rules, however, they will become automatic. Realising that you are doing this spontaneously is satisfying because you know you are saving time and writing better at the same time.

*Never use the passive where you can use the active*

The passive voice is much maligned in style guides – but not in *the Oxford Guide to Plain English*. Most style guides have not, however, been written specifically for scientific texts. Many writers say they 'have been told' to make more use of the active voice when writing, as it is more direct and immediate. The source of this advice is often unclear and also often turns out to be that elusive 'native speaker' vaguely recalling a 'rule'. This may well be sound advice for a novel or a piece of scientific writing intended to have popular appeal. But in an objective piece of scientific and medical writing, the passive definitely has its place – and an important place too. For our context, therefore, I am not able to support Orwell's rule. Instead, a reasonable mix of active and passive voices is the best.

This is illustrated in Table 1, which gives the same text in all passive voice, all active voice, and a mixture of the two. The text is a typical Material and Methods section of an abstract. I have chosen this section because it is here and in the Results section that the passive voice is most appropriate.

The problem with the active voice is that you always need a subject, and in the context of medical writing this is often a person. The result is that the classic subject-active verb-object sentence

Table 1: Material and Methods text in the passive voice, active voice, and mixture of passive and active voices

*All passive*

Informed consent was obtained from each patient to analyse their findings. The French version of the Ureteral Stent Symptom Questionnaire (USSQ) was completed by 474 patients with unilateral inserted indwelling stents on the day of stent removal. Ten self-developed questions (SDQ) regarding type and quality of patient education on pain and urinary symptom were also answered. The questionnaires were applied after recovery from the procedure. Correlations between the influence on economic aspects and total scores, sub-scores, and single item scores were analysed.

*All active*

We obtained informed consent from each patient to analyse their findings. Four hundred and seventy-four patients with unilateral inserted indwelling stents completed the French version of the Ureteral Stent Symptom Questionnaire (USSQ) on the day of stent removal. They also answered 10 self-developed questions (SDQ) regarding type and quality of patient education on pain and urinary symptoms. A clinical research assistant applied the questionnaires after the patient had recovered from the procedure. The team statistician analysed the data for correlations between the influence on economic aspects and total scores, sub-scores, and single item scores.

*Mixed active and passive*

We obtained informed consent from each patient to analyse their findings. The French version of the Ureteral Stent Symptom Questionnaire (USSQ) was completed by 474 patients with unilateral inserted indwelling stents on the day of stent removal. They also answered 10 self-developed questions (SDQ) regarding type and quality of patient education on pain and urinary symptoms. The questionnaires were applied after recovery from the procedure. Correlations between the influence on economic aspects and total scores, sub-scores, and single item scores were analysed.



structure is used in too many successive sentences, leading to a wooden and sometimes rather staccato text that is not comfortable to read. Is it really important in the ‘all active’ text in Table 1 whether the clinical research assistant applied the questionnaires or that the team statistician did the analysis? Why not remove this unnecessary information and opt for the passive in both sentences, which automatically results in using the questionnaires and the correlations as the much more important grammatical subjects of the sentences. If the person who did something is important, and this is usually the exception, you can use the active voice or add ‘by ...’ as the agent in a passive sentence.

You can also introduce desired emphasis by your choice of the active or passive voice. What you mention first in a sentence is usually – or should be – the most important piece of information. Thus, in the second sentence, if you want to stress that you had 474 patients, you would use the active formulation; and if you want to stress that you used the French version of the questionnaire, you use the passive formulation.

*Never use a foreign phrase, a scientific word, or a jargon word if you can think of an everyday equivalent*  
Disregard the reference to scientific words in this rule. We obviously have to use them when writing for an audience who can understand them, but they should be avoided when writing for patients.

Avoiding the use of foreign phrases also does not concern us, as I think Orwell was referring to the affected use of foreign phrases like *de trop*, *deplacé*, and *aficionado* where they are not needed, and not to foreign language terms in widespread use in medical English, such as *in vitro*, *de novo*, and *ex vivo*. These are now so firmly embedded in medical English, like *a la carte* and *resume* (US English for CV, no accent when written but when spoken) in everyday English that they can be regarded as English and do not need to be italicised. Other examples are *fiasco*, *angst*, and *grand mal*; and there are many more. The safest way to determine whether foreign terms are acceptable is to refer to the literature in your specialist area, but don’t be afraid to substitute a plain English term, especially for a fancy plural. For example, don’t let anyone tell you that addendums, forums, focuses, memorandums, or stomas are wrong and that *addenda*, *fora*, *foci*, *memoranda*, and *stomata* are correct.

So we are left with jargon, which includes many abbreviations, and must be avoided in regulatory and medical communication texts. Before the days of the Internet, I remember hunting around for

hours to see what had actually happened when, in a subject narrative, I read that a patient *coded*, and I finally had to ring a colleague in the USA to find out. Only the enlightened know that this means that the patient *went into asystole* or *suffered cardiac arrest*. The British love to talk about *bd dosage* and the Americans about *q12 h regimens*, both of which mean b.i.d. (*bis in die*). The careful writer, however, spurns such jargony abbreviations and writes what is clearly understandable, in this case *twice daily*. This also follows Orwell’s advice not to use a foreign phrase if an everyday equivalent will do. The dividing line between jargon and acceptable terminology is blurred, however, and some jargon eventually enters the realm of normal language: how many of us still insist on writing out *laboratory* because some unsuspecting reader may not understand *lab*? At some point, too, you will start to write *the patient failed therapy with [chemotherapeutic drug]* in an oncology report, because it starts to sound silly insisting on *the patient failed to respond to therapy with ...*

*Break any of these rules sooner than say anything outright barbarous*

There are no laws in language. There will always be cases where you have to deviate from a rule or give in after resisting change. This is because formulations that were previously regarded as incorrect eventually become acceptable because of abuse of spoken and written language. This will also partly be because you simply do not have time to refine your text until it is as simple as possible, and sometimes because it is just not worth it.

*Five rules to add to Orwell’s to contribute to plain English*

- *Don’t oversimplify to the point of condescension:* When preparing texts for patients, it is easy to slip into what is almost baby talk, such as using *tummy* instead of *stomach* or *abdomen*. This is something you must look out for and avoid.
- *Check your texts for overuse of punctuation, especially items that can irritate the reader, such as too many brackets or commas:* I often find I have overused round brackets when I don’t want to deemphasise information, as in ‘just give (an) example(s)’. In this case, remove the annoying brackets and write *such as*.
- *Ensure consistency of terminology in regulatory texts and journal articles:* Don’t confuse the reader by varying terminology to make a text ‘more interesting’.
- *Avoid making the reader backtrack:* Short sentences, careful use of *it* as a pronoun (is it

clear what 'it' refers back to?), avoid use of *respectively*, *former/latter*, and try not to have more than half a line between the subject of your sentence and the verb.

- *Avoid dummy subjects (there and it)*: Starting with dummy subjects always leads to a longer and more complex sentence. Don't say: *there was an improvement in the patient's condition*; instead: *the patient's condition improved*. But, as I said above, language knows no laws, and sometimes the best solution is to introduce the main idea in your sentence with a dummy subject.

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# How CDC is promoting a clear communication culture

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## Abstract

Both the federal Plain Writing Act and the mission of the US Centers for Disease Control and Prevention (CDC) to protect and promote people's health require CDC to communicate clearly so that people can understand and act on the important health information it provides. Decades of research shows that health information and services are often unfamiliar, complicated, and technical, even for people with many years of formal education. Although individual skills are important, the actions of health professionals in communicating health information are influential as well. In response to both the challenges faced by those who need health information and the opportunities for improvement among those who provide health information, CDC is taking steps to promote a clear communication culture to make its health information and services accessible and understandable by the different audiences it serves.

**Keywords:** Plain language, Plain Writing Act, Clear communication, Health literacy

## Introduction

The US Centers for Disease Control and Prevention (CDC) is responsible for communicating vital, scientifically sound health and safety information to millions of people every day. This information is often unfamiliar, complex, technical, and dependent on quantitative risk calculations that reflect population, not individual, level estimates. Despite these challenges, both CDC's mission to protect and promote people's health and the 2010 federal Plain Writing Act in the USA require CDC (and all US federal agencies) to write clearly so that people can understand and act on this information.<sup>1</sup> However, writing is only one way in which CDC communicates with the public. CDC staff also present information in community meetings, interview people exposed to infectious diseases or

harmful substances, and produce radio interviews, podcasts, and videos so that information is available to as many people as possible. CDC has committed to use plain language in all its communication formats, not just writing.

Plain language is one of several techniques CDC uses to make its information clear to different audiences. In addition to language and document organisation, a broad set of factors affect the clarity of CDC's health information. These include the types of actions and recommended health behaviours involved; the novelty and technical complexity of the information; the amount of information being presented; the status of scientific knowledge about the topic of interest; how numbers are used; and the ways statements of risk are included and explained. CDC applies insights from the fields of health literacy, health communication, numeracy, science literacy, risk communication, visual communication, and design to address these elements of clarity.

Health literacy is 'the degree to which individuals have the capacity to obtain, process, and understand the basic health information and services they need to make appropriate health decisions' (see the Patient Protection Affordable Care Act of 2010, Title V).<sup>2</sup> Limited health literacy is a national public health issue that affects almost 9 of 10 US adults.<sup>3</sup> Health literacy depends on people's skills as well as the cognitive and communication challenges created by organisations that produce information for different audiences. Taken together, the Plain Writing Act, the public's limited health literacy skills, and the increasing recognition of organisations' responsibility in responding to the health literacy needs of its audiences have prompted the CDC Office of the Associate Director for Communication to promote an organisational culture that values clear communication as a matter of routine practice. We describe here six steps CDC is taking to promote a clear communication culture to make its health information and

services accessible and understandable by the different audiences it serves.

### *Step 1: Plan*

The significance of clear communication in the achievement of US national health goals is visible in major health policy activities and federal legislation. The activities include the Healthy People 2020 Health Communication and Health Information Technology Objectives,<sup>4</sup> the National Prevention Strategy,<sup>5</sup> the National Stakeholder Strategy for Achieving Health Equity,<sup>6</sup> and the Institute of Medicine's (IOM's) Roundtable on Health Literacy.<sup>7</sup> The Patient Protection and Affordable Care Act includes some health literacy requirements, and writing government documents in plain language – one aspect of health literacy – is now federal law under the Plain Writing Act.

In congruence with these policies and strategies, the US Department of Health and Human Services (HHS), of which CDC is a part, published the National Action Plan to Improve Health Literacy in 2010, calling on health organisations to respond with their own strategic plans.<sup>8</sup> The plan's first and second goals include strategies on plain language. CDC responded by creating its own health literacy action plan that cascades from the national plan.<sup>9</sup> The CDC Health Literacy Council (Council) has representatives from across the agency's organisational units of Centers, Institute, and Offices (CIOs). Using agency-wide staff input, the Council drafted a high-level strategic action plan in November 2011 that guides the agency's approach to use clear communication and health literacy methods. The CDC action plan is organised around three health literacy goals and 18 supporting strategies. The three goals are:

1. To develop and disseminate health and safety information that is accurate, accessible, and actionable.
2. To integrate clear communication and health literacy in public health planning, funding, policy development, research, and evaluation.
3. To incorporate accurate, standards-based, and developmentally appropriate health and science information and curricula in educational settings from childcare through university levels.

Goals one and two include using clear communication for CDC materials and encouraging organisations that CDC interacts with to use clear communication. CDC's health literacy action plan also aligns with the HHS Plain Writing Act

implementation plan.<sup>10</sup> For more information about CDC's health literacy goals, visit <http://www.cdc.gov/healthliteracy/planact/cdcplan.html>.

### *Step 2: Connect*

The success of any plan to create and sustain a new organisational culture requires opinion leaders and gatekeepers to implement a strategic plan and persevere through the process. The Council is the primary connection between the agency's high-level action plan and the on-the-ground implementation. Council members work with their CIOs to:

- Apply the action plan's goals to their missions and audience.
- Provide technical assistance so that CIOs can tailor operational plans to align with the action plan.
- Assist the CIOs by developing guidance; proposing procedures, standards, and measures; and coordinating the planning and reporting processes.
- Provide CIOs with a list of resources to help them develop and implement their operational plans.

CDC's health literacy website (<http://www.cdc.gov/healthliteracy/>) is a major channel for connecting CDC staff, grantees, contractors, partner organisations, and other stakeholders with health literacy information and resources. In September 2014, CDC refreshed and expanded the website to include new online training courses, information on culture and health literacy, and more resources to develop materials.

Senior agency officials also reinforce plain writing by sponsoring and releasing staff for training, requesting briefings, and inviting presentations at staff meetings. For example, CDC's basic plain language training slides quote the CDC Director emphasising the importance of clear communication. CDC leadership continually reinforces the importance of complying with the Plain Writing Act through CDC's intranet, newsletters, and agency-wide announcements.

Another important connection for creating and sustaining a new organisational culture is that of an organisational champion to inspire, coordinate, and provide vision for the agency. The CDC Office of the Associate Director for Communication strives to maintain the agency's momentum by leading clear communication activities throughout the year. For example, in 2013, the Office of the Associate Director for Communication coordinated an agency-wide clear communication challenge to incentivise

the use of plain writing and clear communication. CIO activities included training staff in plain language, developing a clear writing checklist and guidance material, creating a clear writing thesaurus widget, and requesting that reviewers consistently require plain language in the materials they review.

**Step 3: Train**

The first goal of both the HHS Plain Writing Act implementation plan and the CDC health literacy action plan focuses on strategies for training staff in clear communication. These plans recognise that clear communication benefits everyone, and to be most efficient, staff should use clear communication methods at the beginning of the document or message development process. Some audiences, such as scientists and researchers, will benefit from more general use of clear communication methods, such as plain language. For a lay audience, staff may need to pay close attention to health literacy issues and must address conceptual and cultural differences, clearly explain scientific processes, and carefully express numbers and statements about threats or harm. CDC offers a range of training options to staff so that they can meet the communication needs of these different audiences.

To comply with the Plain Writing Act, CDC continues to train its existing workforce and introduce new employees to basic plain language techniques.

CDC’s Council members identify staff with regular duties in writing, editing, designing, and clearing documents for the public, as well as web developers, and train them in plain language.

Staff training options include in-person small group classes, on-demand online training from CDC and the US National Institutes of Health, and self-study with the plain language training slides and the Federal Plain Language Guidelines available from <http://www.plainlanguage.gov>.

CDC University, the in-house training unit, offers health literacy, clear communication, plain language, and web development courses to staff on a periodic basis and consults with individual organisational units to schedule training based on need. Council members identify and contact new employees to find out whether they will write, edit, design, review, or approve materials for the public. If so, the Council member refers the new employee to the training options. Figure 1 shows a checklist CDC uses to promote staff use of plain language. Course instructors encourage staff to post this checklist at their workstation and use it as a convenient reference to the Federal Plain Language Guidelines.

CDC also trains staff to recognise and address health literacy issues for different audiences. In 2014, CDC released four intermediate-level, online health literacy courses. The courses apply health literacy research insights to writing; using numbers and expressing risk information; creating easier to understand lists, charts, and graphs; and speaking with the public. Learners can take these online courses when it’s convenient and print a certificate of completion. The new offerings supplement an introductory course, Health Literacy for Public Health Professionals, and are located in the Find Training section of <http://www.cdc.gov/healthliteracy>.

In 2013, CDC implemented a new research-based tool called the Clear Communication Index (the Index) (<http://www.cdc.gov/ccindex/>), which helps staff to develop and assess the wide range of messages and materials CDC produces for its audiences. The Index references the Federal Plain Language Guidelines and expands the items considered for clear communication to include those related to behaviour recommendations, the use of numbers, and explanations of risk. It contains 20 items, each with a numerical score of 0 or 1. The individual scores are converted to an overall score of 0–100, with a higher score indicating more clarity. CDC has trained over 1000 CDC staff as well as staff at other public and private sector organisations to use this tool to create easy-to-understand materials for the lay public, health departments and

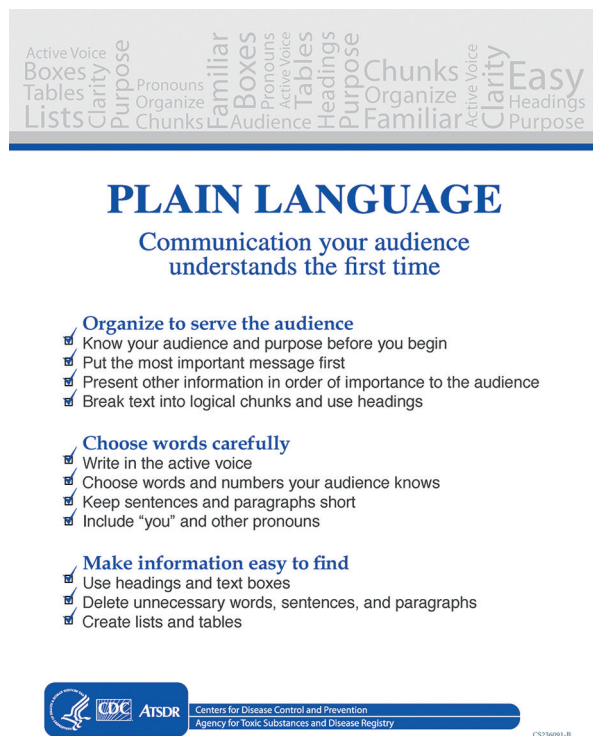


Figure 1: Plain language checklist for convenient CDC staff reference.

other partner organisations, and health care professionals.

#### *Step 4: Produce*

CDC produces many types of documents across a broad range of public health topics. The federal Plain Writing Act requires plain writing when these documents are for the public. The Council has identified categories of documents intended for public audiences. These include brochures, campaign messages, fact sheets, federal register notices, funding opportunity announcements (public announcements of opportunities to apply for federal government funding), infographics, media advisories, mobile apps, press releases, social media messages, webpages, and more.

