Medical Writing

Writing for Lay Audiences

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Contents

Themes of upcoming issues of *Medical Writing*

March 2016: The theme will be 'Authors and authorship'. The issue will include articles on GPP3 and the Sunshine act, who should and should not be an author on publications, and medical writing practice/ ghost writing survey. This issue is now closed to new submissions.

June 2016: The theme will be 'Medical communications'. This will include articles on careers in medical communications and medical education and the different kinds of documents that people in these fields prepare. *The deadline for feature articles is February 14, 2016.*

September 2016: The theme will be 'Statistics'. This will include articles on presenting and understanding basic statistics for medical writers. The deadline for feature articles is to be determined.

December 2016: The theme will be 'Project and team management'. The deadline for feature articles is to be determined.

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**.

Writing for lay audiences

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For most of us, medical writing is highly technical. We prepare regulatory or clinical documents or write materials targeted to medical doctors. Medical writing for lay audiences is different, and it does not come naturally to most of us because we are often locked into our specialties and specialised way of writing. What's more, most of us started our careers as scientists. **Joyce Salita** explains that scientists (and therefore most medical writers) face a variety of challenges in writing for lay audiences.

Writing patient education materials, for example, requires a skillset unusual for most medical writers. **Stella Hart** describes that writers preparing patient education materials need to be able to empathise with the patient's experience, ask interactive questions, and write in a way that is appropriate for their audience's literacy level. This touches on issues of readability and 'health literacy', and it means that the writer must be able to explain complex medical issues in a way that can help patients make choices related to prevention and treatment – not an easy task.

Writing for lay audiences is also increasing relevant for regulatory writers. According to **Lisa Chamberlain James**, there has been 'a paradigm shift in the pharmaceutical industry and regulatory agencies towards transparency and an emphasis on the benefit-risk ratio of medicines'. Risk management plan (RMP) Section VI.2, established in 2013, and Regulation EU 536/2014 require regulatory writers to prepare lay summaries and explain risk-benefit to lay audiences in a way that avoids bias and confusion. As pointed out in Lisa's article and a second article by **Kerstin Prechtel** and **Stefanie Rechtsteiner**, the RMP legislation creates an enormous challenge because it requires submission of a public summary that must simultaneously be understood by regulators, industry, healthcare professionals, and patients; must be medically accurate; and must convey all relevant information needed for a medicine's authorisation. In addition, as described by **Claire Gillow**, recent EU legislation also requires that a layperson summary accompany clinical trial summaries – even though regulatory guidance is not yet available.

Regulatory writers are also called on to prepare package leaflets. The legislation and template for the preparation of patient leaflets have been around for more than 15 years, but **Antoinette Fage-Butler** explains that they have not necessarily simplified the task of preparing these materials. She advocates replacing the template with a set of recommendations that allows regulatory writers greater freedom to respond to patients' needs.

With the different skills needed to write for lay audiences (not to mention the evolving requirements and guidelines), how can a medical writer feel confident that the documents they write for lay audiences are understood and accomplish their objectives? One answer is user testing, in which feedback from test users is used to improve the quality of educational materials. **Theo Raynor and colleagues** describe their experience in employing user testing to test and improve not only information for patients but also information for professionals and other audiences.

For those medical writers who already have a knack for lay writing, medical journalism might be attractive. **Jo Whelan** describes medical journalism and how a medical writer might find work, and **Sonya Collins** describes how elements of storytelling are used in medical journalism. Finally, **Stevan Mijomanović** and **Sofija Mićić Kandijaš** discuss medical blogs, an extension of medical journalism and an increasingly popular way of communicating medical information.

A new look for 2016

In 2011, the EMWA journal had its name changed from *The Write Stuff* to *Medical Writing*. This was part of a move to a professional journal publisher. However, since making the switch, we have received many comments expressing a desire for a less academic look and layout. This desire was

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confirmed by responses to a survey this last summer. A less academic look better fits our focus on practically useful information rather than academic-style research. I am happy to report that starting with the first issue of 2016, we will have a new, friendlier look. Other positive changes are afoot, so stay tuned.

President's Message

Sam Hamilton

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Dear EMWA Members,

As we came together in the historic city of The Hague in November 2015 for another successful and enjoyable conference, we were particularly delighted to welcome our Benelux members who turned out in force. The usual EMWA egalitarian spirit was boosted with a little cocktail shaking and salsa dancing this time around. These great socials were the icing on the cake of a packed learning programme: 21 foundation and advanced level workshops bolstered with a fantastic range of free events including the InScience Communications-sponsored lunch symposium; a question and answer session on the first EMWA Special Project, the CORE (**C**larity and **O**penness in **R**eporting: **E**3-based) Reference project; an update on the second EMWA Special Project, the PVSIG (Pharmacovigilance Special Interest Group) and the lively Freelance Business Forum - and all in 2 days!

As memories of The Hague settle, and we approach the end of 2015, it is time to think about our hopes for the coming year. As elections for the Executive Committee are around the corner, please consider the contribution you might make. We need committed people to help shape the future of our association. Remember the key aspirations that underpin EMWA's growth and longevity: retaining experienced members and influencing our industry. If challenges like these make your creative juices flow, why not step forward?

In such a deadline-driven industry, we all need to rest at times, so I wish you all a relaxing festive season. With your feet up, browse this December 2015 issue of MEW on writing for lay audiences, and look forward to the new-look MEW in 2016 with our new publisher. Happy 2016!

Best wishes,
Sam Hamilton

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Writing for lay audiences: A challenge for scientists

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Abstract

Writing for lay audiences, especially lay summaries, is needed to increase health and science literacy, but this kind of writing can be difficult for scientists. The article describes why it can be so difficult and gives some advice on how scientists can cope with the challenge and how institutions and organisations can help.

Keywords: Lay writing, Lay audiences, Lay summary

Changes in media landscape have made specialised information readily accessible to the public and have allowed companies and organisations to advertise their products widely. Healthcare providers, research institutions, and individual scientists have found electronic media an effective way of educating and informing, that is, to 'market science by one click'.[1]

The ability to write for lay audiences is increasingly important for scientists. For example, the PLOS journals publish non-technical summaries for peer-reviewed articles[2] as part of their commitment to public engagement. Public funding bodies and charities also require lay summaries for grant applications[3] because they recognise the importance of having lay audiences evaluate whether they are funding research that corresponds to the needs of their members.[4] In addition, some research organisations have blogs to inform and update the public and express opinions about certain aspects of research not necessarily discussed in scientific papers. In this way, organisations help the public to better understand science, while increasing their social media presence.[5] A quarter of scientists blog for the same reasons.[6]

Involving the public in this way can improve the quality of research and help develop new research strategies.[4] This process also aids in transparency, which is not only an ethic issue[7] but can also facilitate interdisciplinary research.[2]

Why it is difficult for scientists to write for lay audiences

Many academics find it difficult to write for lay audiences.[8] Not everyone can blog like Martin Robbins or write informative pieces for lay audiences like Stephen Hawking or E.O. Wilson.

Specialised knowledge and language

A scientist's specialised knowledge is often a hindrance to effective lay communication.[9] Effective lay communication requires that the expert anticipates the audience's knowledge or perspective on the subject.[10] Scientists are trained to publish scientific papers and to discuss findings with peers, which often makes them unable to understand how others think.[11] A study by the Royal College of Practitioners (RCGP) in England showed that about a half of adult patients do not understand the verbal advice given by doctors even if it is supported with written patient information.[12] In fact, much patient information material is criticised for not serving its purpose.[13,14]

Another problem is that scientists often use specialised language or jargon because they fear being inaccurate.[3] The use of jargons is of course discouraged in lay communication because lay audiences find jargon difficult to understand and confusing. However, whether a word is jargon or a standard term can sometimes be difficult to determine.[15] For example, words like *acute*, *chronic*, and *significant* can be considered jargon because not everyone truly understands what they mean.[16] Also, some expressions can be misinterpreted by lay audiences, for example, *positive correlation*, which may be interpreted as something good.[17] Other words that might be interpreted differently by scientists and lay audiences are listed in Table 1.

Some words are not easily expressed in simple terms, such as *nitrogen fixation* and *oxidation*.[2] Also, doctors and scientists have a distinct writing style, as shown by their use of prepositions and articles, such as in the examples below:[16]

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- *treatments working in patients* instead of *for patients*
- *drugs used in hypertension* instead of *on/for/against hypertension*
- *bacteria that are deadly in mice* instead of *to mice*
- *prospects for recovery after stroke* instead of *prospects for recovery after a stroke*

Expressing statistics and uncertainty

Also, scientists are used to expressing uncertainties or demonstrating validity through statistics, which can be hard to translate in lay language. For example, *a slight but statistically significant ($p = 0.001$) difference in growth rate* is difficult to express in lay terms. The problem gets worse if the results are conflicting and a straightforward conclusion cannot be drawn. Although most lay readers have no knowledge of and are not interested in statistics,[18] many scientists find it difficult to leave out such details, feeling that they are necessary to accurately transmit their message. Science journalists, who often act as bridge between scientists and lay readers, have often been criticised of oversimplifying or even filtering information.[8,18] For instance, *could*, *might*, and *may* are not necessarily good substitutes for carefully formulated statements, and *powerful evidence* or *a breakthrough* can sound exaggerated.

Risks of generalising

As a result of generalising and leaving out details, information can mislead. This is a concern for 'broad collective citizen participation'[19] because the public might negatively react or overreact to a new finding. For example, a discovery in medicine may be misinterpreted to suggest that a cure to a disease will be soon available,[8] or a new virus might be hyped and cause unnecessary panic. On the other hand, some say that scientists are partly to blame for the public's confusion and indifference about climate change; they say that the use of too many levels of likelihood terms (*likely*, *unlikely*, and *most likely*) makes climate scientists sound unsure of themselves.[17] This can make the dissemination of scientific information counterproductive.

Heterogeneous audience

Lay audiences are heterogeneous. Scientists find it easier to write for peers because it is easier to focus the message. A lay audience is a mixture of different ages, cultures, professions, and socio-economic backgrounds, each with its own 'language'. In many cases, the lay audience is poorly defined[4] so that the scientist is left groping in the dark.

A culture of exclusivity

Some scientists are guilty of intentionally writing 'abstrusely…to prove their intellectual superiority',[3] and some think that what academics write does not have to be understood by everyone,[20] quoting Stephen Jay Gould, 'science selects for poor writing'.[3] For example, although many scientists blog to bring science to the public, others find 'writing for masses' a waste of time[21] or think that lay summaries are not 'a good use of a researcher's time'.[2] In a discussion in Research Gates' online forum on the difference between writing a textbook and a peer-reviewed article, one of the respondents admitted that writing a textbook was one of the most difficult accomplishments he had had. However, whereas 'anyone' can write a textbook, few can publish in high-impact journals.[22] This greater emphasis on peer-reviewed articles highlights the special 'culture of exclusivity' around academia, which is strengthened through the 'publish-or-perish tenure process'.[21] Writing for lay audiences can therefore be 'professionally risky'[23] and have little incentive for scientists.[6]

What to do about these difficulties

Common writing tips

For scientists who see the importance of lay communication and do not consider it a 'sacrifice' of

Table 1: Scientific terms that have different meanings for lay audiences

Scientific term	Meaning for lay audiences	Suggested equivalent for lay audiences
Significant	Important	Did not happen by chance
Fraction	Small part	A part
Trauma	Psychological event	Physical damage
Enhance	Improve	Intensify, increase
Positive trend	Good trend	Upward trend
Positive feedback	Good response, praise	Vicious cycle, self-reinforcing
Theory	Hunch, speculation	Scientific understanding
Uncertainty	Ignorance	Range
Error	Mistake, wrong, incorrect	Difference from exact true value
Bias	Distortion, political motive	Offset from an observation
Values	Ethics, monetary value	Numbers, quantity
Scheme	Devious plot	Systematic plan
Anomaly	Abnormal occurrence	Change from long-term average

Based on Freeman[16] and Somerville and Hassol.[17]

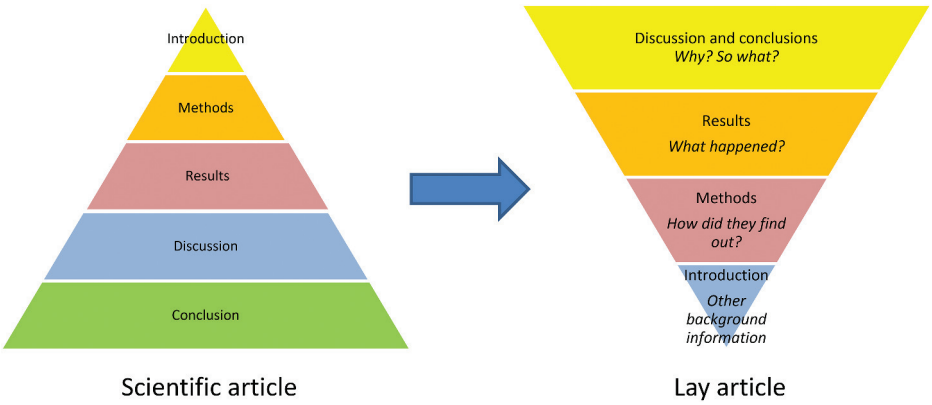

Figure 1: Structure of scientific articles and lay communications. A scientific structure has a pyramid structure in which the information starts with an introduction and ends with the discussion and conclusions. In contrast, a lay summary has an inverted pyramid structure in which the reader is first told about the conclusions and is then led in the opposite order to the more detailed background information. In this way, the interest of the lay reader is captured, and the interest is held while they are informed about the details of what happened, how they found out, and other aspects of the background.

their academic performance, there is much advice on how to write for lay audiences.[24–26] Common tips include:

- Avoid jargon
- Exclude details that may not be interesting for the readers
- Use plain language (see also issue 24(1) of *Medical Writing*)
- Use the active voice
- Use visual aids

Identify what the reader needs to know

Heterogeneity of the lay audience is a difficulty, so it is advisable to at least identify what is important for the lay reader to know[26] and to provide this information.[3] Technical writers who write instruction manuals expect that readers want to know how a product is used. Therefore, for a manual to be user-friendly, it should contain step-by-step instructions with short and simple sentences and well-labelled pictures; detailed information about the properties of the product is found somewhere else. On the other hand, lay summaries of research proposals should answer '*So what?*' or '*Why* is the research important?' instead of '*How should the research be conducted?*'[27]

Identify the reading level of the audience

If possible, the age group or reading level of the audience should be identified.[28] Readability calculations are based on several readability statistics, each of which has pros and cons.[28,29] Readability can be computed manually or with word processing software (e.g., MS Word, Open Office) and online word processors such as Google Docs.[28] All readability statistics only provide an idea of complexity or wordiness and do not assess the effectiveness of your writing because they are 'insensitive to meaning or intention'.[30] Nonetheless, they can be a good indicator of how well your readers can follow your text.[28]

Make your writing interesting

Tell your story with enthusiasm – share your knowledge in a compelling way.[11,25,26,31] One idea is to write using an inverted pyramid structure, wherein the article starts with the conclusion and discussion (as they contain the most important message) and end with the introduction or background information (Figure 1).[25,26] Writing plainly on *what, who, when* and *where* can be dry, whereas answering *why* and *so what* can make your writing more compelling.[27]

Other tips

Other good tips include reading your text aloud to non-specialists and using their feedback to detect jargon and other forms of inaccessible language.[4,23] Remember also that 'practice makes perfect' – your lay writing skills will improve over time.[23]

Role of scientific and funding institutions

Many efforts have been made to improve communication targeted at lay audiences. For example, to address the problem of jargon, many organisations publish a glossary of lay terms. Organisations should cooperate to standardise their glossaries to avoid contradictory information, facilitate sharing, and improve usability.[4]

Guidelines and guidance notes

Guidelines or guidance notes are available from most organisations requiring lay summaries, such as the Asthma UK Foundation and the Muscular Dystrophy Campaign.[4] These guidelines include not only information on content and structure of lay information but also instructions on what language should be used (e.g., UK English or plain English), as well as details on punctuation and spelling, use of active voice, and appropriate tone. Each organisation should develop its own guidelines to meet the objectives of its lay texts. The size limit of lay versions is not always provided and can vary. For example, the UK Research Councils permit 4000 characters, the Stroke Association allows 1000 words, whereas the Proceedings of the National Academy of Sciences of the USA allows only 120 words and the British Heart Foundation allows only 100 words.[23,27]

Templates and forms

Templates and forms are also very helpful in writing for lay audiences. The Stroke Association requires that lay summaries answer the questions that lay people have about the research.[4] To achieve this, they provide forms with questions of interest to a lay person (Figure 2).

Evaluation of lay material effectiveness

Writing lay summaries and patient information materials are useless if they are difficult for the target group to understand. Organisations should provide a means for lay audiences to evaluate written materials.[4] Although most organisations provide a 'comments' section, the wide variety of responses can be difficult to evaluate. Organisations should instead use surveys, interviews or easy-to-use feedback systems to gather measurable information on how understandable their lay materials are as practised by some US CDC offices.[32] This may also help to avoid the current mismatch between readability level and literacy skills.[28] The US CDC measures progress made in production of lay materials through feedback from lay audiences and regular reports from its staff on the changes.[32]

Different levels of information

Content of lay materials should be produced at several readability levels.[2] Also, different lay audiences require information to be presented in different ways.[3,6] Some museums have several types of audio guides available not only in different languages but also for different age groups (children, teenagers and adults), which has increased interest in museums.[33] Different levels of detail and presentation of a lay material can be worthwhile.

Specialised education on lay communication for scientists

The importance of specialised training for writing for lay audiences has been recognised by Cancer Help UK[34] and the CDC.[32] They understand that researchers find it hard to write for lay audiences, so they have provided their team with training. Also, PLOS has a team of editors and writers that write lay summaries for peer-reviewed articles.[34]

A: About the research

(i) What is the research about?

(ii) How will the research have an impact on stroke survivors?

(iii) How does the research build on research that has already been done?

B: About the researchers

(i) What is the applicants' experience in stroke research?

C: How will the research be carried out?

(i) What does the research involve for people taking part? Are there any risks?

(ii) What information will you collect, and how will you use it?