The agency employs several strategies to ensure public documents follow plain language guidelines and use clear communication techniques. First, CDC includes clear communication review, including plain language principles, in the clearance process before documents are publicly released. Several CIOs use electronic systems to track and monitor documents as they move through the agency clearance process and incorporate plain language requirements in these systems. Second, staff apply the Index to the development of new materials and some CIOs require minimum Index scores before documents are released. Third, some staff use software to analyse documents for plain language elements like sentence length, passive voice, and jargon so that staff can revise them in accordance with the Federal Plain Language Guidelines. Finally, some communication offices test their materials with the intended audiences and ask for feedback on the language, organisation, and amount of information provided.

#### *Step 5: Measure*

CDC's success in creating a culture of clear communication depends on identifying where positive changes happen, creating feedback loops so that people perceive cultural shifts, and correcting the course towards desired goals when necessary. Measuring and tracking progress are critical components of initiating, improving, and sustaining the agency's efforts. CDC uses several mechanisms to track and measure progress in implementing the CDC health literacy action plan, which includes the plain language requirements of the law.

Once a quarter, Council members report relevant activities via an electronic fillable data form. Items on the data form directly align with the Plain Writing Act requirements and the goals and strategies outlined in the CDC health literacy action

plan. To track and measure staff training, the Council makes a considerable effort to enter all training offerings into an electronic learning management system that allows training participants to be confirmed and assigned credit. This learning management system then allows individual organisational units within the agency to run reports so that they can see their specific staff training data. Council members report the number of documents produced and cleared in plain language across more than 30 communication product categories, such as fact sheets, web pages, and reports. They also report audience testing methods, efforts to meet the information needs of people whose native language is not English, sharing of clear communication guidance and tools with funded partners and grantees, and other strategies from the CDC action plan.

#### *Step 6: Report*

An annual report card summarises the quarterly data collected and reported by the Council. This report summarises for CDC staff what the agency is doing to improve how it creates and shares health information with different audiences. Progress is reported on the 18 action plan strategies on a four-point scale: no, little, some, and substantial progress. In addition, CDC submits these data annually to the HHS for its annual Plain Writing Act report. The most recent reports are located on the HHS plain writing and clear communications webpage (<http://www.hhs.gov/open/recordsandreports/plainwritingact/>).

## **Conclusion**

Training thousands of staff, creating and revising materials to meet clear communication criteria, and tracking health literacy-related activities is a large investment of agency resources. These activities require staff commitment at all levels, as well as an organisational champion to inspire, coordinate, and persevere through challenges. However, the impact of this investment is greater accessibility of the important health information CDC provides to the audiences it serves. The US National Action Plan to Improve Health Literacy observes that it will take everyone working together in a linked and coordinated manner to improve access to accurate and actionable health information and usable health services. By focusing on a broad set of health literacy issues that include the need for plain language and organisational change strategies, we are working to make CDC's information accessible, understandable, and useable by all the audiences that we serve.

## Declaration

The findings and conclusions in this paper are those of the author(s) and do not necessarily represent the views of the Centers for Disease Control and Prevention, or the US Department of Health and Human Services.

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# Making leaflets clearer for patients

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## Abstract

This article examines the clarity of several health information leaflets issued to the public in Europe. It finds that some of the language is quirky, ambiguous, and confusing. In one leaflet, the size of type is too small for easy reading, even by people with good eyesight. The article briefly discusses euphemism in health information. It also offers some principles for plain-language writing and sources of further guidance.

**Keywords:** Patient information, Communication, Plain language, PPIs, Readability, Euphemism

According to the Old Testament, God smote the Philistines of Ashdod – who had made the serious tactical error of stealing his Ark – with ‘emerods in their secret parts’. The Good Book is silent, though, about what ointment the victims applied to their bleeding behinds, or whether it came with the kind of leaflet that (in the 1980s) accompanied tubes of Nupercaine and described that popular emerod/haemorrhoid treatment like this:

*A non-greasy, water-miscible cream with a marked anti-pruritic and analgesic action. The special base achieves intimate contact with moist surfaces, has a drying effect on exudative skin conditions and is particularly suitable for application to exposed surfaces.*<sup>1</sup>

For me, this is pitched at too high a level for a mass audience. As a rough and unscientific guide, the website Readability-Score.com gives it a required UK reading age of about 19 years. The (UK) National Literacy Trust’s website implies that the average adult has a reading age of about 13 years (I simplify a little).<sup>2</sup> So there is a wide gap here, with words like *miscible*, *pruritic*, *analgesic*, and *exudative* being unknown to most. This evidences the difficulty familiar to authors trying to communicate technical matters to a lay audience – how do they

write clear, interesting, defensible, concise, and accurate material without losing vital details or writing in a nursery-book tone?

## Some leaflets assessed

Regulatory pressure and calls for plain language have led many companies to clarify their patient information in the years since the Nupercaine leaflet came out. Having not seen a really bad example for some time, I did a little digging among packets of pills and potions lurking in my relatives’ bathroom cabinets. After all, what else are family visits for?

Any optimism I may have felt about the plain-language movement’s success was lessened by a 2013 leaflet from Mölnlycke Health Care AB of Sweden for Mepilex Lite, an absorbent silicone dressing. The leaflet uses many unusual terms such as *minimizing maceration*, *peel forces*, *moist wound environment*, *compromised skin*, *exudate*, *skin stripping*, *adherent side*, *excoriation*, *fixate Mepilex with a bandage or other fixation*, and *dressing regimen*. ‘Peel forces’ is an interesting example of compression as it means, I guess, the forces applied when the dressing is peeled off.

A devil’s advocate may plead that context often helps explain unusual vocabulary for proficient readers. Which may be true, but weaker readers tend to have poor guessing skills. How much would the context for two of the most difficult words, italicised here, help?:

- ‘Mepilex Lite is thin and highly *conformable*, making it easy to keep the dressing in contact with the wound surface...’.
- ‘As Mepilex Lite maintains a moist wound environment, supporting *debridement*, there might be an initial increase in the wound size’.

Too little, I fear. Readers may consult a dictionary, but I think they’re more likely to skip what they don’t understand or just cast the leaflet aside. ‘The



Living Word Vocabulary’,<sup>3</sup> which lists what words will be understood by people with particular US-grade-level attainment, includes neither word, so they are probably rarities. Among readers without a medical background, perhaps only one reader in 500 will understand them. *The New Oxford Dictionary of English*<sup>4</sup> says conformable means similar in form or nature; and debridement does not mean, as you may think, the ejection of a bride from her wedding ceremony, but the removal of damaged tissue or foreign objects from a wound.

Manufacturers must provide the information needed to use dressings and other devices safely and properly, taking into account the knowledge of potential users, according to Medical Devices Directive 93/42/EC<sup>5</sup> issued by the European Commission (EC). The UK Medicines and Healthcare Products Regulatory Agency (MHRA) told me: ‘[...] where the device is intended for a professional user it would be acceptable to use technical terms and where it is used by patients themselves we would expect the language to be simpler for general understanding’.<sup>6</sup>

So if the wording is unclear for its main audience, how legible is it? The text type is tiny, about 5.5 pt – only just big enough for people with good eyesight to read. It’s well below the size stated in EC guidance on the legibility of patient information leaflets (also known as patient package inserts or PPIs), which says: ‘[...] a type size of 8 points, as measured in font ‘Times New Roman’, not narrowed [...] should be acceptable as absolute minimum’.<sup>7</sup> This leaflet is not a PPI, because Mepilex Lite is classed as a device not a medicine, but why does the type have to be so small? After all, the 64-page multilingual booklet has 24 blank pages, so space is available. The MHRA said: ‘The size the information is presented in is not specified in the Directive but is nonetheless relevant in that it cannot be said to enable the device to be used safely if it is too small to be read and understood’.<sup>6</sup> Mölnlycke did not respond to my requests for a comment.

PPIs to be issued to European users of medicines must pass a face-to-face clarity test with real people. This is more rigorous than a mere desk-based check using readability formulas of the kind shown at Readability-Score.com, useful though these can sometimes be as a rough yardstick.<sup>2</sup> Official guidance on the EC test says: ‘A satisfactory test outcome [...] is when the information requested within the package leaflet can be found by 90% of test participants, of whom 90% can show they understand it. That means to have 16 out of 20 participants able to find the information and answer

each question correctly and act appropriately’.<sup>7</sup> It goes on: ‘In approving package leaflets the competent authorities will look for evidence that people who are likely to rely on the package leaflet can understand it and act appropriately’.

The PPI for Bendroflumethiazide from Bristol Laboratories Ltd, a UK company, is full of technical terms but these are generally well explained, e.g. ‘dispyramide (used to control an irregular heart-beat)’ and ‘gout (high levels of uric acid in the blood), causing crystals to deposit in [the] joints of hands or feet causing pain (hyperuricaemia)’. The leaflet helpfully uses bold type to emphasise important points. There are some oddities, though. Symptoms of an overdose are said to include ‘decreased volume within blood vessels’ (how would a lay person know?), while you are supposed to tell your doctor if you notice you have ‘low blood magnesium and sodium levels’ (again, how would you know?). Better is the fact that the leaflet is willing to equip highly literate people with unusual terms they may wish to know, e.g. ‘dizziness on standing due to low blood pressure (postural hypotension)’ and ‘skin that is red, flaky and peeling (exfoliative dermatitis)’. Writing extra-clearly for people who can’t read very well need not mean disadvantaging those who can.

There are several verbose and clunky sentences. For example, concerning a visit to the doctor, the leaflet says, ‘Take your medicine in its original packaging with you in order to enable the doctor to identify your medication easily’. This could be more crisply put as ‘Carry your medicine with you in its original packaging so the doctor knows exactly what it is’.

The explanations sometimes seem vague, for example, ‘It is recommended not to take alcohol with Bendroflumethiazide tablets as it may aggravate dizziness on standing due to low blood pressure’. This seems a strange word order and is unclear, having at least three possible meanings:

1. I will always get dizzy on standing if I have low blood pressure, and if I take the tablets and alcohol at or near the same time this may make the dizziness worse.
2. My blood pressure will be lower because I am on these tablets. This may make me feel a bit dizzy when I stand up. So I should not drink any alcohol within X hours of taking the tablets.
3. I should not drink any alcohol during the whole time I am on these tablets because it could worsen any dizziness I feel when I stand up.

Similarly, I am puzzled by: ‘Bendroflumethiazide tablets can cause dizziness, make sure you are not affected before driving or operating machinery’. Even ignoring the horrible comma (should be a stop), is this the best expression? Perhaps it could say: ‘Bendroflumethiazide can cause dizziness. If you feel dizzy, do not drive or operate machinery’.

The leaflet for Betahistine dihydrochloride from Accord Healthcare Ltd (UK) seems generally clear, with a decent layout and a heading system that follows the standard (and good) pattern, namely: What the medicine is and what it is used for; What you need to know before you take it; How to take it; Possible side-effects; How to store it; and Contents of the pack. Regrettably there is a proof-reading howler early in the text: ‘If any of the side-effects, talk to your doctor’. The word ‘efficacy’, which in a long and varied reading life from Thomas the Tank Engine to Turgenev I have never before encountered, is not explained. And ‘exacerbated’ is unusual, too. The ‘Living Word Vocabulary’<sup>3</sup> rates it as a US grade 13 word (British reading age 18 years). Perhaps we could use ‘worsened’ or ‘made worse’. A handy source on how to decide which words are easy to understand, based on the ‘Living Word Vocabulary’, is the ‘Plain English Lexicon’.<sup>8</sup>

The leaflet about paracetamol from Bristol Laboratories Ltd has many good explanations, e.g. ‘Paracetamol is an analgesic and an antipyretic which means it relieves pain and reduce[s] high temperature and fever’. But it tells readers to inform their doctor if they notice ‘a severe reduction in the number of white blood cells’. Time to get out the home testing kit again! One of the most important sentences is, oddly, written in the impersonal passive: ‘Immediate medical advice should be sought in the event of an overdose’. (Prefer: ‘Get immediate medical advice if...’.) And it ends by dropping a dreadful (but thankfully non-clinical) clanger when it says: ‘Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These medicines will help to protect the environment’. (For ‘These medicines’, read ‘This’).

Occasionally, the PPIs I examined lapsed into a mixture of business and marketing speak, like the first few sentences of the leaflet for Gengigel HMW Hyaluranon, a gel for treating gingivitis (Ricerfarma SRL, Italy):

*What is Hyaluranon? Gengigel products contain naturally-derived high quality, high molecular weight (HMW) Hyaluranon, a substance found*

*naturally in your soft tissues but in especially high concentrations in your gums (gingivae). It is an important component having both a structural and regulatory role.*

Users may wonder what ‘naturally-derived’ and ‘high molecular weight’ mean and why these terms might be relevant to them – the all-important ‘So what?’ question. Some will not understand ‘high concentrations’ or, indeed, ‘soft tissues’ outside the box-of-Kleenex context – an explanation of ‘soft tissues’ arrives about 90 words later. The final sentence above, about Hyaluranon’s ‘structural and regulatory role’, requires high-level literacy and abstract-thinking skills because even if readers know the words ‘structural’ and ‘regulatory’, they may find them hard to relate to their gums.

This brief snapshot of patient information leaflets suggests that there is a long way to go before they satisfy the description of ‘plain language’ due to be adopted by the Plain Language Association InterNational: ‘A communication is in plain language if its wording, structure, and design are so clear that the intended readers can easily find what they need, understand what they find, and use that information’.<sup>9</sup>

## **Avoiding the dirty habit of euphemism**

On a hospital ward I once heard a nurse asking a newly admitted young woman, ‘Have you opened your bowels today, dear?’, to which she replied apologetically, ‘I’m sorry, nurse, I haven’t brought them with me’.

I’ve never understood why some medics talk to patients about ‘stools’ and ‘back passages’, as if they are in a hardware store. To avoid the confusion that can arise from both taboo and high-register language, I’ve occasionally persuaded health trusts to use words like ‘poo’ and ‘pee’ in their leaflets, and these are becoming more widespread. Of course, there’s a difficult line to tread between being clear and causing offence, but I feel it’s better to err on the side of clarity. These days, ‘What colour is your poo?’ is likely to be well understood by most people without any embarrassment. Few people understand ‘faeces’, and even fewer can pronounce it.

Ridicule was heaped on National Health Service (NHS) Tayside physiotherapists in 2006 for their leaflet ‘Good Defaecation Dynamics’. Yet, for them to explain better bowel habits was both brave and worthwhile – it was just their title that was fabulously absurd. Had they ditched the jargon and

called it ‘How to crap well’, they would doubtless have offended a few precious souls but struck a blow for clear, basic English.

When the Canadian blogger Mark Rabnett had to provide a poo sample, he was nonplussed by the apparently Dracula-themed title of the kit that arrived from Helena Laboratories, Beaumont, Texas, namely ‘ColoScreen: a test for fecal occult blood’. The weird and medicalised 600-word instructions – which included ‘Do not ingest high doses of aspirin’ and ‘Specimen Handling: It is very important that the stool specimen be applied as a very thin smear to the Occult Blood Slides’ – culminated in the instruction ‘Flush tissue with stool’. This remarkable phrase actually meant ‘Flush the used tissue and the rest of your poo down the toilet’.

Rabnett wryly remarks: ‘[This episode] has convinced me that the literate need to learn how to write as badly as the illiterate need to learn how to read’.<sup>10</sup> The UK’s NHS now sends everyone who reaches the age of 60 a birthday present, namely a poo-sample collection kit to test for bowel cancer. My pleasure in the clarity of the instructions – they really were pretty good – greatly exalted this dismal task.

### Some principles on writing plain language for a mass audience

The usual advice on writing clearly for a mass audience will, I’m sure, be familiar to journal readers: keep sentences to 15–20 words on average; use words your parents/grandparents are likely to understand; favour the active voice unless the doer is unknown or obvious or you want to focus on the person or thing being acted upon; personalise your writing with ‘you’ and ‘we’ when that’s suitable; eschew footnotes and acronyms whenever possible; use well-labelled pictures and diagrams; organise the material in a reader-centred and easy-to-use way (what will most people want to know first, second, and third?); and involve typical readers as much as possible in the writing and testing process.<sup>2</sup> It helps a lot if authors use ‘The dog ate the biscuit’ word order and prefer concrete to abstract language. And it does no harm to politely challenge the producers of over-complex writing, whoever they may be. I’m helping someone make a personal injury claim against an optometrist, and the opposing insurer has just hit me with this 75-word sentence:

*We would also mention that cataract surgery is undertaken with local anaesthetic in the vast majority of cases and the very remote possibility*

*that another medical condition would arise, which would be a contra-indication to this and require an operation under general anaesthetic, which in turn would be contra-indicated due to further medical complications, would not have been in contemplation when considering whether or not a cataract operation would have been appropriate six years ago.*

Suspecting an ulterior motive when intelligent people do not explain themselves clearly, I have asked for a restatement in plain English.

Verby not nouny writing is good, too. Consider this example from a UK Department of Health report<sup>11</sup>, which I first saw reproduced verbatim in a health authority’s leaflet for parents – not its original purpose, of course – as if it were the last word on how to feed their under-fives:

*The provision of adequate dietary energy to ensure normal growth and development should be a principal determinant of the diets of children under five years of age.*

This is nouny in a way that only academic style can be, the main nouns being *provision, energy, growth, development, determinant, and diets*. What if we want to get the same ideas across to a mass audience? Terms like ‘principal determinant’ and ‘dietary energy’ will be puzzling. According to the Department of Health, the latter just means ‘calories’, a technical term whose ubiquity will probably make it well understood. The sentence holds an important message for parents of under-fives, namely, ‘Give your children plenty of calories, otherwise they could die of malnutrition’ – which has happened occasionally. A sprinkling of verbs will make it more concrete. For example, we could say:

*To ensure that children under five grow and develop normally, one of the main things they need is calorie-rich food.*

We could then say what else they need, as if we are speaking to a parent face to face:

*While Helen is under five, she needs food that has plenty of calories. This means things like a, b, and c. These foods will help her to grow and develop normally. She also needs some x, y, and z for taste and variety.*

So while the original is good English, it needs rewriting if its purpose and audience change. This

is not dumbing down – a criticism often levelled at those who advocate plain language – but clearing up.

What are regarded as common words may sometimes be misunderstood. A study on the meaning of ‘unconscious’ among 700 people visiting an accident and emergency department with a head injury<sup>12</sup> found that 16% thought they could still talk when unconscious, 16% said they could stand up, and 41% believed their eyes could not remain open after losing consciousness. The study has implications for the design of public health information, including the scripts that emergency services use when responding to phone calls. In a leaflet, the signs of unconsciousness would have to be stated; in a call script, questions designed to test for unconsciousness would have to be included.

At Liverpool’s Alder Hey Children’s Hospital during the 1980s and 1990s, parents signed consent forms saying, ‘I hereby consent to a post mortem examination and to the removal of tissue (other than for the purpose of transplantation) at the time of this examination [...]’. They were unaware that this allowed doctors to harvest and store body parts and whole organ systems. Using similar consents, various hospitals are thought to have stored 150 000 organs. The word ‘tissue’, taken direct from the Human Tissue Act, wasn’t apparently difficult. But its legal meaning differed from its everyday meaning and should have been explained. The grief of those parents whose children’s organs had been stored without their knowledge led to a government inquiry and fierce legal disputes.<sup>2</sup>

We can also break up complex information into lists. A piece of text about antiretroviral therapy explains why osteonecrosis (death of bone tissue) might occur. It uses a complicated sentence where the main verb is long delayed:

*The length of combination antiretroviral therapy, corticosteroid use, alcohol consumption, severe immunosuppression, higher body mass index, among others, may be some of the risk factors for developing this disease.*

As an exercise, researchers rewrote this in a list as:

*‘People may be more likely to get this condition:*

- if they have been taking combination therapy for a long time
- if they are also taking anti-inflammatory medicines called corticosteroids
- if they drink alcohol
- if their immune systems are very weak
- if they are overweight’.

In a small-scale test, most of the 10 respondents had some difficulty in clearly identifying the risk factors for the condition when using the original version. None had any difficulty in using the rewrite and all preferred it.<sup>13</sup> The European Medicines Agency accepted the revised text.

## Some sources of guidance

For guidance on plain language generally, *the Oxford Guide to Plain English*<sup>2</sup> (reviewed on page 36 in this issue of the journal) is a good source – and if it isn’t, I am wholly to blame. You can also subscribe to Plain Language Commission’s free newsletter, Pikestaff, through <http://www.clearest.co.uk>. Sarah Carr, a former NHS manager, has written an excellent book called, self-explanatorily, *Tackling NHS Jargon*.<sup>14</sup> The best source of information on melding the disciplines of writing, design, and testing in things like medical labelling and patient leaflets seems to be the website of the Communications Research Institute of Australia, [communication.org.au/](http://communication.org.au/). The NHS England website gives details of its certification programme for health and social care organisations, the Information Standard, at <http://www.england.nhs.uk/tis>. As a commercial service, Plain Language Commission gives editorial advice and accreditation of individual documents and websites under the Clear English Standard scheme (<http://www.clear-est.co.uk>).

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English' and (with Emma Wagner) 'Clarifying EC Regulations'. The latter is available on free download from <http://www.clearest.co.uk>. Martin lives near Buxton, Derbyshire, England.

## From the land of mixed metaphors

Sometimes you wonder what people are thinking. While researching the epidemiology of dengue virus, a colleague came across this amusing title:

*Lessons raised by the major 2010 dengue epidemics in the French West Indies*<sup>1</sup>

This had us wondering what questions were learned...

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# Online plain English and readability resources

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## Abstract

To encourage individuals and businesses to write in simpler, more readable English, private and government-backed enterprises have created a number of freely available online resources. While most relate to general English use, some are devoted to writing about medical matters. In this summary article, I take a brief look at what is available and how good it is.

**Keywords:** Plain English, Plain language, Online, Medical dictionary, Medical thesaurus, Readability

'Plain Language – It's the Law' proclaims the homepage of the Plain Language Action and Information Network (PLAIN),<sup>1</sup> a group of US federal employees dedicated to promoting plain English in government communication. And it is indeed the law. In 2010, Barack Obama signed an act requiring federal agencies to write in a way that the public understands. Predating the new law, the Federal Plain Language Guidelines<sup>2</sup> are a set of tips from PLAIN on writing clearly, each with illustrative examples. The guidelines cover familiar topics such as using the active voice, avoiding jargon, and writing short sentences, as well as the specifics of writing for the web. They are extensive and excellent, and are supplemented by similarly excellent guidance on writing letters and using headings.

An even heftier resource is the so-called 'Toolkit for Making Written Material Clear and Effective' from CMS.gov (Centers for Medicare and Medicaid Services),<sup>3</sup> available as five ZIP archives with a combined size of some ~50 MB. Guidance on writing is just one of 11 chapters, with others covering topics as disparate as culturally appropriate translation, how to test written material, considerations when writing for older adults, and issues with readability tools (more on which later). A second toolkit, from the Program for Readability In Science and Medicine (PRISM),<sup>4</sup> gives advice on various aspects of readability and explains the principles and importance of plain English.

On this side of the Atlantic, two private plain English organisations – Plain English Campaign and Plain Language Commission – provide a bounty of resources. In addition to a general guide on how to write in plain English, Plain English Campaign<sup>5</sup> offers a generous list of simpler alternatives to what it describes as 'the pompous words and phrases that litter official writing'. It further provides glossaries of financial and legal terms, as well as guides on specific subjects such as how to create clear websites and business emails. Plain Language Commission<sup>6</sup> has a number of complementary resources, including a fascinating 2700-word lexicon that tells you how likely readers are to understand different words you might use and a checklist of 15 tips on writing plain English, my favourite being 'Apply common sense and scepticism to all guidance about writing'.

## Medical resources

There are a number of resources to help us write about medicine in plain English, but how good are they? The Plain Language Thesaurus for Health Communications<sup>7</sup> from the US Centers for Disease Control and Prevention (CDC) contains approximately 1100 entries, but it doesn't seem to have been updated since 2009. Some of its plain English alternatives to medical terms are fine. *Fever* instead of *pyrexia*, for example – perfect. Others are baffling. *Hazard* comes back as *hazard*, *vomit* as *emesis*, and *serology* as 'study of blood strength' (whatever that means). And does *x-ray* really need explaining as 'picture of your bones; picture of your insides'? Thankfully, an insider assures me that a revision is in the pipeline.

Plain English is tied up with health literacy, defined in the 2010 Patient Protection and Affordable Care Act ('Obamacare')<sup>8</sup> as 'the degree to which an individual has the capacity to obtain, communicate, process, and understand health information and services in order to make appropriate

health decisions'. As part of a health literacy awareness project, the University of Michigan Taubman Health Sciences Library came up with the Plain Language Medical Dictionary.<sup>9</sup> It contains fewer entries than the abovementioned thesaurus – and similar flaws. While B cells are helpfully described as '*disease fighting cells; cells that are made inside your bones and help fight disease; white blood cells*', *lymphocytes* are defined as *lymph cells*. What does lymph cells mean to someone who doesn't know what lymphocytes are? Elsewhere, *virus* is defined as *virus* and *temperature* as '*heat, fever*', as if it were some obscure technical term. The Plain Language Medical Dictionary is now available as a free app.<sup>10</sup> The latest version supposedly contains 'updated dictionary content from the latest version of the Plain Language Thesaurus for Health Communications, with more accurate and proper definitions to more terms'. Sounds good until you remember that said thesaurus hasn't been updated or corrected in the last 6 years.

The PLAIN website – which incidentally is pretty hard to navigate – has a page on improving health literacy. It contains links to a number of resources (including the Plain Language Thesaurus). One link led me to a decent list of 'plain language alternatives [...] for medical and other high-level difficult terms'.<sup>11</sup> The list's author, medical editor, and plain English consultant Sharon Nancekivell, writes: 'The list is not yet comprehensive, although I hope it will be some day'. And yet she doesn't seem to have updated it since 2008. Meanwhile, another link – to health literacy resources from the American Medical Association Foundation – is dead. One wonders whether this is symptomatic of a general lack of devotion to the health literacy component of the PLAIN project.

Nancekivell's list is available from [healthcommunications.org](http://healthcommunications.org), which collates a wide range of plain English, readability, and related resources, including a couple of useful, if very similar, plain English checklists. Depressingly, I was only the seventh visitor to the Toolkit (resources) page.<sup>12</sup>

One of the better online resources I found is Plain English Campaign's guide called 'How to write medical information in plain English'.<sup>13</sup> In addition to a modest but handy list of alternatives to medical terms, it provides brief but pertinent advice on a couple of critical topics: writing information to accompany over-the-counter medicines (with genuine examples of impenetrable language from medicine leaflets) and phrasing letters to patients.

Finally, the PRISM toolkit<sup>4</sup> boasts a superior but by no means comprehensive collection of plain English substitutes for scientific and medical

words and a checklist to use when writing information for clinical trial participants. It also includes standard plain English texts that can be used in informed consent forms and instructive examples showing how to improve readability and formatting. PRISM complements the toolkit with a free 1-hour tutorial on improving the readability of consent forms and other participant-targeted information.<sup>14</sup>

## Readability tools

How easy is your writing to read from a stylistic perspective? To help answer this question, there are several online tools for checking the readability of word processed documents.<sup>15-17</sup> ReadabilityFormulas.com<sup>15</sup> calculates scores for seven readability tests simultaneously. When I used it to check the first section of this article, it variously rated it as 'difficult to read', 'hard to read', and at the reading level of 'college students'. Good thing this isn't a children's book I've written. I should point out that all of the readability tests I found base their calculations on word and sentence length. Sophisticated they are not. Interpret their results judiciously (note: you can also check readability in Microsoft Word [Word 2013: File → Options → Proofing → When correcting spelling and grammar in Word → Show readability statistics]. The output includes 'Sentences per Paragraph', 'Words per Sentence', 'Characters per Word', and 'Passive Sentences' [%], as well as the scores for two readability tests).

## Conclusion

While there are some splendid online resources on plain English, those specific to health and medicine are generally flawed and in desperate need of correction and completion. The impression I get from perusing them is that a number of plain English projects have been started with the best of intentions but that the people involved forgot about them, lost interest, or chose to focus on other things. What we urgently need is a concerted effort to create, manage, and publicise usable plain English resources for people who communicate health information to the public. But who should take the lead?

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## Author information

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# Get real: Avoiding corporate gobbledygook

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## Editorial

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One spring morning, I was wandering ‘lonely as a cloud’ with a ‘host of golden daffodils’ before me. Then someone stopped me in my tracks:

*What do you think of the changes in Big Pharma?*

The illusion was shattered. There was an ominous silence. The clouds gathered. With a flash of lightning, the tension was unleashed, and thoughts came flooding in ready to be verbalised but hopefully never completely tamed.

In my opinion, Big Pharma has been through a mind-numbing decade or so of changes in an effort to generate a super-efficient machine. There needed to be some shake-ups because all the best expertise wasn’t in one institution or place. Efficiency is good if it frees up time, but sometimes, even aspirations such as innovation and creativity have been over-processed. Associated with this move towards increasing efficiency has been an increase in corporate gobbledygook (also known as ‘bullshit’ in the US) and competency jargon. Speaking this way seemed to work if you wanted to progress. As writers, we use a range of styles and language. A bit of flowery language and even gobbledygook works well in some communications to create a particular feel or ambience.

I can sense a change for the better. Maybe there is awareness that some efficiency measures have been killing the human spirit and are in danger of creating a culture of human drones.

Phenomenal advances in technology and life science research are a massive stimulus for this change, which is about to revolutionise medicine

and healthcare. After initial excitement some years ago, we reached a point when it seemed to be all theory. There was a lull, a dearth of practical breakthroughs – but research can be like that.

A phase of increased collaboration has taken off with more cross-industry partnerships and collaboration between companies, academia, government, and non-profit organisations. This should work because scientists usually love their work, and some successes are in sight. People want to make this work.

Most people loved their subjects when they embarked on their careers. They genuinely want to be part of the technology and life sciences revolution. Let them tap into these feelings. Beyond their company role, they have different lives and perspectives. Let’s not lose this opportunity to engage people. Keep an eye on the negative forces of ambition and corporate gobbledygook. From time to time ask people what they really think – to be ‘real’ and not to speak in gobbledygook – so that they can flourish and reach their targets. Then they can say, ‘Yes actually I am happy to be part of this’.

Plain language is essential in many circumstances, especially for ensuring that science, instructions, or methodology are understood, although to ensure accuracy of meaning, over-simplification should be avoided. It is so easy to slip from plain language into the gobbledygook mode. In business, when you need to hear the truth from others, beware the pitfalls of encouraging corporate gobbledygook. Why make business decisions in a fog of pretension? Get heartfelt, truthful input.

# Transferring regulation into practice: The challenges of the new layperson summary of clinical trial results

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## Abstract

The new European Clinical Trials Regulation, published on 27 May 2014, requires sponsors to provide summary results of clinical trials in a format that is understandable to laypersons. The lay summary is to be made publicly available in the yet to be finalised EU database. In this article, we review the proposed content of the layperson summary and identify issues related to the writing of such documents.

**Keywords:** EU Clinical Trials Regulation, Disclosure, Transparency, Layperson summary

## Transparency of clinical trial results

The initiatives for greater transparency in clinical research and for public sharing of clinical trial results have been gaining momentum in recent years. In 2008, the updated Declaration of Helsinki included a statement that making study results available to the public was an ethical duty.<sup>1</sup> Starting in 2008, sponsors have been obliged to publish summary results of clinical trials on the US National Institute of Health website ClinicalTrials.gov. The results have to be posted not later than one year after trial completion or 30 days after approval of an investigational product in the US.<sup>2,3</sup> Since July 2014, EMA has required posting of summary results in the EUDRA CT database 12 months (or 6 months for paediatric trials) after study completion.<sup>4,5</sup> In July 2013, member companies of the European Federation of Pharmaceutical Industries and Associations and the Pharmaceutical Research and Manufacturers of America committed to publishing summary results of clinical trials for products approved in the US and the EU or its member states. Meanwhile several pharmaceutical companies have started sharing trial results with trial participants.<sup>6</sup>

The European Clinical Trials Regulation (no. 536/2014) introduced new requirements on data

disclosure for clinical trials with at least one site in an EU member state.<sup>7</sup> Once the regulation is fully implemented (the earliest by 28 May 2016), a lay summary of the trial results needs to be provided within a year of trial completion in the EU. This lay summary will be made publicly available via the EU database (Article 37 [4]) that is however yet to be established. Unfortunately, the guidance provided for the content of the lay summary is limited and consists only of a list of 10 items placed in Annex V of the regulation (see Box 1).

## General concerns

The list in Annex V can hardly be considered a guidance document, since the individual items are stated without any explanatory instructions. Each item needs interpretation and many important aspects of lay summaries are missing. These limitations of the guidance could either be intentional to give sponsors leeway in fulfilling the requirements or could indicate that the thinking on this topic has not yet been finalised.

There are no instructions on the format and the overall length of the lay summary. Sponsors are therefore required to make reasonable assumptions. Given the intention to summarise the trial results for non-specialists, anything beyond two pages seems inappropriate. Importantly, the EU regulation does not specify the target reading level for the lay summary (often expressed by the Flesch Kincaid grade level or readability ease score). This omission requires sponsors to set their own reading level target and depending on this decision, both content and style can vary considerably across companies. Another aspect that is not addressed is the language of the lay summaries. Usually key documents of clinical trials are written in English. Therefore, it seems straightforward to also provide the lay summary in English. However, English is just one of the languages in the EU. While

**Box 1**

The summary of the results of the clinical trial for laypersons shall contain information on the following elements:

1. Clinical trial identification (including title of the trial, protocol number, EU trial number and other identifiers);
2. Name and contact details of the sponsor;
3. General information about the clinical trial (including where and when the trial was conducted, the main objectives of the trial and an explanation of the reasons for conducting it);
4. Population of subjects (including information on the number of subjects included in the trial in the Member State concerned, in the Union and in third countries; age group breakdown and gender breakdown; inclusion and exclusion criteria);
5. Investigational medicinal products used;
6. Description of adverse reactions and their frequency;
7. Overall results of the clinical trial;
8. Comments on the outcome of the clinical trial;
9. Indication if follow-up clinical trials are foreseen;
10. Indication where additional information could be found.

Source: Annex V of the European Clinical Trials Regulation<sup>7</sup>

proficiency in English is high in certain EU countries and in some age or professional groups, many citizens would still be excluded if the documents were provided only in English.

Summaries for a lay audience might increase the accessibility of clinical research data but they also have potential risks. People unfamiliar with clinical research might be in danger of drawing far-reaching but unwarranted conclusions. Each lay summary should therefore be accompanied by a disclaimer to prevent misinterpretation of trial results. It should alert readers that the results of any individual trial do not represent the complete medical knowledge about a substance and that patients should therefore not change their current therapy based on their understanding of the results.

### **Content of lay summaries of clinical trials according to the EU Clinical Trials Regulation**

In the following, we will go through the points provided in Annex V of the EU regulation and indicate where we see potential issues.

*1. Clinical trial identification (including title of the trial, protocol number, EU trial number, and other identifiers).*

*2. Name and contact details of the sponsor.*

Providing the protocol number, the EU trial number, and the name and contact details of the sponsor is easily implemented. However, stating the full clinical trial protocol title is unlikely to be helpful for a lay audience. Protocol titles are designed to reflect the scientific and medical contents of a trial and are intended for a medical audience. Therefore, protocol titles are often long, and rich in technical terms and abbreviations.

Titles typically include dosages (e.g. 100 mg bid, 5 µg/day), study design features (e.g. multiple rising dose, two-way crossover), and descriptions of the patient population (e.g. patients with advanced non-squamous non-small cell lung cancer) that are usually not easily understandable for a layperson. Thus, we propose that a shorter, simplified lay title be provided. The challenge will be to formulate the lay title in such a way that it is succinct without being misleading or inaccurate.

*3. General information about the clinical trial (including where and when the trial was conducted, the main objectives of the trial and an explanation of the reasons for conducting it).*

This requirement seems straightforward as the only difficulty is providing a clear and brief explanation of the trial's rationale. Issues may arise if details of a disease need to be included to make the rationale understandable for laypersons. For instance, the reasons for conducting a trial may involve discussing current treatment options and unmet medical needs for patients with a particular severity of a condition (e.g. stage IV chronic obstructive lung disease). Medical information such as severity gradings is often not useful for laypersons but might nevertheless be needed.