(iii) Will people have to travel to take part? Will you pay their expenses?

(iv) How will you make sure no-one is out of pocket by participating?

(v) How will you keep the people that took part informed about progress and results?

D: What happens when the project is finished?

(i) What will you do with the information you collected from people who took part?

Figure 2: Questions to guide writing a lay summary required for grant applications. Source: Stroke Association (https://www.stroke.org.uk/research/looking-funding/apply-project-grant). Reprinted with permission.

After all, lay communication is not just taking out jargon and replacing it with more understandable text but rather a complete 'repackaging' of the scientific message.[35]

Brownell *et al.* plead for including a lay writing course in the curricula of undergraduate and graduate science programs.[8] Scientists should be trained early enough not only in how to communicate with lay audiences but also about the importance of the associated values, namely, that informing the public is a duty and not a time-consuming downgrading of scientific work.

Scientists should be made aware that communicating scientific work directly to the public is a positive step towards eliminating the impact of misinterpretation or misrepresentation by the press.[23] They should also be informed that lay communication is rewarding and academically productive because it is the best way to gain public support.[7] Through time and re-education of the new generation of scientists, the needed cultural change will take place.

Journals and publishers

Journals and publishers should require lay versions of publications[23]. This will strengthen the scientist's effort to communicate their science to lay audiences. The editor-in-chief of *Ecology* agrees but is worried that an ineffective lay version will only be ridiculed by scientists.[2] A truly good lay version should still communicate the relevance of the research, but this may require additional writing support and

A

Background

Patients retained in HIV care but not on antiretroviral therapy (ART) represent an important part of the HIV care cascade in the United States. Even in an era of more tolerable and efficacious ART, decision making in regards to ART offer and uptake remains complex and calls for exploration of both patient and provider perspectives. We sought to understand reasons for lack of ART usage in patients meeting the Health Resources Services Administration definition of retention as well as what motivated HIV primary care appointment attendance in the absence of ART.

B

Background

AIDS has killed about 39 million people since the first recorded case of the disease in 1981, and about 35 million people are currently infected with HIV, the virus that causes AIDS. HIV, which is usually transmitted through unprotected sex with an infected partner, destroys CD4 lymphocytes and other immune system cells, leaving infected individuals susceptible to other serious infections and to unusual cancers. Early in the epidemic, most HIV-positive individuals died from an AIDS-defining illness such as recurrent pneumonia, severe fungal infection, or Kaposi's sarcoma (a type of cancer). Nowadays, although there is still no cure for AIDS, treatment with antiretroviral drugs (antiretroviral therapy or ART) can hold HIV in check, and, at least in affluent countries, HIV-positive individuals who are on ART now have a near-normal life expectancy.

Why Was This Study Done?

HIV-positive individuals originally only started ART when their CD4 cell count fell below 200 cells/mm3 blood. As ART became more tolerable and more efficacious and as the harmful effects of viremia (HIV in the blood) became clear, the treatment threshold shifted upwards. Nowadays, the US ART guidelines, for example, recommend treatment for all HIV-infected individuals irrespective of cell count and, because ART reduces the risk of an HIV-infected individual transmitting the virus to an uninfected sexual partner, also endorse offering ART for the prevention of HIV transmission. However, 40,000 HIV-positive individuals in the US receive regular HIV care such as virus monitoring but are not prescribed ART, and 5% of individuals starting ART discontinue treatment. It is important to understand why HIV-positive individuals do not use ART, but decision making in relation to ART is complex, involving both the HIV-positive individual and their HIV care provider. HIV-positive individuals may refuse ART if they think their care provider does not believe they really need treatment, for example, and providers may not offer ART to someone they think will not adhere to treatment. Here, the researchers undertake a qualitative patient-provider dyadic study (an analysis of contrasts and overlaps between pairs of narratives) to investigate why some HIV-positive individuals are retained in HIV care but are not on ART and what motivates these individuals to attend HIV care clinics.

Figure 3: Example of a lay summary based on a publication in a peer-reviewed journal. (A) Background part of the abstract provided by the author(s). (B) Corresponding parts of the non-technical lay version as written by an experienced editor. Source: Christopoulos *et al.* PLOS Med. 2015 Aug 11;12(8):e1001863. Reprinted under Creative Commons open access.

therefore cost. An example of a non-technical version of the background part of an abstract is shown in Figure 3. To support the usefulness of lay summaries, cost-benefit assessment and, therefore, additional evidence about the public's attitude towards lay information is needed.[36]

Conclusion

The path towards lay communication will not be simple, but if scientists are willing to learn how to balance accuracy and accessibility,[23] they can overcome the pitfalls. Not all scientists are gifted writers, but because they are trained to think clearly, they should be able to write clearly and share their enthusiasm with not only their peers but also with the public.[11] Cooperation between scientists and organisations can truly strengthen the commitment to engage the public and to make scientific information accessible .

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Patient education accessibility

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Abstract

Patient education that overcomes literacy barriers supports quality care. This article provides an overview of health literacy, describes the concepts of readability and accessibility, and discusses how to empathise with the patient's experience and ask interactive questions. The tips in this article are based on a learner-centred approach and 20 years of publishing X-Plain® patient education tutorials. This information should help health content writers facilitate patient comprehension, improve health outcomes, and achieve care goals set by healthcare providers.

Keywords: Patient education, Patient engagement, Accessibility, Health literacy, Readability

Patient education accessibility involves creating health materials that are designed and presented so that they can be understood by audiences of diverse literacy levels. Certain instructional design principles, along with strategies to enhance readability, help facilitate patient understanding, bridge gaps in health literacy, improve health outcomes, and reduce readmission rates. Successful patient education enables patients and their families to become active members of their healthcare team, empowers them to ask questions, supports communication with healthcare providers, and results in shared decision making.

Health literacy

Health literacy is the ability to understand and process health information in order to make competent choices related to prevention and treatment of health problems. Health literacy is a stronger predictor of health outcomes than age, income, employment status, education level, or race.[1] Low health literacy is associated with poorer health outcomes, including increased rates of hospitalization and mortality. Low health literacy is related to general illiteracy. According to the National Assessment of Adult Literacy, 14% of the United States population struggles to write, read, listen, or speak effectively.[2] The cost of low health literacy for the United States economy is estimated at up to $238 billion U.S. dollars each year.[3] In fact, the mortality rate attributable to low education is comparable to the mortality rate for smoking tobacco, and educational disparities widen with each successive generation.[4]

Medical writers are tasked with simplifying content so that it reaches all patient populations, especially those most at risk for not understanding critical health information. Various educational models and adult learning theories can help medical writers achieve desired behavioural outcomes and support long-term recall of information for health consumers. Common behavioural goals in patient education include making informed decisions, developing skills for self-care at home, committing to medication compliance, and modifying habits for a healthier lifestyle.

Readability and accessible language

Reading level can be calculated with automated formulas that are based on word length, punctuation use, and number of syllables.[5] However, automated readability calculations can be misleading. For instance, you might write 'See a healthcare provider for treatment without ado.' According to an online readability calculator, this sentence is written at a fifth grade reading level, even though the word 'ado' is not widely used. Saying 'See a healthcare provider for treatment without delay' is easier to understand, but the formula generated by a computer gives this sentence a higher readability level because the word 'delay' is longer than 'ado.' This sentence could still be made clearer: 'See a healthcare provider for treatment right away.' The reading level for this sentence is second grade. Writers should therefore use tools that calculate readability in conjunction with their own judgment.

Using such formulas is not the only way to improve readability. Content should be simplified, presented impartially, and organized in a logical order. Content structured so that it gradually

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builds understanding from the simple to the complex helps consumers understand the main points and supporting details. The structure and organization of the lesson should be apparent to the patient in advance so that he or she knows what to expect from the program. An 'advance organizer' provides clear orientation for users to process the information they are about to take in. Such a map is critical for individuals with learning disabilities or low literacy levels.[6]

Writers should break down complex medical concepts into short words and sentences.[7] Speaking directly to the patient, using active voice, and avoiding clichés and idioms increases accessibility and reduces confusion.[7]

Punctuation and numerical values should be chosen based on what is most understandable to the audience. Symbols should be used cautiously.[8] For example, not all patients may recognize the ampersand symbol (&).[9] Conversely, the per cent symbol (%) is more understandable and recognizable than the word 'per cent.'

Writers should explain technical or uncommon words with definitions and examples.[7] Information that may be new or unfamiliar to a reader can be phrased strategically so the reader can gather clues from the context to increase comprehension. Using the same word consistently instead of synonyms can also help prevent confusion.

Using concrete or practical examples to illustrate a point can help further a patient's understanding and influence their behaviour. For example, 'Your healthcare provider may recommend that you increase the amount of vitamin A in your diet. Foods that are high in vitamin A are dark green, leafy vegetables and deep orange vegetables. Examples include spinach, carrots and squash.'

Keeping the patient's experience in mind

Learning that you have a disease or disorder or that you need a procedure can be frightening and can impact your identity. Stress, such as that caused by an illness or injury, can detrimentally affect a person's health literacy abilities.[10] Medical writers should be conscious of the patient's potential experience, while being careful not to sacrifice educational effectiveness. Keeping the patient and their potential sensitivities in mind while developing content can help increase the patient's satisfaction with the care they have received. Increased understanding and satisfaction empowers patients to ask questions and become active members of their healthcare team. It also facilitates communication between healthcare providers and patients, which saves providers time, enhances the quality of care, and improves health outcomes.[11]

The tone of patient education should be factual and empathetic. A judgmental or patronizing tone can impede the learning process and negatively affect the patient. Unless writers are aware that their audience has a background in healthcare, it is better to assume they do not have medical field experience or an understanding of biological concepts. Evaluation studies on X-Plain® (the patient education materials published by the Patient Education Institute) show that users who have more experience or who are highly health literate are not offended by simplified content.[12,13]

Viewing the patient as a person, rather than a condition, and writing with person-first language are of primary importance.[14] 'Disabilities are not persons and they do not define persons,' so medical professionals should refer to affected patients as people with a medical condition or disability, rather than as disabled people.[15] For example, writing 'people with diabetes' is more sensitive than 'diabetics.' Similarly, 'to have' may imply possession and 'to be' may imply identity; using 'have' rather than 'be' is considered less stigmatizing. For example, it is better to say 'a person with hearing loss' rather than 'a person who is hearing impaired.'[13] Table 1 lists further examples.

Table 1: Examples of terms that could be offensive to lay readers and empathetic alternatives

Term that could be offensive	Empathetic alternative
Amputee	A person with an amputated limb
Bipolar man	A man with bipolar disorder
Cancer patient	A patient with cancer
Autistic child	A child with autism or a child who is on the autism spectrum
Wheelchair-bound woman	A woman who uses a wheelchair

Sensitivity to norms within a community makes patient education empathetic and increases the writer's credibility. For example, many individuals with hearing loss prefer to use the term 'Deaf' to describe their community and culture.[16]

To ensure that educational programs are accepted and understood by the target audience, involve patients in reviewing the materials during the development process.[7] Patient involvement and review increases accessibility and the likelihood of success as the solution is implemented. Direct online feedback from real patients in clinical settings simplifies

Figure 1: An online feedback form for the Arabic-language version of X-Plain®.

the collection and analysis of patient feedback. An example of an online feedback form is shown in Figure 1.

Visual instructional design

Research shows that text paired with simple line drawings engages readers more than text or graphics alone. Line drawings also prevent overstimulation that could impede cognitive processing.[17] Line drawings that clearly represent a concept are more accessible than complex or highly realistic images, such as photographs.[18]

In a study published in *Patient Education and Counselling*, researchers analysed peer-reviewed studies in health education, psychology, education, and marketing journals. They found that:

> 'pictures closely linked to written or spoken text can, when compared to text alone, markedly increase attention to and recall of health education information. Pictures can also improve comprehension when they show relationships among ideas or when they show spatial relationships. Pictures can change adherence to health instructions. All patients can benefit, but patients with low literacy skills are especially likely to benefit. Patients with very low literacy skills can be helped by spoken directions plus pictures to take home as reminders or by pictures plus very simply worded captions.'[19]

The design and layout of text and graphics can be used to increase understanding. Text should be presented in a large, simple font.[17] Plenty of blank space should be used to balance the graphics and text on the page. Whenever necessary, bullet point lists can be used to break down or organize information. An example is shown in Figure 2.

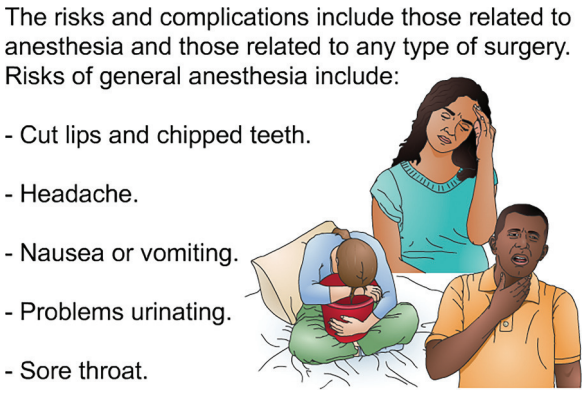

Figure 2: An example of patient information in which graphics, blank space, and bullet lists are used to improve readability.

Asking questions

Interactive questions can be used to facilitate learning while providing corrective and reinforcing feedback. An example of an interactive question and answer set with feedback is shown in Figure 3.

The following guidelines for developing questions and answers are based on 20 years of publishing X-Plain® tutorials and enhancing them based on user feedback:

- Questions should be written so that they apply to a wide variety of patients in different healthcare settings.
- Questions should be written about the most important point of the preceding section of the lesson. The most important point could be a concept that will be expanded on in later sections; understanding the concept could be

Figure 3: An X-Plain® question and answer set with feedback.

necessary for the patient to understand what comes later. The most important point could be related to how the patient can practice self-care at home, prevent medication errors, identify a complication, or know when to contact their healthcare provider.

- Ask questions about how the patient can help themselves and improve their health or quality of life. Testing viewers on terminology is not always critical to understanding main concepts. Common misconceptions should be targeted as question topics whenever possible. For instance, during the informed consent process, patients may conclude that the risk of complications for a procedure is high after reading about the many potential complications. It is necessary to emphasize the rarity of complications after listing risks – when the clinical evidence applies – by asking a question confirming the rarity of complications. Confirming that the risk is a possibility, however, helps mitigate liability. An example is shown in Figure 4.
- Clear and simple questions increase the likelihood that the patient will retain correct information later on. Questions should not test the patient on concepts not explained in the lesson. 'Trick questions' can undermine patient confidence. Being able to answer a question correctly increases patient satisfaction.
- When a patient answers a question incorrectly, the feedback should explain the correct answer and give the patient a hint.

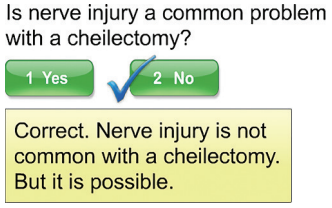

Figure 4: A sample question that confirms the rarity of complications.

Conclusion

Medical leaders have identified patient engagement as one of the most critical concerns of health systems during the digital transformation of the healthcare industry.[20] To truly engage patients, health education materials should be designed so that they are accessible to audiences of diverse literacy levels and learning styles. Medical writers should make creative and thoughtful instructional design decisions, and the final product should respect the humanity of patients.

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Legislation and the lay audience: Challenges of communicating benefit and risk in the light of new regulations

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Abstract

There is a paradigm shift in the pharmaceutical industry and regulatory agencies towards transparency and an emphasis on the benefit-risk ratio of medicines. The recent changes in legislation surrounding clinical documentation have produced significant challenges for medical writers, who are now tasked with translating and explaining complex concepts for the lay audience. This article explains some of the challenges faced by medical writers in this new era.

Keywords: Lay audience, RMP, CTR summary, Benefit-risk, Medical writing, Lay summary

'Patient-centricity' and 'transparency' are buzzwords right now. They are not new, but they are increasingly important in the context of regulatory documentation. 'Transparent' and 'patient-centric' documents are intended to help the lay audience understand complicated issues so that they can make an informed decision with their healthcare provider about a drug or treatment. Such shared decision making is attractive to over-stretched and under-funded health services because it dovetails nicely with patient groups' demands for more (and better) information about their medicines and treatment options. 'No decision about me without me' has been a mantra in the UK for the last 3 years.[1] At the same time, the thirst for information about health-related topics continues unabated. In a recent survey, 72% of internet users in the US stated that they had looked online for health information of one kind or another within the past year, and worryingly 35% said they did **not** visit a clinician to get a professional opinion.[2] This means that the quality of health information available to patients is a major concern and increasingly important.

Legislation

The importance of patient information has not been ignored by the Regulatory Authorities (RAs), and regulations have been updated to mandate the provision of information aimed directly at the lay audience. This is clearly an opportunity for medical writers, who are now tasked with converting complex information into a form that holds true to the tenets of scientific accuracy and is also unbiased, clear, and understandable by the lay.

However, many medical writers only have experience of writing for RAs or academics, who require a specific writing style and tone, have a very high level of health literacy, and may also have a vast knowledge of the specific disease or therapy area. Writing instead for an audience with an often low level of health literacy, and perhaps little or no disease and therapy-area knowledge, is a challenge. When the information to be conveyed involves complex assessments of the benefits and risks (or harms) that could be expected, this challenge becomes significant. Identifying and then translating this information into a form intelligible by the lay audience requires an empathy and understanding of the motivations of the layperson, and also an understanding of the challenges faced by them in digesting and understanding complex information.

The challenges faced by medical writers in this new era of transparency can be illustrated using two new pieces of EU legislation: the recently introduced Risk Management Plan (RMP) Section VI.2 (the lay summary), and the planned EU No 536/2014 (Clinical Trial Regulation [CTR], which is expected to include a lay summary of the clinical trial results).