*4. Population of subjects (including information on the number of subjects included in the trial in the Member State concerned, in the Union and in third countries; age group breakdown and gender breakdown; inclusion and exclusion criteria).*

Providing the number of subjects in the member state concerned, the EU, and third countries has not been commonly done in the reporting of clinical trials; however, this requirement can be fulfilled easily. Age group and gender break-down are

self-explanatory and also not a problem. However, the lists of inclusion and exclusion criteria in the trial protocol might be too long for a lay audience and may contain criteria that are relevant only for specialised readers, e.g. the investigators. We therefore suggest limiting the number of inclusion and exclusion criteria to the most important ones; a total of five criteria or less might be desirable. It may be useful to mention those criteria that a layperson can observe by him- or herself or is likely to be familiar with. Some of the technical terms used to define a patient population (e.g. forced vital capacity percent predicted <50%) are not informative for a lay audience and could be omitted.

#### 5. *Investigational medicinal products used.*

Like some other elements in Annex V, this requirement is fulfilled easily. However, studies in early phases of clinical development may only be able to provide the sponsor's internal compound code, which will be completely uninformative. At later stages of drug development, the international non-proprietary name (INN) becomes available and can be used. For reports of studies in the more advanced stages of clinical development, it seems advisable to provide both the sponsor's internal compound code and the INN, as this would allow the reader to link the information to previous studies. The situation may become more complex for studies of marketed products that have several trade names across the EU. Ideally all identifiers, i.e. the sponsor's internal compound code, the INN, and the trade names should be provided. The same information for every comparator product, including placebo, should also be given, as they are considered investigational medicinal products under the regulation (Article 2 [2 (5)]).<sup>7</sup>

#### 6. *Description of adverse reactions and their frequency.*

To comply with this requirement, a number of decisions need to be made. First, we need to clarify the term 'adverse reaction'. The EU regulation defines adverse reactions in accordance with the EU directive 2001/83/EC as 'a response to a medicinal product which is noxious and unintended'.<sup>8</sup> This represents the concept of drug-related adverse events, i.e. those for which a causal relationship between the event and the medicinal product has either been established or cannot be ruled out. However, the concept of 'adverse reaction' and 'drug-related adverse events' might be challenging for a lay audience. Sponsors could therefore also consider reporting adverse events irrespective of them being deemed drug-related or not.

For the collection and description of adverse events, reports from patients about 'any untoward medical occurrence' need to be categorised to enable comparisons across study sites and across studies. This categorisation is commonly based on the Medical Dictionary

for Regulatory Activities (MedDRA). Although widely used by sponsors and regulatory agencies, many MedDRA terms are not easily understood by a layperson. MedDRA maps its terms to a number of hierarchical categories among them the lowest level terms (e.g. feeling queasy), the preferred terms (e.g. nausea), the high-level terms (e.g. nausea and vomiting symptoms), and system organ classes (e.g. gastrointestinal disorders). Commonly, the presentation of adverse events in clinical study reports is based on preferred terms and system organ classes. For the lay summary it needs to be decided, whether MedDRA terms will be used and if so which level of granularity is most appropriate. A translation of the MedDRA terms into lay language may often be necessary. Writers who write patient information leaflets face the same problem of translating MedDRA terms into lay language; it is therefore advisable to make use of the thesauruses they have developed.

Although not explicitly mentioned in Annex V, we believe that the section on 'adverse reactions' should also include information about deaths, serious adverse events, and adverse events leading to discontinuation. Furthermore, sponsors need to decide whether data on clinical laboratory findings and vital signs should be included.

#### 7. *Overall results of the clinical trial.*

The scope of this requirement is not clear. In most cases, 'overall results' of a trial would include both efficacy and safety results. As the safety results are largely covered by requirement 6 (see above), we suggest providing only efficacy data in this section. The primary and the key secondary endpoints should always be reported. Where applicable, data on endpoints related to quality of life can be included, as they might be of particular relevance for the patient. To be statistically and medically evaluable, endpoints in study protocols need to be phrased in a detailed, technical way. It will be a challenge for the writer to rephrase the results for the endpoints in such a way that the description is adequate and accessible for lay readers.

#### 8. *Comments on the outcome of the clinical trial.*

This is potentially the most problematic requirement for lay summaries. The word 'comments' leaves a wide spectrum of interpretation. It entails the notions of 'making a statement', 'expressing an opinion', and 'discussing the meaning'. Accordingly, we understand this requirement as the wish of the EU regulators to have a section in which the trial results are presented on an aggregate level and in which conclusions are provided.

As all summarising texts, such comments will need to use more general terms and will need to combine them to form high-level statements. For example, the efficacy results may be summarised by saying that

treatment with the study drug was efficacious (because the primary endpoint showed a highly significant difference to placebo/comparator). Similarly, the overall result of the different safety analyses may be summarised by ‘no critical safety issues could be identified’. The terms that need to be used for generalising statements (‘showed efficacy’, ‘raised no safety concerns’) are more comprehensive and hence open to misinterpretation. The need to use generalising terms may lead to legal issues because such statements could be perceived as being promotional. It might be for this reason that most of the lay summaries that are currently available on the internet (November 2014) do not contain a summarising or concluding statement. For the writer, the task is providing a high-level summary that does not overstate results. Therefore, the extent of comments on the outcome of the trial has to be considered carefully.

9. *Indication if follow-up clinical trials are foreseen.*

10. *Indication where additional information could be found.*

Requirement 9 can be addressed by a simple statement detailing whether additional clinical trials are ongoing or planned. Requirement 10 can be fulfilled by including a link to the sponsor’s homepage where further information such as the synopsis of the clinical study report may be available. However, this requirement might become even easier to comply with as the regulation (§ 67) states that the EU clinical trial results database will enable hyperlinking of ‘the summary, the layperson’s summary, the protocol and the clinical study report of one clinical trial, as well as linking to data from other clinical trials which used the same investigational medicinal product’.<sup>7</sup>

## Summary

Lay summaries of clinical trials will become standard in clinical research in the near future. While they are yet another commitment for the pharmaceutical companies, they will hopefully play a role in promoting health literacy in the general population. The current guidance, as provided by the EU regulation, is scant and key issues such as length, format, reading level target, and language of lay summaries are not

covered. For the time being, sponsors therefore need to make assumptions and need to define their own approach to lay summaries within the broad limits provided by the regulation.

## Declaration

The views expressed in this article are those of the authors and do not necessarily reflect those of Boehringer Ingelheim Pharma.

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# Profile

## An interview with Art Gertel on the Budapest Working Group

### Correspondence to:

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Art Gertel (AG), with nearly 40 years of increasingly senior management level positions in the pharmaceutical industry, is an expert in the preparation of large, complex corporate and regulatory documents and is thoroughly familiar with relevant US, Canadian, European Union, and International Conference on Harmonisation (ICH) guidance documents. He has also held leadership roles in professional organisations, as past President of the American Medical Writers Association (AMWA), a fellow of AMWA and EMWA, a member of the Clinical Data Interchange Standards Consortium (CDISC) Glossary and Protocol Modelling groups, and serves on the Advisory Boards of The International Publication Planners Association and Hummingbird Institutional Review Board. He has been awarded the AMWA Swanberg Medal for distinguished contributions to medical communications, and he is a founding Member of the Global Alliance of Publication Professionals. Art is a Registered Agent with the US Food and Drug Administration (FDA), a Senior Research Fellow with the Centre for Innovation in Regulatory Science, and has recently established a strategic regulatory consultancy – MedSciCom, LLC. He may be familiar to many EMWA members as a perennial workshop leader and for his positions on the Nick Thompson Fellowship and Geoff Hall Scholarship Committees.

Art is presently involved in the EMWA Budapest Working Group (BWG), an ICH E3 (clinical study report (CSR)) and E6 (good clinical practice) forensics project, and we have turned to him to enlighten us on key aspects of the project.

*Medical Writing (MEW): ICH E3 and ICH E6 are 20 years old, and thus, the need for a review is clear, but why now?*

AG: Over the past two decades there have been many advances in the process of developing, registering, and communicating about new medicines. The core source documents upon which these efforts are based, at least from the clinical perspective, are the CSR and the clinical study protocol (CSP). These are addressed by ICH E3 and E6, respectively. When we brainstormed at the EMWA Budapest meeting in May 2014, we wondered

whether there might be a way to provide a resource to those who prepare these critical documents via written guidance that reflects current practices and anticipates, to the extent possible, future developments. Many new considerations are being integrated into the new drug calculus, including disclosure and transparency, structured risk-benefit analyses, electronic data capture, and electronic filings for marketing approval. These have all arisen since the ICH E3 and E6 guidances were promulgated.

*MEW: What is the hoped for outcome of this ambitious enterprise?*

AG: We hope to provide a ‘Users’ Guide’, if you will. This will be an interpretive document that will provide medical writers and others who are involved in the preparation of CSRs and CSPs with a pragmatic tool that will make it easier to follow a consistent pathway. I should emphasise that we have assembled a broad-based coalition of partners who will be involved in all stages of the process. In particular, we have ensured that there will be a high-level ‘Stakeholder Review’, conducted by representatives of the pharmaceutical industry, regulators (including the US FDA, the European Medicines Agency, and HealthCanada), and professional associations (EMWA, AMWA, and the Drug Information Association). Importantly, we continue to engage and collaborate with other organisations which are in the process of developing protocol models – CDISC, and TransCelerate Biopharma, a collaboration of pharmaceutical companies focused on advancing innovation in research and development. Thus, we hope to create a synergy among these organisations to ensure that we will be able to leverage the accomplishments of the others in pursuing our common goal.

*MEW: At what stage is the project now?*

AG: As reported at the EMWA meeting in Florence, we have made significant progress in the forensic review of the ICH E3 guidance. Oversight evaluation is nearly complete for E3, and stakeholder introduction packs have been distributed. *De novo* review has begun for the CSP guidance. We expect that the BWG reviews will be completed in

January 2015, and that stakeholder reviews will commence in March. We concluded a total of 17 hours of round table discussions by spending a full 9-hour face-to-face meeting day prior to the Florence Conference, labouriously going through the first series of consolidated comments, and assessing how best to communicate the myriad of subtleties and nuances contained in the existing E3 guidance. In this context, extensive work has been necessary in respect of the CSR. The protocol sections of ICH E6 are much more skeletal, allowing more opportunity for *de novo* interpretation.

I must emphasise that despite the labourious process, the team has been a pleasure to collaborate with – we take this effort seriously; however, we enjoy the interaction and respect each member's expertise. Of course, Sam Hamilton has been a tireless 'Ringmaster'.

*MEW: What is your specific role in this process?*

*AG:* While I have an extensive medical writing background, I long ago strayed from hands-on CSR writing, so I hope that what I can provide is knowledge of process and application. I bring a gestalt view of drug development, review, and approval and an ongoing involvement with CDISC protocol modelling. Terminology is also a critical element, since we have to be able to clearly communicate concepts in commonly understood terms. My role in developing the CDISC glossary will allow us to tap into this existing lexicon. Finally, my greatest contribution may be as a connector. I have been employed in and around the pharma industry for a long time and this has afforded me many points of contact with experts in many of the areas touching on the CSR and CSP. Thankfully, many of them do return my calls and emails, and I have been able to bring them into the BWG effort as reviewers and stakeholders. To my mind, the multi-party collaboration is a key to the success of this daunting effort. If we can represent a consensus across the broad spectrum of applications influenced by these guidances, we have a better chance

of establishing an invaluable reference tool for our industry, investigators, and patients.

AG has given us a broad view of what the BWG project entails, and it really seems to be an outstanding initiative. We do hope this important effort will be considered in any possible revision of or addition to ICH guidance documents. We thank him and all the BWG team for their work!

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In May 2014, EMWA initiated collaboration with many stakeholders to review ICH E3 in a 2-year project. ICH E3 (effective 1995) and ICH E6 (effective 1996) are the main current ICH regulatory guidance documents for developing CSRs and CSPs, respectively.

The initiative comprises experts in ICH E3, ICH E6, CSP, and CSR templates; experts with experience in clinical trial disclosure and transparency; and a strategist who is working with partner and stakeholder organisations.

The review will:

- align guidance documents with current practices,
- increase transparency in the reporting of clinical trial data, and
- focus on protecting the anonymity of trial participants, since CSRs are to be made publicly available.

This is a major step along the way to ensuring that all sponsors of clinical trials adhere to the principles of responsible clinical trial data sharing.

Walther Seiler and Sam Hamilton presented their first publication of the project at the EMWA Conference in Florence last November, followed by an open access paper that was published in MEW last December (<http://www.maneyonline.com/doi/full/10.1179/2047480614Z.0000000254>).



EUROPEAN MEDICINES AGENCY  
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The articles included in this section are a selection from the EMA's news and press release archive for August–November 2014.

More information on the work of the EMA can be found on its website: <http://www.ema.europa.eu>

## European Medicines Agency publishes booklet on European regulatory system for medicines

26 August 2014 – The European regulatory system for medicines and the European Medicines Agency (EMA) – A consistent approach to medicines regulation across the European Union (EU).

The EMA today published an illustrated leaflet explaining how the European regulatory system for medicines operates. It describes how medicines are authorised and monitored in the EU and how the European medicines regulatory network – a partnership between the European Commission, the 50 medicines regulatory authorities in the EU and the European Economic Area (EEA), and the EMA – works to ensure that patients in the EU have access to safe and effective medicines.

The booklet is available at [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Brochure/2014/08/WC500171674.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Brochure/2014/08/WC500171674.pdf).

## Regulatory information - European Medicines Agency updates guidance on European Union periodic-safety-update-report single assessment for nationally authorised medicines

1 September 2014 – The EMA has updated its procedural guidance to ensure that marketing-authorisation holders are prepared for the submission of periodic safety update reports (PSURs) for nationally authorised medicines subject to EU single assessment.

The single assessment of nationally authorised medicines is a deliverable of the 2010 pharmacovigilance legislation. It aims to harmonise and strengthen the

review of the benefits and risks of all medicines across the EU. PSUR single-assessment procedures involving a combination of centrally authorised medicines and nationally authorised medicines have been in place since April 2013.

All EU PSUR single assessments result in a recommendation from the Agency's Pharmacovigilance Risk Assessment Committee (PRAC).

Marketing-authorisation holders with medicines subject to a PSUR single assessment involving nationally authorised medicines only, for which the frequency and dates of submission of the PSUR have been established in the list of EU reference dates (EURDs), have to submit their PSURs to all Member States where their medicine is authorised, and to the EMA. This applies to medicines with data lock points falling on or after 1 September 2014.

These PSURs will be assessed by either a PRAC member for single-assessment procedures involving a combination of centrally authorised medicines and medicines authorised through mutual-recognition, decentralised or purely national procedures, or a Member State appointed by the Coordination Group for Mutual Recognition and Decentralised Procedures – Human, for PSUR single-assessment procedures involving nationally authorised medicines only. This will result in one single-assessment report which will be shared among the marketing-authorisation holders whose medicinal products are part of the PSUR single-assessment procedure. Marketing-authorisation holders have the possibility to comment on the assessment report, following which the PRAC will adopt its recommendation.

For all EU PSUR single-assessment procedures starting from October 2014, the procedure number will be published in advance in the EURD list. Marketing-authorisation holders should therefore include their procedure number when preparing their submission. Marketing-authorisation holders of nationally authorised products should also complete Annex I of the formatted table template of the cover letter.

The PSUR timetable has also been adapted to integrate the PSUR single-assessment procedures containing nationally authorised medicinal products. This timetable was published in July 2014.

As of 26 August 2014, marketing-authorisation holders have to pay a fee for assessment of PSURs.

The updated procedural guidance further clarifies how and to whom PSURs should be submitted. For



nationally authorised medicines containing substances or a combination of active substances for which no single-assessment procedure has been established in the EURD list, the assessment of the PSUR will remain at national level.

PSURs are reports providing an evaluation of the benefit–risk balance of a medicine. They are submitted by marketing-authorisation holders at defined time points following a medicine’s authorisation. The Agency uses the information in PSURs to determine whether there are new risks identified for a medicine or whether the balance of benefits and risks of a medicine has changed, to decide whether further investigations need to be carried out or to take action to protect the public from the risks identified such as updating the information provided for healthcare professionals and patients.

## **New legislation for veterinary medicines**

10 September 2014 – New rules have been proposed by the European Commission to improve the health and wellbeing of animals by stimulating the development and availability of veterinary medicines.

The legislative proposal also tackles the growing concerns over antimicrobial resistance by proposing a series of tools to minimise the risks that may arise from the use of antibiotics in veterinary medicine.

The proposal represents a major evolution of the legal framework for the authorisation of veterinary medicines in the EU.

The document has been published on the Commission’s website together with questions and answers under Revision of the legal framework for veterinary medicinal products [External link icon](#).

The revision aims to:

- simplify the regulatory environment and reduce administrative burden for companies developing veterinary medicines through streamlined marketing-authorisation procedures and simplified pharmacovigilance rules;
- stimulate the development of new veterinary medicines, including products for small markets (minor use and minor species), with the introduction of special rules in certain areas such as apiculture and aquaculture and better mechanisms to reward companies’ investments in the development of innovative medicines;
- facilitate the circulation of veterinary medicines across the EU, through streamlined procedures and clear rules for internet retailing of veterinary medicines within the EU;
- fight the development of antimicrobial resistance through specific measures such as a

restriction of the use in animals of certain antimicrobials that are reserved for the treatment of infections in people.

The EMA welcomes the publication of this proposal as the availability of veterinary medicines and the fight against antimicrobial resistance are two major priorities for the Agency, as reflected in its work programme.

Today, the Commission has also adopted a proposal for a revision of the EU legislation on food for animals containing medication. The aim is to ensure that medicated feed is only produced by approved manufacturers using authorised veterinary medicines.

Other EU institutions, including the European Parliament and the Council, will now consider the Commission’s proposals and will adopt their positions in due course, in accordance with the co-decision procedure.