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Challenges of legislation

RMP Section VI.2

An RMP, by definition, deals with the benefits and risks of a particular drug in a given indication, and how these benefits and risks are to be addressed. In 2013, the EU introduced an new section to the RMP, Section VI.2–the lay summary, the details of which have been discussed elsewhere.[3,4]

In the one-year pilot phase of the regulation, the target audience for this section was stated as, 'the lay audience'. However, this initial target audience is to be amended in a shortly awaited update from the EMA. The new description of the target audience is:

- *Primary*–'stakeholders with professional interest in medicines';
- *Secondary*–'members of the public - should be understandable to those who are looking for more information on medicines but who may not be familiar with medical terminology'.[5]

This expansion of the target audience creates a significant challenge for medical writers, as the primary and secondary audiences are likely to have very different health literacy and numeracy levels, interest levels, and motivations for seeking the information. This is implicitly acknowledged in the phraseology used: the primary target audience of individuals with a 'professional interest' would be expected to understand medical terminology, whereas it is clearly stated that the secondary target audience is not expected to 'be familiar with medical terminology'. Considering that the average reading age in the UK is below 14 years of age,[6] the challenge of explaining the risks and harms of treatments as laid out in a risk management plan becomes apparent.

Sections in the RMP Section VI.2 such as, 'The epidemiology of the disease being treated', 'The clinical benefits of the drug', and 'A more in-depth discussion of the important identified risks and the important potential risks', are particularly difficult to write in lay language. The epidemiology section naturally incorporates numerical presentations of incidence and prevalence data, both of which are difficult concepts to explain to the lay. Similarly, discussions of the benefits and risks or harms of a drug are often supported by statistical information, and risk information in particular is usually given in numerical terms. Simply providing these numbers is not sufficient for the lay audience–an understanding of what the numbers *mean* must be conveyed, so that the risks, benefits, and incidence/prevalence can be put into context.

CTR EU 536/2014

All clinical trials performed in the EU will be required to be conducted in accordance with the new CTR EU No 536/2014 starting May 2016. One of the main characteristics of this new regulation is increased transparency in terms of clinical trial outcomes. All information in the EU database submitted in the Clinical Trials Application and during the assessment procedure will be publically accessible, allowing the public to access extensive details. Additionally, the regulation obliges the sponsor to produce a summary of results for the lay audience one year after the end of the trial in the EU. Further detail of the regulation regarding this summary is presented elsewhere.[7,8]

To make sense of the results of clinical trials in the CTR summary, the lay audience needs the medical writer's help. Merely presenting the 'facts' (the results of the trial) expects the reader to have a level of clinical knowledge sufficient to extrapolate the facts into medical outcomes. Some context or explanation should be given to allow the reader to translate these findings into what it means for them, that is, what are the risks of harm and what are the benefits of taking the drug? This must be done without bias, and in the context of the trial and the therapy area in general. However, it is important to remember that these results will be presented to the lay audience as a stand-alone piece of work; the context of clinical development will not be given along with them. RAs and the pharmaceutical industry do not assess a drug using the results of a single clinical trial, and it could be dangerous (and certainly inappropriate) for the lay audience to take the results of a single trial and make assumptions based on this alone. This is a particularly difficult challenge, and extensive discussion will be needed when preparing the CTR lay summary to address this aspect. In the meantime, medical writers are tasked with presenting this information clearly and without bias.

A summary of these challenges is given in Table 1 below.

Benefit-risk communication

Underlying all of the challenges relating to the legislation described above is the more general challenge of communicating benefit-risk information in terms that do not rely on statistical values or parameters to convey the plausibility of results. Without a background knowledge of statistics, how can a lay audience weigh the relative merits of the data they are given, or even really understand the relevance of, for example, a *p*-value?

Table 1: Challenges of legislation

Document Section	Legislation	Summary	Main Challenges
RMP Section VI.2	Guidance on format of the risk management plan (RMP) in the EU–in integrated format EMA/465932/2013	This section is a summary of the RMP aimed at stakeholders with professional interest in medicines and members of the public - should be understandable to those who are looking for more information on medicines but who may not be familiar with medical terminology	• The expansion of the target audience to 2 diverse groups; providing one document for both groups will be difficult • Description of facts that are normally supported and described numerically (e.g. epidemiology, prevalence, incidence) • Description of the credibility of benefits and harms without using complex statistical terms
Clinical Trial Results Summary	CTR EU 536/2014	This is a summary of clinical trial results aimed at the lay audience.	• Providing context for the results to allow the lay to interpret the results correctly • Providing complex data in an easily understood format • Deciding the granularity and depth of detail to provide • Avoiding bias

How individuals make decisions, and the effects of data presentation and framing, are scientific specialties in their own right, and the intricacies are beyond the scope of this article. However, some basic principles should be borne in mind, particularly in the context of medical writing and the description of benefit and risk/harm information.

Bias

Human decision processes are limited by heuristics (mental 'short cuts') and biases, and the effects of these biases are greatest in decisions involving risk or a degree of ambiguity. The amount and type of bias also differ between individuals, and have more impact on people with low numeracy levels.[9] Therefore, how a drug or treatment's risks or harms are 'framed' (logically equivalent choice situations described in different ways,[10] and the context in which they are explained, can be crucial in how they are understood, and therefore in the outcomes that result.

For example, the chances of death or survival from a particular treatment option may be judged as relatively more attractive if the outcome is described as a 90% chance of survival than if it was described as having a 10% chance of mortality. Both statistics mean the same thing in terms of outcome, but patients may be more willing to undergo the treatment if they are given the outcome as a 'positive' 90% rather than a 'negative' 10%.[11]

Although the full impact of framing is difficult to assess,[12] the medical writer must nevertheless decide how the framing should be done and how much context to give to ameliorate these potential biases.

Wording and statistics

The wording used can have a large impact on outcomes, and so should be considered carefully. For example, when an effect was described using the word 'percentage' it is perceived to be larger than if terms such as 'reduced by' or 'relatively reduced' are used.[13]

Most people are risk averse–to the point of choosing a less effective treatment if they think it is 'safer',[14] and some will also avoid making a decision at all if ambiguity is involved–'ambiguity aversion'.[15] If a term is poorly understood (if at all), it becomes ambiguous. Therefore, using statistical (or any complicated medical) terms can be counter-productive when writing in lay language. If, for example, confidence intervals are used to try to explain how much 'trust' the reader can place in a result or a statistic, the perception of the risk can increase,[16] and lead to a reluctance to take the drug.

Relative risk, absolute risk, and probability

It is also known that describing an adverse effect in relative risk terms ('taking drug X will lead to a 50% increase in heart attack compared with people who don't take drug X') will communicate a greater size of risk than describing the adverse effect in absolute risk terms ('2 people out of 100 who took drug X had a heart attack, compared with 1 person out of 100 in the group who did not take

drug X′).[17,18] This bias caused by the different statistical formats is also true for effect sizes. A large Cochrane review found that interventions are perceived to be more effective if the results are expressed as relative risk reductions rather than absolute risk reductions: the lay audience perceives risk reductions to be larger, and are therefore more likely to adopt an intervention, if the effect is presented in relative terms.[18]

Additionally, it is far more difficult for a lay audience to understand the probability of an effect (e.g. '0.05') than the frequency of an effect (e.g. '5 in 100').[19] Therefore, frequencies and absolute risks should be used wherever possible.

In this way, giving the lay audience complex, numerical, benefit-risk information is often counter-productive and can lead to impaired decision making.[20] It also calls into question the value of disclosing complex clinical trial results without some degree of context and explanation (neither of which is currently mandated by the regulation). For example, publically disclosing that 30% of subjects in a trial reported that their leg turned blue temporarily sounds very dramatic and might stop potential patients taking a drug or participating in a future trial, but what if 29% of the general population had blue legs from time to time anyway? An increase of 1% over the general population level is suddenly much less scary or serious, and may well make the drug worth taking…. but this relies on the individual reading the trial results *knowing* the baseline level of blue legs in the population and being able to put this into context.

When writing for the lay audience, the medical writer must anticipate and understand the audience's level of prior knowledge, and use their skills to explain complicated statistical information in a lay-friendly format.

Therefore, empowering patients to become involved in their healthcare and the decisions made about their treatment means more than just publishing the results of trials or a summary of the RMP. If this information is not given in context and in a form that the lay audience can understand and interpret, 'transparency' can do more harm than good.

What does this mean for medical writers?

Producing the RMP Section VI.2 and the Summary of Clinical Trial Results typify the challenges for medical writers brought by the need and desire for increased transparency in the pharmaceutical industry. As medical writers writing for the lay audience, our job is to determine the appropriate level of granularity needed, to tease the key messages from data and to present them clearly and accurately. Of course, this applies whether our target audience is a regulatory authority or a member of the general public, but the words we choose, and the way we explain and express them, differs dramatically for each audience.

Our latest challenge is to present data and messages in a way that the lay audience can both understand and use in their healthcare decision making. This is a means for the pharmaceutical industry to engage with the general public in a way that has never been permitted before. But it is also a huge responsibility and requires an extensive medical writing skill set that differs in many ways from that carefully honed by medical writers who write regulatory documents. Writing in lay language is far more than just translating clinical words into simpler ones, particularly when discussions of benefit and risk are involved. However, in the quest for transparency and patient-centricity, medical writers are clearly set to play a crucial role.

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Medical writing for two audiences – The RMP public summary

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Abstract

With the introduction of the new EU Legislation in 2012, RMP requirements have changed significantly, triggering content- and process-related changes. An RMP is written as part of a submission dossier and is submitted for assessment to the EMA. The most important information is outlined in Part VI of the RMP, which forms the basis for the summary that is subsequently published on the EMA website. For medical writers the task of writing for expert and lay audiences at the same time poses new challenges.

Keywords: Risk Management Plan (RMP), RMP summary, Lay audience, EMA website, RMP Part VI

Introduction

New challenges have evolved for medical writers with the introduction of the 2012 'EU Pharma Package' (Regulation (EU) No 1235/2010 and Directive 2010/84/EU) and the transparency initiative, which follows the EMA's decision to better inform the public about the processes around medicine authorisation and evaluation of a medicine's safety.[1] One of these challenges is writing the public summary in Part VI of the European Risk Management Plan (RMP). This summary is made publicly available on the EMA website for regulators, industry, and healthcare professionals, as well as for patients, i.e. a lay audience. To author Part VI of the RMP thus means to serve two masters: while the information provided must be medically accurate and convey all relevant information needed for a medicine's authorisation, it should at the same time be written so that it can be understood by a lay reader.

The RMP, and especially its publicly available summary, have become one of the 'hot topics' in the pharmacovigilance world, and a large number of questions have arisen. Many of these questions are related to the content of the public summary (please also refer to the article by Lisa Chamberlain James in this issue of *Medical Writing*, pp.195–199), but also to the new RMP process that had to be established. This process needs to allow for transparency on the one hand, and data protection on the other hand.

In this article, we briefly touch on the EMA RMP guidance, templates, and useful reference documents (see Table 1). We look at the RMP structure, explaining how the relevant pieces of information from the individual modules and parts merge into an overall summary in Part VI. And we discuss the purpose of Part VI of the RMP, its main data and information sources, the functions involved in its creation, and the main difficulties the writer faces. Once the RMP is submitted to the EMA, the assessment procedure starts, and with it the review of the public summary, which is detailed in the last part of this article.

Table 1: Infobox showing useful information sources

- 'EU Pharma Package' – Regulation (EU) No 1235/2010 and Directive 2010/84/EU[1]
- EMA RMP webpage,[4] including:
  - GVP Module V – Risk management systems (Rev 1)[3]
  - EMA RMP template[5]
  - Q&A on RMP summary[9]
- EMA webpage: public summary examples[6]
- PRAC website[7]
- CHMP website[8]

Guideline requirements and RMP structure

As described in the June 2015 issue of *Medical Writing*,[2] the RMP provides a detailed description of a medicine's safety profile and the measures to prevent or at least minimise the risks that a medicine has. The regulatory basis of the RMP is Good Pharmacovigilance Practices (GVP) Module V–Risk

Management Systems.[3] With its modular structure, the RMP touches various sources of information and stages of drug development. In each of the RMP modules, a conclusion needs to be drawn, stating whether safety concerns were detected. In the RMP parts that follow the safety evaluation, the related pharmacovigilance activities and risk minimisation measures are described.

The RMP is a comprehensive document that provides the reader with an abundance of information on, among other topics, epidemiology, clinical and non-clinical data, limitations of the clinical trial programme, and post-authorisation data. All of this provides the basis for the identification of safety concerns, pharmacovigilance activities, and risk minimisation measures. RMP Part VI summarises in an abridged form the important information compiled in the complete RMP and thus provides the essence of the medicine's overall safety profile.

RMP Part VI – RMP summary

In the EMA template, Part VI is split into two segments. The first one contains 'Elements for Summary Tables in the EPAR' (European public assessment report) and includes tables from Module SVIII and Parts III, IV, and V. The second segment, 'Elements for a Public Summary', provides short summaries (50 to 300 words, depending on the number of indications) on several topics as detailed below. Figure 2 shows which modules and parts

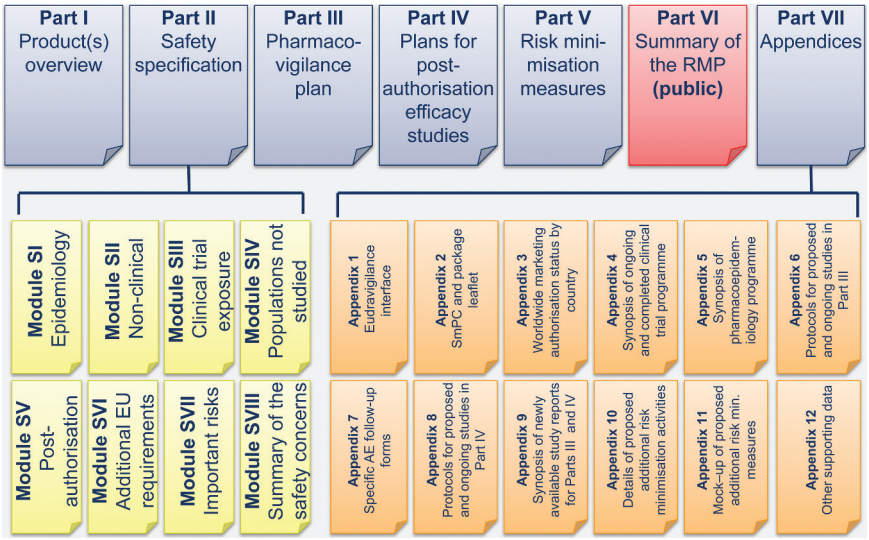

Figure 1: The Risk Management Plan[3].

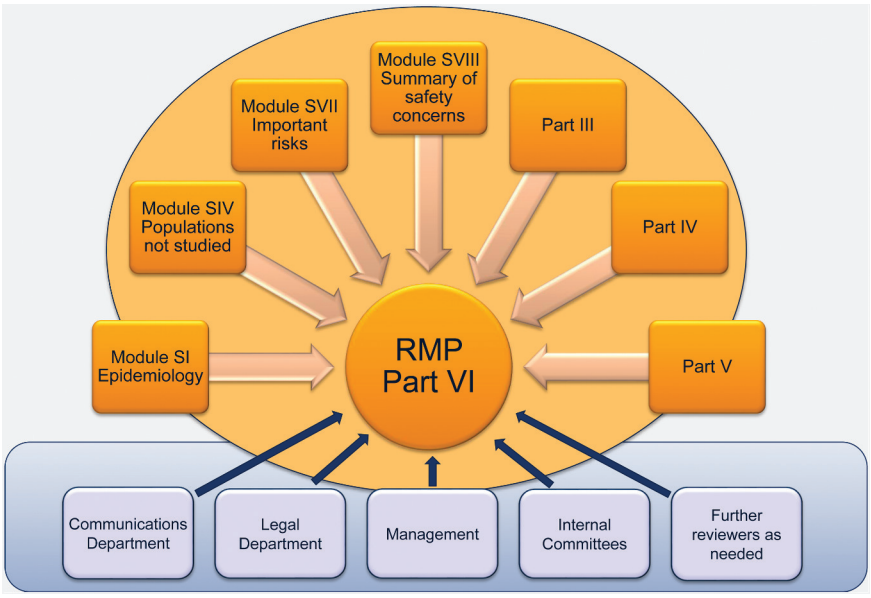

Figure 2: RMP Part VI: Public summary.

form the basis for Part VI, and which functions are involved in the creation of Part VI.

Once the RMP is approved, this second segment is used by the EMA as the basis for the RMP summary that is published on its website. Therefore, lay wording is required. The purpose of the public summary is twofold: it is supposed to summarise all relevant information for regulators, and at the same time should make the medical context, benefits, unknowns, and, most importantly, safety concerns clear to the lay reader. With a single text, the writer therefore needs to reach two different audiences with very different needs: experts and lay readers. To achieve this can be a challenge in regulatory writing, since conveying correct and exact medical information can prove difficult if medical terminology is to be avoided. This is especially true if the word count is limited, meaning that explaining medical terms or using both medical and lay terms is not an option.

In addition to writing the RMP summary for two different audiences, the writer also serves as an 'interface' between the expert functions that contribute to the RMP summary and the lay readership. In most cases, the content provided by the expert functions needs to be 'translated' into lay language. Due to this, the writer is often caught between two antipodal positions: the expert contributing to the RMP is often concerned that important medical information will get lost with the use of lay language and may thus be reluctant to omit medical terms, whereas the EMA requirement is to use lay language to make the information also accessible to the general public.

The requirements and detailed instructions for RMP Part VI can be found in GVP Module V and in the EMA template on the EMA RMP webpage.[3–5] More and more medicines now have published RMP summaries, examples of which can be found on the EMA website.[6]

How do the EPAR summary, PL, and RMP summary connect?

Patient-friendly documents such as EPAR summaries and the package leaflet (PL) are already available from the EMA. The EPAR summaries explain for lay people what the medicine is, how it works, how it has been studied, what it is used for, what the benefits and risks are, and why and how it was approved. In other words, the EPAR summary explains the scientific and regulatory context of the medicine. Tables from the first segment of RMP Part VI feed into this EPAR summary.

The PL contains instructions for the patient on the actual use of a medicine, i.e. how to take it properly (e.g. administration, dosage), anticipated side effects, etc. The PL therefore places the medicine in the context of everyday use and daily medical practice.

The RMP summary provides yet another angle on the medicine and further enhances transparency and public access to relevant information. It introduces the concept of 'risks' related to a medicine, which is not covered in the EPAR summary or the PL. The RMP summary, EPAR summary, and PL thus complement each other and provide a complete picture of a medicine's safety profile.