## **Regulatory update - Changes to scientific advice procedures as of 17 November 2014**

24 October 2014 – As of 17 November 2014, the EMA is introducing changes to the procedures for scientific advice, parallel advice with health technology assessment bodies, protocol assistance, and qualification of novel methodologies. These changes are expected to further streamline the timetables and will apply to applications starting in January 2015 onwards.

These changes are as follows:

- the time between submission of the letter of intent and the start of procedure has been reduced to approximately three weeks for applications that do not require a presubmission meeting;
- the time between submission of the letter of intent and the start of procedure has been reduced to approximately seven weeks for applications that require a presubmission meeting;
- a draft briefing package should be submitted together with the letter of intent to allow quicker start of procedure. The final briefing package is expected in the week prior to the start as per current procedure.

For any enquiries please contact [scientificadvice@ema.europa.eu](mailto:scientificadvice@ema.europa.eu).

## **Regulatory update - EMA encourages companies to submit quality type I variations for 2014 by end of November**

24 October 2014 – The EMA is advising marketing authorisation holders to submit any type IAIN and type IA variations for 2014 by Friday 28 November

wherever possible. This will enable the Agency to acknowledge the validity of the submissions before the Agency's closure between 24 December 2014 and 2 January 2015 within the 30-day timeframe set out in Article 14 of Commission Regulation (EC) No. 1234/2008 [External link icon](#).

Marketing authorisation holders intending to submit type IB variations or groupings of type IBs and type IAs in December 2014 should liaise with the EMA prior to submission. An email should be sent to: [IBquery@ema.europa.eu](mailto:IBquery@ema.europa.eu) indicating in the subject line: 'Type IB December Submission' and mentioning in the body of the email the name of the product, the intended submission date and the scope(s) to be applied according to the Classification guideline [External link icon](#).

Type I variations are minor changes to the marketing authorisation of a Type IAIN and IA variations have no impact on the quality, safety or efficacy of the medicine. Type IAIN variations must be notified to the national competent authority or the EMA immediately following implementation, in order to ensure the continuous supervision of the medicine. Type IA variations do not require immediate notification and should be notified to the national competent authority or the EMA within 12 months of implementation, or earlier in certain cases.

Type IB variations must be notified to the national competent authority or the EMA before implementation, but do not require a formal approval. Upon acknowledgement of receipt of a valid notification, the marketing authorisation holder must wait for a period of 30 days to ensure that the notification is deemed acceptable by the national competent authority or the EMA before implementing the change.

## **Regulatory update – All referral procedures to be sent via eSubmission Gateway / Web Client from 1 November 2014**

24 October 2014 – Companies subject to a referral procedure for human medicines should send all their submissions via the eSubmission Gateway or the Web Client [External link icon](#) from 1 November 2014. After that date, the EMA is no longer accepting electronic submissions for referrals on CD or DVD.

The use of the eSubmission Gateway or the Web Client allows companies to submit their documentation to the EMA securely over the internet, thereby improving efficiency and reducing costs.

The use of the electronic Common Technical Document (eCTD) and electronic submission channels, i.e. the eSubmission Gateway or Web Client, has been mandatory since 1 April 2014 for submissions related to referral procedures for centrally authorised medicines.

For submissions related to referral procedures for nationally authorised medicines, the EMA is now strongly encouraging companies to make their submissions using the eSubmission Gateway or Web Client in either the eCTD or Non-eCTD electronic submission format. Submissions on CD or DVDs will no longer be accepted.

The use of electronic submission channels offer companies the following benefits:

- easier and quicker way to send eCTD submissions securely over the internet with possibility for companies to send updates within very short deadlines;
- feedback to the sender on the receipt of the submission, the outcome of the eCTD technical validation and the upload to the EMA's eCTD review system;
- no need to submit a physical copy of a dossier to the EMA.

All marketing authorisation holders are invited to register to use the eSubmission Gateway or the free web-based Web Client solution as soon as possible.

For more information on the eSubmission Gateway/Web Client go to the eSubmission website.

## **European Medicines Agency publishes first summary of a risk-management plan for a medicine**

3 November 2014 – The European Medicines Agency has published the first summary for the public of the risk-management plan (RMP) of a newly authorised medicine. This RMP summary, which concerns the medicine Neuraceq, describes what is known and not known about the medicine's safety and states what measures will be taken to prevent or minimise its risks.

The Agency will pilot the publishing of RMP summaries for all newly centrally authorised medicines during 2014 and at a later stage will start producing RMP summaries for previously authorised medicines.

This new type of publication is a further step towards increased transparency and public access to relevant information on medicines and is one of the requirements of the new European pharmacovigilance legislation. The RMP summaries complement the public-friendly information already available in the Agency's summaries of the European public assessment report (also known as EPAR summaries).

The RMP summaries are expected to be consulted by stakeholders with a professional interest in medicines, but will also be a useful resource for any member of the public who would like to have more information about their medicines.

This initiative is part of the Agency's continuous drive to improve information about medicines for the general public. The Agency recently revised its EPAR summaries based on feedback received from various stakeholders, particularly patients and healthcare professionals.

The format and content of EPAR summaries have been updated in order to make them more user-friendly and to better explain the reasons that led to the approval of the medicine. In particular, changes have been made to the way a medicine's benefit and safety profile are described and more information is provided on the benefit-risk balance. The Agency has been using this new format since 2013 for all new summaries and is also gradually updating previously published EPAR summaries.

### **Regulatory information – New tool for companies to facilitate maintenance of information on authorised medicines**

10 November 2014 – The EMA has made available a new tool to facilitate editing of key data fields by marketing-authorisation holders as part of the maintenance of information on authorised medicines that they have submitted to EMA.

This tool is available to users of the eXtended EudraVigilance Medicinal Product Dictionary Data-Entry Tool (EVWEBExternal link icon). A user manual explaining how to use this tool has been published.

As announced in January and June 2014, marketing-authorisation holders are required to complete previously submitted information on medicines with additional data elements that are included in the new data-submission format by the end of 2014. Companies are also required to bring medicine information up-to-date and to check that the quality of the information is in line with the updated reporting requirements.

Companies are reminded that they need to complete this process by 31 December 2014.

For user convenience, a direct link to full details on the data-submission requirements is now available on the homepage of this website (see 'Data submission for medicines').

In line with Article 57(2) of the 2010 pharmacovigilance legislation, holders of marketing authorisations must submit information to EMA on all medicines authorised for use in the EEA and keep this information up-to-date.

This database reinforces the supervision of medicines in the EU, as it supports pharmacovigilance data analysis, facilitates follow-up of regulatory actions and monitoring of legal obligations, and strengthens communication with EMA's stakeholders and partners. By streamlining the identification of products relevant to pharmacovigilance procedures, this database is expected to simplify adverse reaction reporting for marketing-authorisation holders and ensure that fees are calculated accurately.

## New in *European Science Editing*

The final 2014 issue of *European Science Editing* revisits a couple of topics featured earlier in the year, namely plagiarism and referencing errors. Former WAME (World Association of Medical Editors) President Farrokh Habibzadeh explores reasons for plagiarism among native English speakers (laziness) and in developing countries (difficulties describing things in English, unawareness of how serious plagiarism is).<sup>1</sup> He advocates the inclusion of writing courses in undergraduate curricula as a means of preventing plagiarism, and harsh penalties for those who plagiarise after taking such a course. Finally, he looks ahead, predicting a future where computers write meta-analyses and systematic reviews, where papers are created by inserting references, protocols, and results into electronic manuscript templates, and where plagiarism is no longer considered misconduct. Hmmm. Elsewhere, Salman Yousuf Guraya looks at rates of reference errors in 30 articles from 10 journals, finding an overall error rate of 18%.<sup>2</sup> He also reports a fall in errors during the period his study covers (2005–2011), which he attributes to more careful editorial checks and increasing use of reference management software. In a letter to the editor,<sup>3</sup> Frank-Thorsten Krell rightly calls for this apparent

decline in the error rate to be confirmed. He then explains how errors in references can undermine metrics and citation-based assessments of academics, and how they often reflect the failure of authors to read the papers they cite. Lastly, Xiaochun Qiu and Qian Liu highlight Faculty of 1000, a web platform whose resources include post-publication reviews of biomedical research papers, a repository for conference posters and presentations, and a manuscript publishing platform that makes peer reviewers' comments available to the public.<sup>4</sup>

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# The Webscout

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## Plain language

The word 'plain' in its original sense just meant 'flat, smooth'. In the thirteenth century, it also gained the meaning 'evident'. And from the fourteenth century on, 'plain' has been used in the way we understand it in the term 'plain language': to refer to something simple, clear, and obvious without superfluous ornamentation:

<http://en.wiktionary.org/wiki/plain> and  
<http://www.etymonline.com/index>.

Several institutions and associations dedicate themselves to the plain language initiative. These are, for example, the **Center for Plain Language**

<http://centerforplainlanguage.org/>,

### Plain Language Association International

<http://www.plainlanguagenetwork.org/>,

### and the Plain Language Action and Information Network

<http://www.plainlanguage.gov/>.

I have searched the web for online tutorials on plain language. The first one I stumbled over was **PlainTrain**, a Canadian initiative:

<http://www.plainlanguagenetwork.org/plaintrain/>.

It contains eight sections to introduce you to plain language, including some exercises to practise what you have just learned about. The NIH provides a more appealing online course, which also has an introductory level:

<http://plainlanguage.nih.gov/CBTs/PlainLanguage/login.asp>.

You can either review the contents of the training modules without receiving credit, or login and receive a certificate after completion of the course.

Dr Lynn Dicks, manager of the Conservation Evidence project at the University of Cambridge, has given a lecture on how to write about science in plain English:

<http://www.youtube.com/watch?v=Mn7f5tsgjx8>.

She presents 12 simple rules to follow in order to bring clarity to your scientific writing.

And what about conveying health information to a lay readership? How can you ensure patients and people interested in health topics get your message? A webinar presentation on how to use plain language to communicate health information may help:

<http://www.youtube.com/watch?v=cU-FDPPsaeI>.

It is not solely on language but rather on the presentation of information on the web in general. The audio quality is not ideal, but it is worth watching anyway. Another useful webinar is on plain language in social media:

<http://www.youtube.com/watch?v=W756zLegQB8>.

A further web-based workshop was designed to help people create consent forms and other materials for study participants:

<http://www.iths.org/events/prism-plain-language-training-researchers>.

You have to register for this course, but it is free of charge.

Clear communication and conveying information are not only relevant in writing, but also in speech. Although we are mainly writers, I want to emphasise the importance of plain spoken communication as well. The term 'plain speech' is associated with the Quakers' 'Testimony of Simplicity':

[http://en.wikipedia.org/wiki/Testimony\\_of\\_Simplicity](http://en.wikipedia.org/wiki/Testimony_of_Simplicity).

The Quakers were famous for their plain speech, which was strictly honest and direct:

<http://www.staff.amu.edu.pl/~bmaurus/plainspeech.html>.

I want to end with a quick look at modern plain spoken presentation. This blog entry gives you some idea about how the way you talk determines whether people pay attention to what you want to tell them:

<http://www.entrepreneurcountryglobal.com/index.php/united-kingdom/ecosystem-economics/item/plain-speech-is-not-the-new-rock-n-roll>.

Did this Webscout section help you or do you have any questions or suggestions? Please feel free to get in touch and share your thoughts.

Karin Eichele

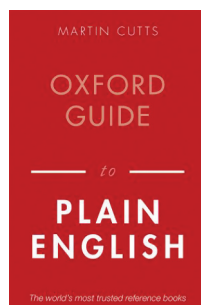
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# In the Bookstores

## Section Editors:

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*Oxford Guide to Plain English*  
by Martin Cutts;  
Oxford University Press, 2013.  
ISBN-13: 978-0-19-966917-2.  
7.99 GBP. 288 pages.

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## Top-notch reference at a giveaway price

The latest edition of *the Oxford Guide to Plain English* is not the kind of book you would necessarily read from cover to cover: the chapters are stand-alone components and there is no benefit in reading them in order. Rather it is a trusty reference to dip into and come back to.

The book's author, Martin Cutts, places the book in context with an extended preface, explaining what plain English is and illustrating what it isn't with examples of barely digestible writing. He also describes the origins of plain language campaigns and policies in the UK, the USA, Australia, and Sweden, and highlights areas where progress has been made. Happily, he makes clear that his book is intended to guide, rather than to prescribe rules.

The main part of the book is divided into 25 chapters, which range in length from 2 to 42 pages. The longest chapter, *Preferring plain words*, includes a plain English word list that is as good as any I've seen. Other chapters cover much-discussed topics such as favouring the active voice, replacing weak verb plus noun constructions with strong verbs (e.g. rewriting *We must perform analysis of the data* as *We must analyse the data*), and shortening overlong sentences. Still others advise on writing in a gender-neutral, non-sexist way and explain why half a dozen myths of writing are wrong. Particularly

useful to me was a chapter devoted to creating and punctuating bullet points, the cause of so many problems.

In addition to providing guidance in specific areas such as these, Cutts also looks at the bigger picture. Importantly, he explains how good visual presentation of information can facilitate comprehension. He further discusses formulas for assessing readability, rightly describing them as 'blunt tools' and cautioning against overreliance on them.

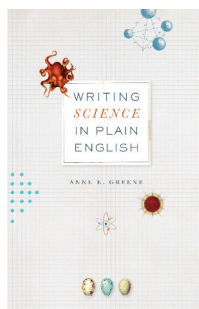
Elsewhere, in a short but welcome chapter on proofreading, Cutts provides a list of 14 proofreading musts, the first being the most important: follow house rules.

Cutts advocates careful planning and reminds us to have the reader at the forefront of our mind when we write. He illustrates his points with pertinent real-life examples from his 'postbag' and other sources, and backs up his advice with feedback from focus groups.

There is much to praise and little to criticise. Perhaps the grammar and punctuation basics are superfluous or could be buried in an appendix. And while the occasional use of idiomatic phrases (against the author's own advice) and non-plain words such as *fusty* may improve the reading experience for some, it could be a barrier to readers whose first language is not English.

Later chapters such as *Clarity for the Web*, *Lucid legal language*, and *Writing low-literacy plain English* head into more specialised territory and might not be essential reading for all, but *the Oxford Guide to Plain English* certainly has something to offer everyone.

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*Writing Science in Plain English*  
by Anne E. Greene;  
University of Chicago Press, 2013.  
ISBN-13: 978-0-226-02637-4.  
9.00 GBP. 124 pages.

## Bargain must-have guide to writing more clearly

The sceptic in me was always going to question the publisher's assertion that this book 'can help writers at all levels of their [...] careers' and that it is 'an essential resource'. Sure, I thought. But those bold claims are in fact not unwarranted. In *Writing Science in Plain English*, Anne Greene delivers what at the very least serves as revision on good writing practices and a crystallisation of the key aspects of plain English. For me, the utility of her book was underlined when I subsequently read the proof of a manuscript I had written and became aware of some of the deficiencies in my writing.

In a convincing introductory discourse on the necessity of plain English, Greene argues that poor writing limits communication between different research fields and with the public. She correctly points out that opaque, reader-unfriendly writing can be self-propagating. This is because young scientists partly learn to write by reading published manuscripts, whose quality of writing is quite variable. It's like learning how to drive by watching and imitating others.

*Writing Science in Plain English* ignores *what* to write and 'focuses entirely on how to write clearly and comprehensibly', promising to 'improve everything you write', irrespective of your scientific field or seniority. Another bold claim – and a justifiable one.

Some of the advice in the early chapters may be obvious: 'If you are unsure of your audience, err on the conservative'; don't write in an abstract way; don't be tentative (avoid timid phrases such as *could possibly*). But it does no harm to be reminded of it. Some things you might not have thought about. For me, the advice to consider mixing formal and informal registers was revelatory.

Chapter 3 (of 11) is concerned with our writing telling a story. To improve readability and reduce the word count, the author urges us to avoid using abstract nouns (e.g. *identification*) as subjects and to replace weak verbs such as *be* and *have* with strong verbs. The central concern is always the reader. Greene advocates placing the verb near to the

subject on the basis that readers will tend to skim over intervening text looking for the verb.

Like almost all writers nowadays, Greene favours the active voice. Unlike everyone else, she provides a good explanation of when the passive voice can be useful.

Her wisdom seems almost endless: use the same terms for the same thing; don't use technical terms if your audience won't understand them; avoid non-parallelism; vary sentence length to avoid monotony; cut out superfluous words (including *the*); use transition words such as *however* and *therefore* to guide the reader; replace wordy phrases with single words. It really reads like a 'What's What' of good writing.

All chapters contain example sentences which the author analyses and improves. However, some of the reworded sentences have meanings or implications that are subtly different from those of the originals. Similarly, Greene advises us to avoid long words, but some of the shorter words she suggests we replace them with have different meanings. These ambiguities are a potential source of confusion.

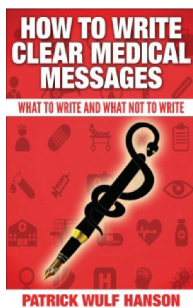
Each chapter is complemented by challenging, thought-provoking exercises which make the reader analyse and improve other example sentences and paragraphs. Excellent, but I do have a criticism: the author's own answers (improved sentences/paragraphs) often contain multiple changes – not just the one that illustrates the point of the exercise. This might make things harder for novices.

I have never read a book on writing where I agree with everything, and this book is no exception. Chapter 7 is on how to structure sentences, where to put certain information. It contains some great tips, but things are not as black and white as the author suggests. Likewise her advice to replace negative phrases (e.g. *did not allow*) with positive ones (in this case, *prevented*). As with active and passive and long and short sentences, I feel a mixture can work well.

The last two chapters deal with designing and organising paragraphs. Greene helpfully describes ways to arrange separate paragraphs so that readers can navigate them easily. Disappointingly, there is no summary after the final chapter. I kind of wanted the author to wish us good luck in our attempts to go out and write more clearly!

I have highlighted this book's flaws in the interests of balance, but really they are massively outweighed by its strengths. Costing just £9, *Writing Science in Plain English* is a steal.

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*How to Write Clear Medical Messages: What to Write and What Not to Write*

by Patrick Wulf Hanson;  
CreateSpace Independent  
Publishing Platform, 2014.  
ISBN-13: 978-1500163532.  
5.84 GBP. 108 pages.

For a while, I have been looking for a book on writing clearly aimed at medical writers or other people writing for the health professions. So I was intrigued when I learned about *How to Write Clear Medical Messages: What to Write and What Not to Write* by Patrick Wulf Hanson. The title sounded perfect for my needs, and as described in the About the Author section at the end of the book, the author seems well-qualified to write on the subject after having worked in scientific research and communications for more than 20 years.

The introduction emphasises the importance of planning your communication. The author explains that the first step in writing a document is to ask the following five questions:

- Why do you want to communicate your message?
- What do you want to communicate?
- What do you want to show?
- What is the purpose of the text?
- To whom do you want to communicate?

Subsequent chapters are on writing as a communication tool. They summarise key points such as using the active voice and basics of English grammar and punctuation; words that can be confused by non-native English speakers, such as *advice* and *advise*; correct usage of numbers and units; and usage of abbreviations and acronyms.

The book then switches modes and discusses a wide range of topics important to medical writers, including ethical considerations, writing for marketing and advertising, communicating research, basics of statistics, and referencing. The final chapters include some overall advice and sources of information and reading.

Unfortunately, this book does not do an adequate job of addressing the author's own five key questions. Who is it for? Is it medical doctors and other health professionals, professional medical and scientific writers, other professional writers, researchers, or non-native English speakers? Several or all of the above? At some point, the author mentions medical writers, but some of the topics would already be known to a professional medical writer. The 'what' and 'why' are also not fully clear, and the purpose of the book and what the author really wants to show are lost between the covers. In addition, the book often has long lists of information or things to consider but usually lacks examples or exercises, so it never really accomplishes its goal of teaching the reader how to write clearly. Finally, the book has a number of glaring errors that should have been caught during a proof-read and certainly before the book went to print. This is rather embarrassing for a professional medical writer and highlights the importance of a key missing chapter: quality control!

I think that the author has a good idea: a book teaching people how to write clear medical messages is needed. But he needs to develop the book further, clarify who the target audience is, move long lists to an appendix, and be more careful about quality control. I encourage him to produce a second edition that truly meets its objective and addresses his five main questions.

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# English Grammar and Style

## Revising medical writing

### Reasons not rules:

### Backtracking, pronoun-induced

### Part 2 – Single syntactic unit revision

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#### Introduction

This is the second of a series of three articles on pronouns that cause distraction by making the reader backtrack. In this article, we examine a technique for eliminating backtracking by making a single change to the construction of the sentence. The technique is to eliminate the pronoun that is causing the distraction by shortening the clause with the pronoun into a pronoun-free phrase.

#### Example 1: 'This' in the subject position of the second independent clause in a compound sentence

The example, from an Introduction section, conveys a description of the research problem, consisting of tandem statements:

*In retina, spectrin is bound to retina epithelium, and **this** results in a different epithelial polarity.*

The problem for the reader is that it is not immediately clear what is the antecedent for 'this'. The answer is that 'this' refers to the first independent clause ('spectrin is bound to retina epithelium'). The backtracking caused by 'this' can be eliminated by transforming the second independent clause ('and this results in a different epithelial polarity') into a modifying adjectival participial phrase, 'resulting in,' which transforms the sentence from compound to simple. The suggested revision is:

*In retina, spectrin is bound to retina epithelium, **resulting** in a different epithelial polarity.*

Notes:

(a) It is appropriate to use the present tense of the present participle 'resulting' because the author is conveying known information in an Introduction section.

(b) In the example, the selection of 'this' over 'that' is determined by the context of the present tense in the first independent clause.

#### Example 2: 'That' in the subject position of the second independent clause in a compound sentence

This example, from a Discussion section, conveys the limitation and counterarguments of the experimental approach:

*For Staph aureus, there were discrepancies in the colony count, and **that** was possibly caused by shortened incubation times or contamination of the culture medium.*

The first clause conveys a limitation; the second, a counterargument. Both are expressed in the past tense, which is appropriate for the understatement of a past observation and an understated (i.e. circumspet) counterargument.

The backtracking caused by 'that' could be eliminated by replacing it with the slightly more specific 'that result'. But why not eliminate the pronoun altogether (as in Example 1, above)? For instance, the demonstrative pronoun in the second independent clause ('and that was possibly caused...') can be eliminated by transforming the clause into a past participial phrase. The suggested revision is:

*For Staph aureus, there were discrepancies in the colony count, **possibly caused** by shortened incubation times or contamination of the culture medium.*

Note: 'That' is used in the example because the time perspective in the first independent clause is the past.

#### Example 3: 'That' in the subject position of a contiguous sentence

This example, from the Material and Methods section, conveys a description of the method and objective:

*The neurologic test scores were analysed by Cluster Analysis. **That** enabled identification of subgroups within the sample of girls with AIS.*

To minimise backtracking, the second sentence beginning with ‘that’ can be transformed into an infinitive phrase, which conveys intent. The suggested revision is:

*The neurologic test scores were analysed by Cluster Analysis **to enable** identification of subgroups within the sample of girls with AIS.*

Note: the use of an infinitive phrase conveys the meaning without any backtracking; this revision is similar to the use of a participial phrase (Examples 1 and 2, above).

#### **Example 4: ‘That’ in the subject position of a contiguous sentence**

This example, from a Results section, conveys a verbal description of the data and preliminary interpretation:

*For the cross-situation, there was a 78% classification rate. **That** indicated a high degree of consistency for the classification scheme.*

There is no need to eliminate ‘that’ when its antecedent is clearly ‘78% classification rate’. However, preceding the demonstrative pronoun ‘that’ with ‘a rapidity’ – which enables commentary about the rate – not only eliminates the minor backtracking

but also conceptualises the gist of the preceding sentence.

*For the cross-situation, there was a 78% classification rate, **a rapidity that** indicated a high degree of consistency for the classification scheme.*

Notes:

- (a) In the revision, ‘that’ functions as a relative pronoun, modifying ‘rapidity’.
- (b) The addition of ‘rapidity’ and transformation from a demonstrative into relative pronoun represent a combination of a semantic and syntactic revision. ‘Rapidity’, a summative modifier, ensures antecedent certainty.

### **Summary**

Pronoun-induced backtracking can be eliminated by transforming: (1) the pronoun-containing clause into a pronoun-free present participial phrase, (2) the clause into a pronoun-free past participial phrase, (3) the clause into a pronoun-free infinitive phrase, or (4) the demonstrative pronoun-subject clause into a summative modifier followed by an adjective clause.

The third article on pronoun-induced backtracking will examine double-syntactic unit revision and syntactic position revision.

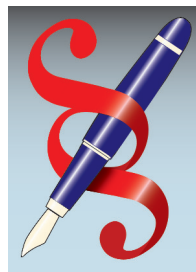
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# Regulatory Writing

## Briefing documents: A case apart

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Health authority briefing documents (also known as briefing packs, briefing packages, and briefing books) are documents prepared by a pharmaceutical company to support its interactions (e.g. pre-submission meetings, requests for scientific advice, and protocol assistance)

with health authorities. These interactions can shape the clinical development of a product and as such are clearly of great importance to companies. A well-written and presented briefing document may be crucial, or at the very least, can smooth the path to the desired outcome.

### A neglected document type

Although medical writers are often involved in the preparation and drafting of briefing documents, and given their strategic importance, it is perhaps surprising that very little is actually offered in terms of training for their preparation. For example, although EMA offers training on a wide variety of document types (clinical study reports [CSRs], investigator's brochures [IBs], components of the common technical document [CTD], informed consent, etc.), to my knowledge briefing documents have so far escaped attention. Likewise, in a search inside the books about medical writing on Amazon, I did not see any references to briefing documents.

The explanation why briefing documents have been neglected in training courses and by authors of books on medical writing may in part be related to the lack of guidance for their preparation. CSRs and many other regulatory documents are subject to specific guidance which is relatively easy to teach and write about. Little guidance is available, in contrast, for briefing documents (though the European Medicines Agency does have a template for protocol assistance/scientific advice, as discussed below). Another factor is perhaps that briefing documents are rather unique documents, which need to be tailored to the particular needs of a given situation and perhaps also to the requirements of the health authority to which they will be submitted.

They are also often interdisciplinary documents (so rather like investigator's brochures, in this respect) requiring input from different functions within a pharmaceutical company. Perhaps the diversity of types of briefing document and the fact that they are rarely purely clinical documents are further reasons why they have not been accommodated in more clinically oriented training programs. Nevertheless, some basic principles nevertheless apply.

### Basic principles

Unlike many other regulatory documents, a briefing document is not intended to be an exhaustive presentation on the subject in question. For example, in a CSR, failure to include comprehensive data may be interpreted as a sign that the company has something to hide. Such considerations do not really apply to briefing documents. It is up to the company to decide what is interesting and important for the project in question, and bring these to the table. Indeed, piles of data may be off-putting to hard-pressed reviewers. In a recent survey on how FDA Advisory Committee members prepare for a public advisory committee meeting, the authors found that 20% of members spend less than four hours preparing for the meeting.<sup>1</sup> Bearing in mind that this time also includes review of the sponsor's slides as well as the briefing pack prepared by the FDA, the time spent actually reading the sponsor's material can be minimal. In addition, as the outcomes of most of these meetings are not binding, a reviewer will perhaps be less inclined to focus on the detail and look more at the big picture. Interestingly, many of the advisory committee members surveyed in the aforementioned study generally preferred less text and more tables while the vast majority wanted the document to be less than 100 pages long (excluding appendices). Admittedly, the public advisory committee meetings covered by the study represent a special case and may not be representative of other types of meeting sought with other health agencies (see McIntyre and colleagues for some background on public advisory meetings<sup>2</sup>), but it is likely that reviewers in other situations will also be hard-

pressed for time, and so considerations about brevity will also be applicable.

### **The EMA template for protocol assistance/scientific advice**

Most briefing documents will begin with some sort of short executive summary, followed by questions with the company's positions. Then, there will usually be a background information section where a reviewer can go for more detailed information, followed in turn by any annexes or appendices. Faced with the lack of examples of briefing books and documents, it is perhaps illustrative to look at the European Medicines Agency template for CHMP protocol assistance/scientific advice, available from: [http://www.ema.europa.eu/ema/pages/includes/document/open\\_document.jsp?webContentId=WC500093259](http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500093259). This template also includes guidance text for each of the main sections (summary, questions and company's positions, and background information).

According to the EMA template, the summary section should be limited to three pages and include the following subheadings: background information on the disease to be treated, background information on the product, clinical development, regulatory status, and rationale for seeking advice. Optionally, this section can also include subheadings for quality development and non-clinical development, if appropriate.

It goes without saying that this section should be well crafted and to the point. Ideally, the text should give the reviewer a good idea as to why the company is seeking advice.

The questions and company position are the crux of the document. The questions need to be carefully formulated; questions that are too vague will likely get answers that are also vague (and so not particularly useful). But specific questions can also be dangerous in that they can elicit specific responses that can tie the company to unwanted commitments; although the outcomes of many of these meetings are non-binding, they will be taken into account in subsequent submissions. Normally, medical writers will not be responsible for drafting the questions (although their input on language

issues may be welcome). Often, when producing a briefing document, the questions are drafted first and the rest of the document constructed around these questions. Each question is followed by the company position, which according to the EMA template should function as a stand-alone argument, although cross-referencing to background information can be used to further substantiate the company's position. These positions should be objective and critical. Ideally, each company position should not exceed three pages.

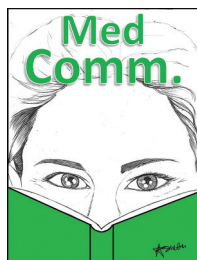
The background information section provides additional supporting information to allow further assessment of the development programme (though essential information should be presented in the corresponding company's position). This section is not intended to be an exhaustive overview. According to the guidance, tabular presentations and graphs should be considered to facilitate rapid understanding. If necessary, further information in the form of study protocols, study reports, and investigator's brochures, for example, can be provided as annexes.

### **The benefits of a well-structured briefing document**

Thus, the overall structure of briefing documents is similar to that of many other regulatory documents, with summarised and selected information at the beginning of the document, but with the opportunity to drill down to greater detail if desired. As with any other type of regulatory document, a logical and well-organised structure will help the reviewers quickly find the information they want at the level of detail they want and so put them in a better position to provide useful feedback.

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## Editorial

Dear all,

A very warm welcome to the first issue of *Medical Writing* in 2015!

This whole issue is dedicated to a subject very close to my heart (as I'm sure you're all well aware of by now) – plain language. Naturally, *everyone* benefits from text that is clearly constructed and easy to understand. But if English is not your first language, *or* your general literacy level is not too high, *or* you're elderly and perhaps in the first stages of a neurodegenerative disease, *or* you're frightened by anything 'medical', *or* you've just been told some devastating news by a doctor, *or* one of many, many other reasons.....clear text and clear messaging are not just 'nice to have' – they are crucial, and can literally be the difference between life and death.

However, converting text into 'plain language' is not as simple as reducing the size of the words and shortening sentences – if this was the case, a talented IT bod would have created a programme

a long time ago to do just that. It takes knowledge and experience to process the information in the first place and then produce it in a simpler form while keeping the messaging and tone intact. Enter the medical writer.

This issue's article is from just such a talented and experienced medical writer – Wendy Kingdom. In her article, Wendy gives us an insight into some of the problems medical writers encounter in this type of work, and she explains why the work is so important and why medical writers should be involved.

As Wendy concludes, this is a newly growing field – and one that I see expanding with the increasingly high profiles of patient advocacy groups clamouring for more and better information, along with the changes in legislation acknowledging this need. Medical writers are uniquely placed to provide the much-needed skill set to cope with the task. Perhaps we should take a leaf out of the advocacy groups' books and increase *our* profile, too!

Bestest,  
Lisa

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## Writing for a public audience

Writing for a public audience is more difficult than it might at first appear. There are some common rules that can be used to make a start. For example, sentences should be short and clear. The author should use everyday words in place of complex words, and must either avoid or explain specialist language. As an example, to write a patient information leaflet for phenoxymethylpenicillin 250 mg tablets, the starting point will be the Summary of Product Characteristics (SmPC). The language used in an SmPC is expected to be technical so we might presume that all we have to do when writing a patient information leaflet is to follow the rules of simplifying the language. The wording in the SmPC might be:

*Phenoxymethylpenicillin is indicated in the treatment of mild to moderately severe infections.*

Straight away, we find ourselves with a question. Do we need to use the word phenoxymethylpenicillin or can we just refer to penicillin? Penicillin is an everyday word; phenoxymethylpenicillin is not. Furthermore, phenoxymethylpenicillin is a very long word and many people would not attempt to read it. We could lose our audience with the first word. However, if we use the word 'penicillin', we are no longer referring to the drug by its approved name, which can have legal implications. Therefore, we might have to use a very long word even if we do not want to. For the sake of simplicity, we will assume that we can refer to penicillin.

The term 'is indicated' is jargon and can be replaced with e.g. 'is used' or 'is prescribed'. The rest of the sentence uses simple, everyday words but the information itself is aimed at a prescriber. The patient does not need to be told that they have a mild to moderately severe infection; they already know why they went to see their doctor. Now we

have a second question. Do we need to include the information at all? The problem is that we all have our opinions but nobody has definitive answers to these questions.

Perhaps the sentence could be rewritten as:

*Penicillin is an antibiotic that kills the bacteria that cause infections.*

The rewritten sentence could pass a readability test but might lead to problems of inaccuracy or errors of omission. The pharmaceutical company's legal department could also be unhappy with how vague this wording is.

The text also needs to pass a 'so what?' test, i.e. the author needs to engage the reader in the text and explain what the information means to them. So, we might want to rephrase '*...that cause infections*' to '*...that caused your infection*'. Now we might be guilty of being over-familiar, possibly bordering on unprofessional, or of making a clinical judgement with no information on which to base it.

Recognising and avoiding jargon can be quite difficult, particularly when we normally spend our working hours communicating with people who have a similar technical knowledge to our own. It is important to be aware of the environment in which we work and to be able to adapt when appropriate. A wonderful example of failing to adapt occurred on national radio relatively recently. A surgeon was being interviewed about the marvels of weight loss surgery. After talking for a minute or two about patients whose type-2 diabetes resolved within a few days of surgery, he told us (i.e. the public) that we should not be referring to weight loss surgery but to bariatric metabolic surgery. Thus is born some jargon that can not only be guaranteed to befuddle the public but would challenge quite a few people who would pride themselves on having a reasonably extensive medical vocabulary.

This example also highlights another complexity in writing for the public. Assuming that the surgery is not intended to remove our bariatric metabolism, the term does not tell us what is going to be done to the patient. If we had to explain it to the public, we would need to know which of several surgical approaches to weight loss surgery are included. Only when we know what will be done to the patient, can we begin to explain it in lay terms.

A common challenge in describing side effects of drug therapy is decoding coded adverse event terms. 'Abdominal discomfort', 'chest discomfort',

'mood altered', and 'neurological symptoms' are a few examples of terms that might be presented to a writer who then has to find a way of explaining them to a lay audience. This is more or less impossible without additional information.

Consider also that while a term might be familiar to someone, that does not mean that the person will understand what it means, or, more importantly, what it means for them. For example, most people are likely to know that a biopsy means taking a sample of something from the body, probably out of a lump, and sending it away for tests. What people might not realise is that the procedure might involve having a large needle inserted, possibly into a sensitive part of the body, which might be very painful. It could also be embarrassing and distressing.

Conversely, some words are unlikely to be understood by the public but they might still be good words to use. For example, the word 'receptor' is often used in patient information, not because it is reasonable to expect a lay audience to have a grasp of receptor-mediated ion exchange channels, but because the word receptor is descriptive. Receptor is similar to receptacle and is evocative of a drug being received by something, which then triggers an effect. In most cases, the precise mechanism of action is not important and we can use the term receptor without worrying too much about precisely how it will be understood.

The necessity for communicating with lay audiences is increasing all of the time. Risk Management Plans now have to include a lay summary of safety concerns. The new European Union (EU) regulation on clinical trials (536/2014) requires a summary of the results of the clinical trial report to be written for lay persons. We can assume that a lay person summary of a clinical trial report is not expected to include everything that is in the technical summary but there is no guidance as yet on what can be left out. Do we have to explain mean  $\pm$  standard deviation or 95% confidence intervals or will it be sufficient to state that one treatment was better than the other (or not)?