The RMP summary is written in lay language and summarises the information in the RMP, which is a long, complex, and partly very technical document. The RMP summary is intended for readers who would like to know more about the risks related to a medicine, in the context of the benefits of the medicine, and how these risks are handled. It includes the following:

- a brief overview of epidemiology (i.e. how common the disease is and which parts of the general population are affected by it)
- a summary of the treatment benefits (based on the main studies conducted)
- a description of the unknowns of treatment benefits (populations not studied)
- a tabular summary of the important risks and how they are managed
- a tabular overview of missing information which needs to be collected
- any additional measures to be taken as required as part of the marketing authorisation
- a list of planned studies to provide more information on the safety and benefits of the medicine
- a tabular overview of updates to the RMP

How RMP Part VI is turned into an RMP summary – The process at the EMA

In a 1-year pilot phase, the EMA started publishing RMP summaries in March 2014 for medicines authorised under the centralised procedure. The proposed target audiences are professional stakeholders as well as members of the public. Eventually all centrally authorised medicines will have a public RMP summary.

The RMP is part of the marketing authorisation application submitted to the EMA for assessment. During the assessment process, the RMP is reviewed

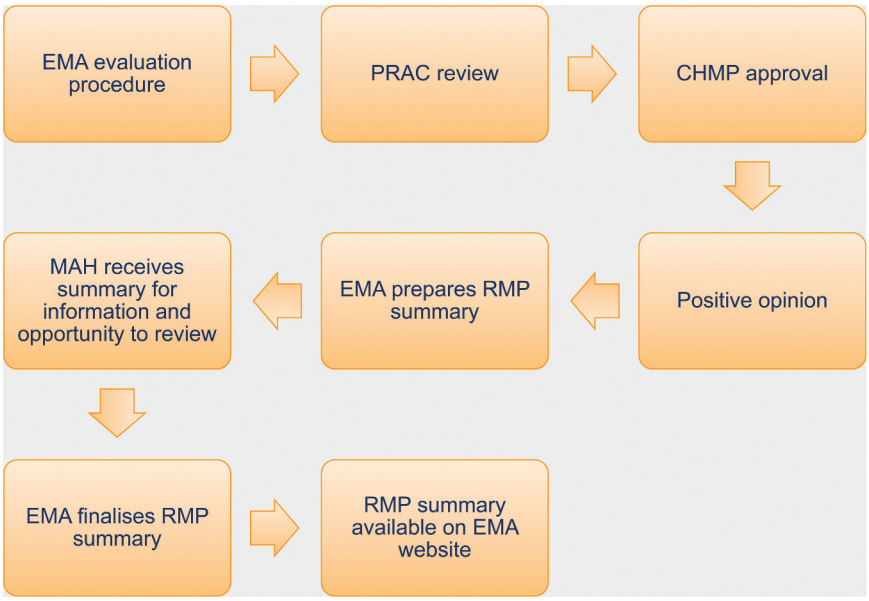

Figure 3: How Part VI is turned into the RMP summary.

by the Pharmacovigilance Risk Management Committee (PRAC)[7] and approved by the Committee for Human Medicinal Products (CHMP)[8] before a positive opinion is issued in favour of marketing authorisation. After the positive opinion has been issued, the EMA transfers the relevant information from Part VI of the approved RMP to the EMA RMP summary template and revises the text according to agency style, format, and naming conventions. The marketing authorisation holder (MAH) then receives the RMP summary and is given the opportunity to review it with a focus on content-related issues only. This review step is short (a few days) and the MAH should be prepared for a quick turnaround. The MAH should also consider whom to include in this short review. For example, it might be advisable not to include the entire multidisciplinary team that contributed to the RMP but rather the relevant Part VI authors only (e.g. drug safety, epidemiology, medical, regulatory) and to add representatives from legal and communications departments, as well as management. After this step, the MAH returns consolidated comments to the EMA, which then finalises the RMP summary for release on its website. The RMP summary is now publicly available.

However, the RMP summary will always be subject to change. In contrast to the other documents in the submission dossier, the RMP is a living document that is updated continuously throughout the life cycle of a medicine. Over time, knowledge about the benefits, risks, and overall safety profile of a medicine will increase and the RMP will be updated to reflect the current status. So whenever there are significant changes to an RMP (i.e. a change in the benefit-risk profile) the RMP summary will be updated as well.

Present and future challenges

Apart from the challenges in writing the RMP summary, there are unanswered process-related questions, as is expected for a new procedure:

- At the moment, the publication of RMP summaries applies only to medicines authorised under the centralised procedure. Nevertheless, Part VI is needed for all RMPs, regardless of the authorisation procedure. Currently, no detailed guidance is available for medicines authorised under other procedures (mutual recognition, decentralised, and national) and information on national publication strategies (if in place at all) is sparse. Also, the template text provided by the EMA is tailored to centrally authorised medicines and is not always suitable for the other authorisation procedures and the MAH depends on feedback from national authorities on local requirements and whether deviations from the EMA template text are permitted or even required.
- An official lay term glossary and style guide for Part VI, available to all MAHs in order to write the lay texts for the RMP summary, would be helpful.
- Due to the transparency initiative, RMPs can be requested by third parties. Therefore,

data protection needs to be carefully considered when writing the RMP and especially Part VI (e.g. patient identifiers should not be used).

- As GVP Module V is currently under revision and feedback from the pilot phase is still being analysed, changes to the RMP in terms of content, process requirements, and target audience can be expected.
- As mentioned above, the EPAR summary, PL, and RMP summary provide different perspectives on a medicine's safety profile. However, the differences in these three documents' concepts (e.g. the distinction between side effects and risks) might not be obvious to the lay audience.
- Although the RMP summary is to be written in lay language with a focus on patients, it is still a very technical document and is not very reader-friendly. For instance, lay audiences will not be familiar with the definitions of 'risk', 'important risk', 'potential risk', 'identified risk', etc. Also, the public summary is only available in English, which not everyone in the EU/EEA is able to understand. In addition to the language barrier, there is an 'information barrier': most people are not aware that an RMP summary, an RMP, or even an EMA website exists and thus simply do not have access to this information.

Conclusion

With the implementation of the EU Pharma Package in 2012, RMP content and process requirements have changed. Since then, both regulators and MAHs have gained experience on the RMP as a whole and the RMP summary in particular. Nevertheless, open questions remain and the new RMP process is still evolving. Medical writers will thus continue to face the challenge of meeting the needs of all stakeholders and working in a dynamic and transforming environment.

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Layperson summaries of clinical trial results: Useful resources in the vacuum of regulatory guidance

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Abstract

To meet the requirements of the clinical trial regulation, preparation for the publication of lay summaries on the European database should be undertaken as soon as possible. However, as of July 2015 (at the time of writing this article), no regulatory guidance has been produced. The main goal of this article is to raise awareness of other resources that writers can use in the interim. This includes templates, guidance, and examples published by the Harvard Workgroup and the Center for Information and Study on Clinical Research Participation, whose work is supported by the EMA and FDA.

Keywords: Disclosure, Layperson summary, The Harvard Workgroup, The Center for Information and Study on Clinical Research Participation

People want to access trial results for various reasons. As participants, they may want feedback on the scientific research to which they have contributed. They may seek information to decide whether or not to start or continue with a treatment, interpret symptoms, or find an alternative treatment. Others may want to find out if a trial exists in which they could participate, or seek information to inform others (loved ones, doctors etc.).

There is evidence to show that unless patients are informed about results they may not participate in future trials,[1] and that at the end of a trial they no longer feel valued.[2]

Informing patients of trial results may not only provide a more positive experience for patients but also improve low clinical trial (CT) recruitment rates.

EU legislation

In the EU, the CT regulation (Regulation (EU) No 536/2014[3]), stipulates that a layperson summary should accompany the summary of CT results. Both are to be submitted to the database within 1 year from the end of a CT in all member states (MS) concerned: Article 37 [4].

The regulation will apply 6 months after the European Commission publishes a notice in the Official Journal of the European Union to verify that the EU portal and database are fully functional; this is predicted to be on 28 May 2016 at the earliest (Article 99). If submission of results within 1 year is not possible (e.g. the CT is ongoing in non-EU sites), they should be submitted as soon as possible; and the protocol should specify this together with a justification.

The informed consent used to enrol patients must explain that the technical and lay summaries will be available in the database and, to the extent possible, *when* these will become available: Article 29 [6]. Within the EU database, the summary, layperson's summary, protocol, clinical study report (CSR), and data from other CTs using the same investigational product will be linked together: L158/8 [67].

Annex V of the CT regulation lists 10 items that must be included in lay summaries. These were discussed by Sroka-Saidi et al.,[4] including the comment that it can 'hardly be considered a guidance document.' However, Annex V is not guidance but a regulation, and in the EU it is important to distinguish between regulations, directives, and guidance. Regulations are binding, inflexible legislative acts that must be applied in their entirety across the EU and leave no room for interpretation. In contrast, although directives set out a goal that all MS must achieve, individual MS devise their own laws on how to implement these. The consequent wide interpretation of the CT directive (Directive 2001/20/EC[5]) by different MS led to disharmony in CT application procedures including the documentation required, approval timelines, and

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assessments performed. This logistical nightmare was one of the main drivers that led to the replacement of the CT directive with a regulation. Guidelines are the most flexible. They represent the agency's current thinking on a topic in more detail, but are not mandatory and can be deviated from (with justification). For example, there was a far-reaching misconception that the ICH E3 guidance for writing CSRs represented a fixed template that could not be deviated from – a misconception that the ICH E3 Q&A document[6] sought to correct.