One last consideration in this brief discussion of writing for the public is that we cannot know what impact our words will have on our audience. We all have our opinions and beliefs, sometimes rational, sometimes not, but always important to us personally. People express opinions such as, 'Hospitals are dangerous places. I know of three people who went into hospital and they died', 'I don't like to take pills!', 'You take one thing and then you have to take something else for the side effects'. No matter how hard we try, we can never know how anyone

who reads what we have written will interpret it. We can only do our best to convey the correct message by keeping the language clear and direct.

Writing for the public is important. There is a vast amount of information, misinformation, and disinformation available on the internet. Medical

writers need to contribute as much as they can, without losing the audience in technical terminology, or boring people with endless pages of information that is not directly relevant to them. This is a growing area that is likely to become a specialism for writers.

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# Lingua Franca and Beyond

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## Welcome to Lingua Franca and Beyond



Writing is something that I have always loved. Actually, as a teenager I would have studied literature, but I changed my mind at the last year at school. I became a paediatrician instead for a few years but then little by little, my career turned towards writing, precisely medical writing. However, I am not a native English speaker – I am Polish. My mother tongue does not even belong to the Germanic languages, and my language roots are completely different. This difference and my overall background made me think that I would never be able to write medical papers in English. Then life started to create a different scenario: I discovered EMWA, a bunch of open and friendly people. Laura Collada, who is EMWA's Public Relations Officer, convinced me to start as administrator of the EMWA discussion group on LinkedIn, and Phillip Leventhal, the Editor-in-Chief of *Medical Writing*, encouraged me to become editor of a new section for medical writers like me, who either write in English as a second language or who write in languages other than English.

I feel strongly that *Medical Writing* needs a section for non-native speakers. Interestingly, I had already been thinking quite a bit about what it means to be a non-native English-speaking medical writer. Does it only mean problems with expressing thoughts correctly or using funny language constructions that make people laugh? Yes, of course, being a medical writer is a lot about having a good command of English, which we, non-native English speakers, must work hard to attain.

While preparing to write this editorial, I Googled a bit for various combinations of 'non-native English-speaking', 'medical writing', 'scientific writing', and so on. Surprisingly, almost all hits related to grammar, vocabulary, punctuation – in summary, to linguistic problems. There were few blogs where people shared their experience in writing or advised how to improve English writing skills. I found no links about what it means to be non-native English-speaking medical writer.

Is it only about language? Definitely not. To me, overall, being a medical writer means understanding science and being able to structure often complicated research concepts in a comprehensible way. It also means being able to communicate with the authors and grasping their ideas. Lastly, while trying to answer my question, I realised that one of the main tasks of medical writers is to help researchers publish their results and communicate their key messages. Here, the difference between non-native and native English-speaking medical writers comes in. Very often, those researchers are non-native English speakers who write poorly in English and who therefore translate their texts, word by word, into English. Language *per se* is a cultural notion, reflecting mentality and the way of thinking, and therefore knowing the mentality and the way of thinking is often critical for understanding and 'translating' texts into proper English.

Eventually, I realised that being a non-native English medical writer has advantages, for example, having the same cultural and linguistic background as those whose texts are edited, and thus understanding much more easily what the authors intended to say. It does not mean, though, that we can manage to make it all happen on our own. We often work closely with our native English-speaking colleagues. Working internationally means working in teams.

So what about medical writers who don't write in English? Everything that I have written so far is about medical writing in English, but many articles are written in our native languages. This aspect must not be forgotten. I am sure that we will read more about our experiences in writing in other languages.

Although I don't know how this section will evolve, I know what I want this section to be: a forum for us, the non-native English-speaking medical writers, where we can tell each other about our work experiences, our thoughts, and our funny stories. I also want us to be able to share our experiences working with clients from different languages and cultures and our thoughts on the international medical writing community.

Finally, I am pleased to introduce the first article in this section. Rossella Ferrari from Milan, Italy shares with us her thoughts on cultural and linguistic differences that impact the way we write.



If you would like to share your experiences and knowledge with other non-native English-speaking medical writers, please contact me at [maria.koltowska-haggstrom@propermedicalwriting.com](mailto:maria.koltowska-haggstrom@propermedicalwriting.com). Everybody is welcome to help make this section interesting reading.

## Acknowledgements

I thank Amy Whereat and Philip Leventhal for help editing this text.

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## Medical writing for non-native English speakers: Burden and opportunity

The amount of information transmitted in a particular language makes it what we define as the ‘language of science’,<sup>1</sup> and the dominance of the English language (the *lingua franca*) in science has been long established.<sup>2-4</sup> However, if we consider the life science peer-reviewed journals, currently non-native English-speaking authors contributed about 50% of publications,<sup>5</sup> a trend that continues to increase.

The circumstances and opportunities of medical writing in English are mainly related to manuscript publication (original or review articles) but not only. Other tasks to complete include training manuals for international sales task forces, PowerPoint presentations, international meeting reports, and fact sheets.

For non-native English speakers (NNEs) involved in medical writing, the challenge consists not only of speaking a second language (English) but also adding a third language, that is, the biomedical language, which gives rise to further difficulties.<sup>6</sup>

As Italian is my native language, in this article I have tried to focus on several ‘aetiological factors’ that give rise to hurdles in medical writing in English; I present practical suggestions wherever I have found them in the literature together with some of my personal reflections. In this approach, some hints coming from scientific writing are suitable even for medical writing in English. I have also benefited from several contributions made by applied linguistic researchers, who have conducted studies in the use of English for academic purposes.

### Needs to meet

In terms of publication success, historically, the rate of acceptance of manuscripts originating from NNEs is lower than from native English speakers (NEs), however this depends on the specific medical area and varies over time. In 2002, an Italian survey was conducted of publications in the journal *Cardiovascular Research*.<sup>7</sup> A group of

American and British authors served as the control group for a sample of 120 articles that were analysed without the knowledge of the author’s nationality and cross-checking. Overall, the control group had almost the same acceptance rate (30.4%) and overall ‘error’ rate as the test group. No direct relationship between acceptance rate and number of language errors was detected even if the badly written articles clearly correlated with a high rejection rate.

The structure of manuscripts, cultural errors, grammar and style, and wording are often identified as the main key issues for NNEs.<sup>8</sup> Stylistic differences between American and British English add further difficulties for NNEs, particularly when a manuscript has to be submitted to a British or American journal. Besides, the definition of a ‘grammar error’ is not always simple as, for example, in the use of tense in the discussion section of original articles.<sup>7</sup>

To extract and disseminate all the relevant scientific information and evidence, including that coming from countries with NNEs who have published in their mother tongue, a bilingual online publication system has been proposed as a first step to overcome language barriers in global scientific communication. Establishing a bilingual society in each European country seems to be the best or the only solution to the problem, but, although theoretically acceptable, reaching this objective may be time-consuming.<sup>9</sup> Since not every medical writer is in the lucky position of having an English professional or colleague who can revise their manuscript, as long as a society becomes bilingual, most NNEs basically have to count on themselves for this task.

### Structure

The organisational strategy needed to publish a manuscript may be one of the major opportunities to improve writing in any native language. Correct structures are the undeniable condition for clear communication because they improve the readability of our texts. For example, a sentence usually starts by creating perspective and then moves on to convey new information in the ‘next stress position’ (at the end of the sentence): this is a rhetorical

English emphasis pattern. The proximity of subject and verb immediately states the essence of information; connector devices create a cohesive flow of information and coherence through paragraphs. This is some of the most fundamental advice to ensure correct text organisation.<sup>10–12</sup>

Organising the structure of a text – meaning the information flow with cohesion and clarity – compels us to provide a logical and sequential order to the ideas we intend to communicate.<sup>13</sup> Yet, as linguistic researchers state, the organisational capabilities and practices are quite different between cultural groups because of different patterns or approaching modalities of the ideas to be presented. This means that different writing structures are linked to different thought patterns: the English pattern is a straight line of sequence, from introduction through to conclusion, whereas the pattern is circular for Asians, underlying an indirect style of presentation of ideas, and the arrangement is a zigzag trajectory for Latin people (Romance style), with the intent of encompassing all the aspects of an issue.<sup>14</sup>

These spontaneous aptitudes of NNEs must be changed in the English pattern to adapt the manuscript for the academic audience. In effect, a more organised sequence of ideas allows not only better control of the logical links between arguments but also more concise text and relevant information to be transmitted.

#### *Cultural errors*

A non-linear structure for scientific articles or discourses can provoke cultural errors, as linguistic researchers tell us. In the English linear structure, themes are presented by a succession of deductions in which one idea is directly linked to the next. Each paragraph begins with the general knowledge or the previous text, then introduces and develops new information, and ends when a new paragraph, with other information, is needed. The text structure should be planned by a hierarchy of importance to spell out the main idea and its subtopics or other ideas. The same key words and pattern of sentences are preferable and effective for showing similarities and differences in the manuscript sections (Introduction, Methods, Results and Discussion); indeed, limited key terms facilitate the readability for readers and reviewers.<sup>13</sup>

Usually, NNEs lack in subordinate sentences, which leads to an undifferentiated or non-hierarchical text structure. The management of defining and non-defining relative clauses may be different in English from other languages and it is often a source of concern for NNEs.

The use of a preposition in the continuum from possibility or probability to certainty, and from specificity to generality, is qualified by means of the modality system, which encompasses an array of devices coming from all the grammatical categories and the syntactical and organisational structure of sentences; this is often a critical area for NNEs. In the analysis of manuscripts prepared by NNEs, the incorrect use of *the* (the definite article), due to its modality function, constituted the most frequent mistake, followed by grammar (tense) and sentence structure errors.

Apart from lexical devices such as mitigators, the hedging use of passive voice is also common in the Italian language. Mitigators like ‘hardly’, ‘to a certain extent’, ‘almost’ are markers of politeness, essential to know and interiorise.

Discourse markers such as connectors or conjuncts ensure the correct flow in an organised structure, providing integration and interconnection among concepts, but their use is minimal; for example, ‘yet’ and ‘still’ (two important signals) are nearly absent in manuscripts prepared by NNEs.<sup>13</sup> The classification of conjuncts and their use in different contexts may also lead us to reflect on their correct use in our native language.

#### *Grammar and wording*

Grammar errors refer to the use of overly long and complex sentences, or unnecessary words, and the preferable use of verbs instead of corresponding nouns, positive statements compared with negative ones, the use of passive in place of active voice whenever possible, for example, in the Results section of original articles. In addition, false friends and other linguistic transfers are constant threats for NNEs during the writing process, particularly in translation tasks.

Other than grammar errors, limited vocabulary and register choices are among the most risky features of writing for NNEs. Wording in English is a challenge sometimes because of its richness of synonyms; nuances of definition or meaning are significant hurdles to overcome. Even Samuel Johnson, the author of the first *Dictionary of the English Language* in 1755, in his comments about some aspect of the language, identified the vast number of phrasal verbs as a remarkable problem for people who try to learn English.<sup>15</sup>

Three main categories of wording (lexical) errors have been recognised: (a) confusing words, (b) unnecessary words, and (c) inaccurate words.<sup>7</sup> In terms of jargon, specific for each discipline, the use of a small number of words has been proposed in

some linguistic studies to pinpoint recurrent key-words and lexical structures.<sup>16</sup>

In the difficult situation of quickly finding the most appropriate words in a discourse, patchwriting has to be pointed out as the wrong method. Patchwriting is a term that describes a writing process for academic purposes based on weaving original and borrowed texts, and it seems to be typical of some NNEs. Patchwriting should be regarded as different from plagiarism,<sup>17</sup> given the absence of clear intent to reproduce original ideas.<sup>18</sup> Paraphrasing or re-writing is challenging for NNEs, so patchwriting may be very tempting. Some NNEs found this habit suitable to meet cognitive needs, drafting their manuscripts not only for wording or lexical structure but also for English language style.<sup>16-19</sup> Moreover, patchwriting also seems to be caused by cultural values or lack of understanding as, for example, in Japanese universities.<sup>20</sup>

For a literature review, as an example, the text sources must be well understood, allowing for re-elaboration and integration, preserving the original meaning and avoiding any kind of plagiarism or patchwriting. Although for NNEs this fundamental process is more difficult and time-consuming than for NEs, the acquisition and re-elaboration of the text imply that the content becomes temporarily 'ours' so that we can convey it with our own expressions: rephrasing or summarising or both.

## Resources

During recent years, the market has boomed for dedicated short training courses or seminars; these ensure effective writing skills, which allow manuscripts to be successfully reviewed by editors and the manuscripts published. However, it is difficult to believe that this works.

In my opinion, continuous basic English language training is relevant for maintaining (or increasing) our linguistic platform. In addition, we can keep up-to-date through medical and scientific writing courses of high quality and effectiveness (if available), regular visits to selected websites and literature (e.g.: EMWA's *Medical Writing*, the *Journal of English for Academic Purposes*), and specialised books.

Given the high level of commitment required, the strength of our determination in carrying out this feat is also fundamental.

## Conclusions

Medical writing in the English language for NNEs is demanding, but I think it is worth making the effort

and taking all possible opportunities for improving our writing skills. Further, a good English level enables us to exchange experiences with colleagues from other countries and to take the opportunity to get up-to-date. Therefore, the most convenient solution is a 'to do list' based on a precise personal strategy, to choose and follow a precise training trajectory, and to capitalise on the burden of improving the structure of all our medical texts: a clear text structure reflects clear ideas.

In addition, linguistic and cultural diversity can provide a significant contribution to the medical writing community by offering different visions, always keeping in mind that language is a tool (or system) to clearly communicate and to give voice to scientific research data, evidence, and ideas that are worth communicating.

## Acknowledgements

I thank Barbara Grossman and Philip Leventhal for the editing of this manuscript.

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# Medical Writing Jumble # 11

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

by Anuradha Alahari, PAREXEL International  
 Illustration: Mobinah Iqbal, PAREXEL International

**PUTIN**   

**NUREI**   

**MORFIN**   

**GMEANA**   



Answer:

See page 58 for the answers.

# Out on Our Own

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## Editorial

With spring comes a renewed sense of optimism. A good time, perhaps, to review where we are in our businesses and consider how we can improve. Michelle Storm Lane of the Association of Independent

Professionals and the Self Employed (IPSE) provides five helpful hints on how we can become more effective freelancers. CV development expert, Matt Craven, tells us how to write an impactful professional profile that 'speaks' to our intended audience and improves our chances of attracting clients.

As has already been announced at previous conferences, EMWA is keen to ensure our more experienced members receive education and development opportunities beyond our foundation and advanced

workshops already offered. Several initiatives are being put in place to do just that, and Debbie Jordan describes these in more detail, with particular emphasis on those relevant to our fellow freelancers. As we look forward to the next conference in Dublin this May, Uwe Kollenkirchen reflects on his first conference in Florence last November. We love to hear from our freelance members, so please get in touch if you wish to write about your conference experiences, or any other aspect of freelancing life you wish to share with us on these pages. We look forward to seeing you in Dublin, Ireland in what is now only a few weeks time.

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## Life beyond EMWA's educational programme

Many people come to EMWA meetings for the excellent training offered through the EMWA Professional Development Programme (EPDP) and to gain their foundation and advanced certificates in medical writing. But experienced medical writers often ask what EMWA has to offer them once they have completed these programmes, or what it has to offer people who don't want to join them. This applies particularly to freelancers who have to fund EMWA membership themselves, and where attendance at conferences comes at considerable cost from conference and workshop fees, flights, and accommodation, as well as time away from the office when paid work is not being done.

One clear benefit of being a member of EMWA is that it is the only professional body for medical writers in Europe. By being a member of EMWA you are showing your commitment to your profession and recognising the importance of being a member of a professional organisation centred on your work. An excellent journal keeps you up to date with developments in the medical writing field and by attending conferences and workshops

you can find out what is changing in the way that we work. It is always good to attend workshops to increase your all-round knowledge – after all, we can always learn new things and it never hurts to hear someone else's view on a familiar topic. Also if you are an expert in a particular area then becoming a workshop leader is a good way to get involved in the organisation. Developing a workshop is also an excellent way of challenging your own knowledge and practices. EMWA conference are also a fantastic place for networking with colleagues to find out what others are doing in their day-to-day jobs and what is changing. There are also opportunities to get involved in running EMWA by joining a committee, or helping in the training aspects of the conferences by joining the EPDP committee, or helping out with EMWA's journal *Medical Writing*, either as a regular contributor, section editor, or assistant editor.

Experienced medical writers can also get involved in special initiatives such as the Budapest Working Group (BWG), which was set up by Sam Hamilton to review the clinical study report (CSR)

International Conference on Harmonisation (ICH) E3 guidelines. The BWG is also developing a similar set of guidelines for the development of protocols (which are currently only briefly covered in the ICH E6 guidelines). Another working group is the Good Writing Practice (GWP) Group that looks at creating standards for medical writing that cannot be found in style guides through a series of articles in the EMWA journal. Ultimately, a handbook on GWP will be produced that writers can use as a reference document.

EMWA has a unique pool of expertise and needs experienced people to share their experience and knowledge with a wider audience. How often do we moan about how badly some official documents are written or the fact that they don't reflect what it is really like to work as a medical writer? Getting involved in initiatives like the BWG and the GWP is a great way of initiating change. We are facing all sorts of challenges in the future as medical writing continues to develop. For example, regulatory agencies have now agreed to publish CSRs so that these are open to public scrutiny. We will also need to write a lay summary of CSRs when EU

directive 536/2014 is implemented in May 2016. EMWA needs to play an active role in these initiatives and needs its members to step up and get involved.

On a personal level, I have completed both my EMWA foundation and advanced certificates, I served on the EMWA Executive Committee for 2 years, I run three workshops at EMWA conferences, I contribute regular articles to *Medical Writing*, and I am involved in the BWG and GWP groups mentioned above. I find getting involved with EMWA on all of these levels to be stimulating and interesting. It stretches me to think 'outside the box' and to be at the forefront of where EMWA and medical writing are going in the future. It is also good to give something back to an organisation that has helped me to develop into the professional medical writer that I am today.

**Debbie Jordan**

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## EMWA Conference Florence 2014 – Insights of a newcomer

After attending nearly 80 scientific and medical conferences throughout my earlier career in the pharmaceutical industry and recently starting my own company in scientific writing, I was excited to attend a conference in my new field after being away from science and drug development for almost three years.

When I was asked to write a conference evaluation by sharing my 'newcomer' impressions in a short article, I felt a little nervous and flattered at the same time by the request. Being a newcomer in the medical writing business with little specific experience, my evaluation could potentially be far off target! But then again, I was asked for my newcomer impressions, so I thought: 'Why not give it a try?'

### *Registration for the conference*

After deciding to attend, online registration for the conference and booking a hotel was easy, but it took me some time to understand the structure of the conference. It mainly consists of parallel sessions in the format of training workshops which need to be booked and paid for in advance. When I tried to sign up for the workshops that interested me, I learned that some were already fully booked. Too

bad! So I looked for 'second choices' and registered for a total of three. Next step was to check on the social programme – important for networking! Unfortunately, most events were already sold out, however, seats at the networking reception on the first evening were still available and at no additional cost. Very good!

Once in Florence, the on-site registration was quickly done. No lining up as at big conferences. I experienced friendly and relaxed service at the registration desk and enjoyed a quick lunch that was already included in the registration fee. A good start!

### *Reception*

Though the workshops started in the afternoon immediately after the registration, the official opening took place in the evening with the usual welcome words by the President, Julia Donnelly, and former president, Andrea Rossi, who welcomed us to his home town. An entertaining lecture on 'What Scientific Societies Need from Medical Writers in the Mediterranean Region' by Ferdinando Fusco then led to the networking reception which provided a common ground for interaction and was supported by excellent local food

and wines. The conference programme promised 'A game where you will experience unique sensations that will inspire your medical writing ...'. I am still waiting for the writing inspiration, but it definitely stimulated vivid exchanges between participants. It also helped me to meet with several colleagues and learn about their business experience, e.g. regulations for setting up your own business in France, or the thoughts that drive a young scientist to make the move from academic research into medical writing. The reception was interesting and diverting, but when it ended, I realised that I had not met anybody who would be a potential client for freelance medical writing services. The majority of attendees seemed to be like me, looking out for contacts in the industry. Admittedly, a look at the list of participants shows that my perception cannot be totally true, but deliberate inclusion of industry representatives might be worth considering for future conferences.

### Workshops

Before discussing the workshops I attended, let me share my thoughts on the conference format.

I like small, workshop-based conferences because they encourage discussion on selected topics and interaction between the participants. This was achieved at the EMWA conference. However, the downside of having a series of parallel workshops divides the audience. Getting a close interaction, lots of discussion, and comprehensive coverage of topics in each of the workshops was great, but participants needed to decide on the topics they prefer most, thereby excluding five or six other concurrent sessions. So, over a two-day meeting, one could only participate in a maximum of four out of the offered 28 sessions and had to disregard the other 24. I am sure the EMWA Executive Committee has discussed this issue already several times before, but there might be still ways to improve on this. (Editor's note: this was the reason for starting the symposium and expert seminar series at EMWA Spring Conferences. However, EMWA membership is diverse and this wide choice is something which has always been welcomed in delegate surveys.)

Once in Florence, I started preparing for the workshops and realised I had overlooked the requirement to complete pre-workshop assignments. Thus, I had to spend time in my hotel room preparing for the courses. Interestingly, Tania Kotsokechagia had described similar experience in her article 'The new girl's EMWA conference'.<sup>1</sup>

However, this albeit brief preparation still helped me to follow the workshops in detail. All three turned out to be very interesting and worth

attending and I would rate all as very good to excellent:

- Walther Seiler gave an expert presentation on all aspects of clinical trial protocols in 'The Clinical Study Protocol: Content and Structure' workshop. The importance of the ICH guidelines E6(R1) and E3 was explained and the CDISC Protocol Representation Model (PRM v1.0) was emphasised as a key organisational model for the structure of clinical study protocols.<sup>2</sup> The content of a clinical study protocol was comprehensively covered and the discussion was lively and interactive.
- Understanding the principles of good clinical practice (GCP) and its application to writing and reviewing clinical trial documents was the objective of the 'GCP Training for Medical Writers' workshop. Gillian Pritchard presented a well-structured overview of ICH guidelines E3 and E6. With a mixture of presentations and group exercises, she successfully converted this potentially dry subject into an interesting learning event. Importantly, useful supplemental information for writing clinical study protocols and reports was discussed, e.g. the SPIRIT and the EQUATOR network.<sup>3,4</sup>
- The 'Writing Guidelines for Manuscripts' workshop by Andrea Rossi focused on manuscripts published in scientific journals. He facilitated the understanding of this large body of information buried in numerous guidelines in a well-prepared presentation supported by practical exercises. Getting articles published in scientific journals has become a very competitive field for authors and the correct application of publication guidelines is key. There are guidelines specific to almost every scientific area. A good overview on publication guidelines is provided by the EQUATOR network.<sup>4</sup>

### Freelance Business Forum

This session was open to everyone and aimed to provide freelancers (approximately 30% of EMWA members) a platform for exchanging experiences.

Short presentations covered the outcome of the recent EMWA survey on type and source of registration documents prepared by freelancers, the survey on fee setting for medical writing services planned for 2015, the benefits for freelance members of EMWA, and the freelance resource centre on the EMWA website.

The main part of the forum consisted of parallel networking table discussions where experienced

freelancers moderated discussions on topics raised spontaneously by attendees, e.g. the setting up of contracts, starting out as a freelancer, organising work in the home office, dealing with agencies who act as brokers between large companies and freelancers, and the billing and payment of freelance services. The participants were allowed to move from one table to the other, thus being able to engage in several discussions. A brief summary was given by the table moderators at the end to the forum.

Overall, the table discussions were very inspiring because of the open format, the possibility to casually interact with the other freelancers and get feedback from experienced medical writers on self-selected topics. I would have welcomed the inclusion of representatives from pharma or contract research organisations in this session because interaction between industry and freelancers in this forum would help in understanding each other's needs and expectations.

### Conclusions

Was it worth attending the 39th EMWA conference?

Yes. Because it was two days of well-organised and professionally conducted sessions and workshops with many opportunities to learn and to interact with other participants. The excellent venue significantly contributed to the pleasant and stimulating atmosphere. Just remember to register early if you want to attend the next conference and get your first choice workshops!

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## How to write a high-impact professional profile or summary

### Overview

Whether you are writing a CV, Executive Biography, LinkedIn profile, or Web Profile, aligning your message with the mindset of your audience is critical. Web-based channels are often restrictive but where you can, change your message for different audiences.

For example, if you are targeting yourself at medical writer roles and also considering opportunities within marketing communications, you would, in an ideal world, have two profiles. If I am looking for a dedicated market-access medical writer, I'll probably hire the person who is telling me that they are 'a PhD-educated medical writer specialising in the production of scientifically accurate and commercially compelling market-access collateral'. I probably won't hire the person who is telling me that they are 'an experienced medical writer with experience across a broad range of medical writing areas'.

This principal can be extrapolated across any discipline and ties in with the basic psychology of buying any product or service. Think about good Pay Per Click (Google Adwords) marketing; if I searched on the term 'Designer Sunglasses', am I more likely to buy from the advert that reads 'Designer Sunglasses' or the one that says

'Sunglasses from Designer Brands'? It is, of course, the former, because the advert is using the same phrase that I had in mind when typing my search term into Google. The same applies to recruiting – the client needs to know that you are a relevant individual for the role that they are hiring for and are going to derive this, initially, from line 1 of your CV.

If you ever wondered about the phrase 'you have 5 seconds to get the reader's attention', then this is exactly what we are talking about here; getting their attention isn't about yellow paper or fancy graphics, it's about presenting yourself as an appropriate candidate for the job!

### Target marketing

Once you have defined your direction, creating a profile needs to be viewed as a marketing exercise. By this I mean thinking about your target audience and what messages and areas of expertise they are going to respond to. Too many people write their profiles thinking introspectively rather than truly aligning their message with the needs of their potential clients. I recommend thinking about the key challenges that they might be facing within your specialist area and the skills they might require to assist them. These areas should be the focus of your profile.



### Go to market description

Start with a description of what you are, which should always relate to some form of functional job title that your clients and employers can identify with. For example, *'PhD-educated medical writer specialising in the production of scientifically accurate and commercially compelling Market-Access collateral'*. Cryptic descriptions get you nowhere – they may make sense to you, but not your audience. As basic as it sounds, job titles are universally recognised, so regardless of your freelance status, I would recommend this approach.

### Value proposition

Once you have defined a description of yourself, think about your value proposition. What I mean by this is: where do you add value to your customers? This leaves your audience under no illusion as to where you might fit in and how you can add value.

Put this together with the previous example, and you end up with a powerful statement as follows:

*A PhD-educated medical writer specialising in the production of scientifically accurate and commercially compelling market-access collateral that*

*drives superior traction for new products in the medical sector.*

### Areas of expertise and your blueprint for success

After you have provided this high-level 'helicopter-view-description' of what you are and what your value proposition is, I recommend describing what your blueprint for success is. Of course, this should be aligned with your client's needs and should tie in to your value proposition. For example: 'performing detailed research and analysis to ensure that literature is scientifically sound'; 'combining first class technical knowledge with commercial acumen to create literature that appeals to both clinical and non-clinical stakeholders'; or 'collaborating with other disciplines and using strong project management skills to ensure that projects are delivered on time, to budget and to specification'.

Note how these are written in a 'features and benefits style' or 'skill leading to xxx benefit'. I recommend four of these, strategically aligned with your marketplace and target audience. Note how they are focused on hard skills rather than vague or clichéd behavioural competencies.

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## The ultra-effective freelancer

An IPSE member recently told me how he had launched himself into freelancing with huge enthusiasm, but quickly discovered that being his own boss was 'no bed of roses'.

Freelancing can be an extremely satisfying and rewarding way of working, but it can also be an emotional rollercoaster. Medical writers often experience a constant cycle of feast and famine – the stress of too much work followed by the worry of not enough. The most effective freelancers are the ones who develop the resilience to deal with the natural dynamics of their business so that they can enjoy their working lives to the full.

Here are five enduring wisdoms used by many in our freelance community to make a bumpy ride a little bit smoother.

### 1. Know your 'rocks'

Stephen Covey is best known as the author of one of the great 'bibles' of productivity, 'The seven habits of highly effective people'.<sup>1</sup>

The third habit is to 'put first things first'. To illustrate the power of this principle, Stephen used rocks as a metaphor for the tasks that we face in our daily lives. Large rocks represent the things that are truly important to us, such as family, health, clients, or career ambitions. Small rocks are all those little tasks that tend to fill our lives without actually leading us to where we want to go.

A video of one of Stephen's popular talks shows the metaphor in action.<sup>2</sup> Stephen asks a volunteer to fill a bucket with a mix of large rocks and pea-sized pebbles. When the small pebbles are placed in the bucket first, the volunteer finds that there is no space left in the bucket to fit the large rocks. Then Stephen asks the volunteer to try it the other way around – placing the large rocks (the things that really matter) into the bucket first. The volunteer is then able to pour the pebbles over the large rocks and finds that they fall naturally into the spaces between the rocks. By putting the large rocks first, all the rocks and pebbles fit into the bucket.

This striking analogy shows how, if you prioritise the things that really matter, everything else tends to fall into place.

So what is the best way to work out what really matters?

Doug Belshaw offers a fairly radical solution: write your own obituary!

In his fantastic ebook, *'#uppingyourgame'*,<sup>3</sup> he recalls:

'I'll never forget the look on the faces of my form class when, as a teacher, I asked them to write their obituary. They thought it was morbid, creepy, and that I was a little bit crazy. Once they got into it, however, they realised, as I had done, how eye-opening it can be'.

He explains that the exercise is a great way to focus the mind on your deeper purpose, the things that you want to be remembered for. You are likely to feel more motivated to achieve something when you know why you want to achieve it. Doug describes this effect as a 'well of productivity'.

## 2. Remove distraction

Phil Dobson, the founder of BrainWorkshops®, runs training courses based on the science of peak performance. He feels that one of the biggest enemies of effectiveness for freelancers is the overwhelming number of distractions all around us.

'When we're plugged into email all the time and we're accessible by so many people, our direction can be led by others', he says. 'We become very reactionary and responsive with this constant stream of requests, and if we're not careful, our direction towards our goal can be compromised'.

Phil warns us to be aware of the addictive power of the alerts that bombard us from every piece of technology we own: 'We feel good when we get a Facebook 'like'. We get a little shot of dopamine and the reward centre in our brain goes 'yes, more of that please', but the cost is that our productivity is destroyed'.

He recommends disabling alerts on smartphones and computers to allow the brain to focus on one task at a time.

'Your brain evolved to notice things that it's not expecting, to keep you alive', he explains. 'So a beep from your phone, just as much as a visual alert on your screen, shifts your brain from what it was doing. It goes from task A to task B, and some studies have shown that the time it takes to shift back to task A can be as much as half an hour. In fact, multitasking has been shown to reduce our effective IQ by up to 10 points'.

The more we encourage ourselves to concentrate on one thing, the better we become at it, thanks to

the brain's plasticity. Conversely, if we constantly multitask, our neurones reorganise themselves to make us more prone to dividing our attention across several tasks, thus decreasing our effectiveness. To put this into perspective, multitasking has been estimated to cost the global economy \$450 billion annually.<sup>4</sup>

Lisa Carter, an independent Chartered Clinical Psychologist, recommends the technique of 'mindfulness' as a useful way of practicing the art of focusing: 'Originally mindfulness was a form of meditation but now it is being used in everyday life by many people. It involves focusing your attention on just one thing 'in the moment'. It's also very healthy to have short-, medium-, and long-term goals, because if you achieve the short-term goals, it gives you that boost in confidence to lead you to the medium-term goals, and so on. So as you achieve the first step, you feel better able to take the next.

## 3. Take breaks

Do you struggle motivating yourself to work?

Often, the opposite is true – freelancers can be particularly bad at dragging themselves *away* from their desks.

But if you fall into the trap of working all night, every weekend, and never taking any holidays, your effectiveness as a professional will suffer.

The dangers of overwork have been well documented for a very long time. An article in the *Journal of the American Medical Association* in 1977 observed: 'Overwork, i.e. working beyond one's endurance and recuperative capacities, may be a hazard in certain personality types engaged in open-ended occupations. Some persons appear to lack an inner 'governor' and for various reasons ignore the commonplace signs that inform one of the need for rest or recreation. If they are engaged in occupations that do not have a finite workday, they may at times exceed their bodies' ability to recover. Clusters of symptoms may then develop, some of which may mimic serious physical ailments'.<sup>5</sup>

In the absence of a corporate structure, the only way for a freelance medical writer to have a 'finite workday', is to create boundaries.

For example, Phil Dobson has set a number of rules for his freelance business. He always has a lunch break away from his desk and uses deadlines to make sure that he finishes work at a reasonable hour.

He also highlights the 'Pomodoro technique'<sup>6</sup> as a way to improve focus and keep the brain fresh throughout the day. This involves working in 25-

minute chunks with a five-minute break between them. Using a timer can provide that extra motivation to focus during the 25-minute session.

Another freelancer, Alison Coward, gives herself an annual holiday allowance of 25 days to ensure that she takes enough time off.

Sean d'Souza goes one step further and schedules three months off every year. In order to fit his heavy workload into the remaining nine months, he hones his skills continually to be able to work more effectively. For example, he has managed to reduce the time it takes him to write an article from two days to 45 minutes. He has also trained himself to rise at 4 am every day, to take advantage of the quiet time, free of distractions, before everyone else wakes up.<sup>7</sup>

#### 4. Pay attention to your body

'Stress is helpful in small doses. It helps us to rise to challenges and motivates us to do our best', says Lisa Carter. But as a self-employed psychologist, she is only too aware of the need to manage stress in order to avoid it becoming a threat to effectiveness.

'Some people thrive on high-level stress and excitement in their life, but others tend to fall apart when faced with smaller obstacles, so it really differs between people as to when stress becomes a problem', notes Lisa. 'But there are certain early warning signs that we might notice. It might include feeling tired all the time, changes in your concentration, minor changes in your health, such as a rash or headaches. Even going to the toilet more often can be an indication of stress'.

Lisa says the problem is that we often don't notice until it has gone too far: 'Particularly as freelancers we tend to soldier on, so we don't notice the little niggles of our body trying to tell us that something's wrong. Added to that, we can't really afford the time off if we're ill. But eventually it could lead to a loss of productivity, because if your concentration and motivation suffer as a result of high levels of stress then you can't do the best that you can in your work. If you're not performing at your best you may damage your reputation and it could have a devastating effect on your business'.

Lisa advocates looking after your body as one of the best ways to prevent stress: 'Make sure you have a healthy diet and really be sure to make time for exercise because the endorphins released through exercise are the best anti-stress, anti-anxiety and anti-depressant drugs out there. Be

aware about putting that into your plan - it's about being clear about what you want to do when'.

#### 5. Don't be too hard on yourself

Freelancers are expected to be high-energy, solutions-focused, and positive all the time, which can be exhausting.

'When we think about being employed versus being a freelancer, clients are much harder taskmasters than bosses and we really do have to be our best', agrees Lisa. 'We can get caught up in expecting too much of ourselves and that can, again, contribute to stress. So we need to be realistic about what we can achieve'.

Lisa believes that freelancers should be brave enough to manage client expectations and negotiate deadlines around what is realistic: 'Clients respect that. It's a case of being realistic about what is 'good' and not being too perfectionistic in your work. A great contributor of stress is having this belief that you need to be perfect'.

'Awareness and willingness are very important', she concludes. 'Be aware that stress can affect anyone, even you. And when you recognise that you might have the symptoms of stress, be willing to manage that stress'.

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## Freelance foraging

...and they say we speak the same language as our friends 'down under'! This sign advertising flip-flops in Darwin reminds us to make that extra language check for every document!



Answers to Medical Writing Jumble #11:  
INPUT, URINE, INFORM, MANAGE.  
The CEO of the opioids manufacturing company  
was fond of saying, "No pain, no gain".