Therefore, we can say that Annex V consists of 10 mandatory items that legally must be included in lay summaries for CTs occurring in at least one MS. It is not intended as guidance or a template. It is sparse, precisely because it is a regulation. Too much legislation would limit the flexibility needed for such documentation, and throw up roadblocks on a journey just begun.

According to the European Patients' Forum (EPF), which has published its own responses and requests regarding Annex V,[7] these 10 items were added by the European Council at the last stage of negotiations, without consultation from patient groups.

In April 2015 at the DIA Clinical Forum, I spoke informally with an EMA representative; they mentioned that although regulatory guidance may not be produced for some time, in the interim it may be helpful to review the work done by the Harvard Workgroup into lay summaries (discussed below).

US legislation

Much of the discussion on lay summaries has been focused on the EU. Back in 2007, however, the US FDA Amendments Act[8] not only expanded CT.gov to include basic results posting but also introduced a provisional requirement allowing for the dissemination of 'a summary of the clinical trial and its results that is written in non-technical, understandable language for patients … without being misleading or promotional' (Title VIII, §801). However, since this is not mandatory by US law, and a final ruling is currently pending, it was widely ignored.

Despite this, the FDA encourages returning results to CT participants and, like the EMA, supports the work done by the Harvard Workgroup and the Center for Information and Study on Clinical Research Participation (CISCRP) mentioned below.

Harvard Workgroup guidance and templates for lay summaries

The Multi-Regional Clinical Trials (MRCT) Center at Harvard Return of Results Workgroup is a multi-stakeholder group comprising 54 members. The group includes individual pharma companies such as Pfizer, Merck etc., the Pharmaceutical Research and Manufacturers of America, the European Federation of Pharmaceutical Industries and Associations, academics, patient advocacy groups (including the EPF mentioned earlier), and non-profit centres including the CISCRP (mentioned below).

From January to September of 2014, the Harvard Workgroup convened to agree on some guidance that sponsors could use to encourage the return of results. They refer to these documents as 'research result summaries,' and although the focus is on returning results to trial participants, they state that their recommendations are 'congruent with the EMA mandate to post results on the EU database.'

In March 2015, they published 2 documents: the Return of Results Guidance[9] and the Return of Results Toolkit.[10]

The Return of Results Guidance document is a practical guide to returning results. It includes advice on process development (from before the study begins, to delivering results and obtaining feedback), timing, document reviewers, format, content, style tips, how to convey numerical results and risk/benefit information, and readability (user) testing. It is a comprehensive document that contemplates the logistical challenges in delivering results and how such challenges can be tackled.

Linked to the guidance is the MRCT Return of Results Toolkit, which includes templates for Phase 1 and Phase 2/3 studies, and early CT closure, and a reviewer checklist. Suggestions for translating endpoints into lay language (Table 1) are provided, along with practical examples on neutral, non-promotional language (Table 2).

Language that could be perceived as being promotional is clearly of concern, so although medical writers are good candidates for writing lay summaries, regulatory and legal input may be warranted.

A disclaimer is included to say that while the documents consider the perspectives of the FDA and the EMA, they are not intended to 'supplant or interpret any regulation or official guidance.'[9]

CISCRP examples of lay summaries

The CISCRP is an independent non-profit organisation dedicated to educating the public and patients about clinical research. In 2011, they began piloting programs with Pfizer and Eli Lilly to return results to trial participants and obtain their feedback. CT

Table 1: Endpoint table with simple language (abbreviated version)

Endpoint	Description of The Type Of Endpoint	Example in Simple, Plain Language
Mortality/ Overall Survival	The goal of this trial was to see if Treatment ABC or Treatment XYZ helped patients with [disease/ condition] live longer.	**If there was NO EFFECT** Patients in both groups lived about the same amount of time, no matter what treatment they got. **If there was an EFFECT** The times given include the middle (average) amount of time that patients in this study lived. Some patients lived for a shorter time and some lived longer. People in Group A (ABC treatment) lived about 15 months. People in Group B (XYZ treatment) lived about 12 months. This means that people in Group A (ABC treatment) lived about 3 months longer than people in Group B.
Non-Inferiority	Non-inferiority trials seek to show that any difference between the two treatments is small enough to allow a conclusion that the new drug has at least some effect or, in many cases, an effect that is not too much smaller than the active control. Non-inferiority endpoints are designed to show that a new treatment or drug is not worse than the control (or other comparison drug) by a pre-specified amount (also termed the non-inferiority margin). Efficacy can, in fact, be worse if there are other benefits (e.g., fewer side effects).	This study showed that the new insulin formulation (insulin A) was not much worse than standard insulin therapy in reducing the level of HbA1c in Type 1 diabetic patients.
Patient-Reported Outcomes	This trial studied patient answers about their [list the main purpose of the questionnaire, e.g. symptom (e.g. pain), quality of life, psychosocial, burden, economics] and if the measurement changed based on whether a patient got A or B. The primary endpoint is less XXX based on the YYY scale. This scale measures ZZZ and how this changes over time.	Pain levels were measured on a known scale. It measured pain, stiffness, and how well people can climb stairs, stand or bend. Questions were asked during each study visit. Patients in Group A (tanezumab) had less knee pain than patients in Group B. Knee pain was lowered by about 1 in 2 people (50%) in Group A. Knee pain was lowered by about 1 in 4 people (25%) in Group B.'

Source: MRCT Return of Results Toolkit March 19, 2015 - Version 1.0.[10]

results were translated into lay summaries written at a validated sixth–eighth grade reading level (ages 11–14).

Four examples of these lay summaries have been published on the CISCRP website: 2 for Pfizer, and 2 for Eli Lily and Company.[11] Their research found that there was a dramatic improvement in the understanding of the CTs by the participants after reviewing the lay summaries, and that over 90% of volunteers were satisfied with their level of understanding.

The FDA suggested the CISCRP program was one that should be adopted industry-wide; the EMA stated that the clinical research industry has a binding legal obligation and a strong moral one to communicate the results to individuals in trials.

Table 2: Neutral language guidance (abbreviated version)

Language to Avoid	Language to Consider
This study proved that using <drug A> to prevent <disease/ condition> is effective.	This study found that people with <disease/condition> who got <drug A> had <primary endpoint>.
<Drug A> works better than <Drug B>, but some people didn't tolerate it as well.	In this study, more people got <study endpoint> with <Drug A>. They also had more safety events that interfered with their daily lives, like <list specific adverse events>.
<Drug A> is better tolerated than <Drug B>.	In this study, fewer patients who took <drug A> had <list specific adverse events> than patients who took <drug B>.
While the combined treatment of <Drug A and B> did not extend life over <Drug A> alone, people felt better and lived longer with the combined treatment.	People in both groups had the same kind of results (outcomes). People who took the combined treatment had milder safety events like <list specific adverse events>. The amount of time they lived depended on how they felt when they started either treatment.
Study groups had the same results. More studies are provided after acceptance for publication in a peer-reviewed journal.	There was no effect in the treatment arms/there was no difference between the groups. All groups still had pain and numbness in their fingers or toes (called neuropathy).

Source: MRCT Return of Results Toolkit March 19, 2015 - Version 1.0.[10]

Other resources

Other lay documents already produced and approved can be consulted for lay terminology. Descriptions on methodology may be taken from the applicable informed consent document, and lay glossaries used for adverse events.[12]

Patient information leaflets (PILs) provide examples of lay safety information and can be accessed from the electronic Medicines Compendium[13] or sponsor websites. Regulatory guidance on PILs is available, including advice on lay terminology, preferred formatting (e.g. use bold rather than italics and underlining) and readability testing.[14]

On the EMA's website, lay language on risk and benefit can be reviewed in the European public assessment reports (EPARs), which contain the final assessment for centrally approved (or rejected) products, and in lay summaries for risk management plans.[15]

User testing conducted on PILs and EPARs greatly improved the presentation of these documents for lay audiences,[16] and will likely be of similar importance for lay summaries.

In addition, patient-oriented websites may be helpful to consult such as Cancer Research UK, which publishes lay descriptions of oncology studies for patients.[17]

Closing remarks

Lay summaries will play an important role in educating patients about clinical research. There is some evidence that too much safety information may negatively impact compliance and that primary health care workers may be inundated with questions.[18] However, there is hope that improved transparency will help regain patient trust by restoring a sense of autonomy in their own treatment decisions, and may improve CT recruitment. For better or worse, they are likely to be influential documents and need to be written with care.

Generalisations that could be perceived as promotional must be avoided and communicating specific findings in lay terms will be challenging, as will keeping the document to a manageable size for improved readability.

Although regulatory guidance is pending, guidance cannot address all situations, and precedents may be of more value. Until these are available, the work done by the Harvard Workgroup and CISCRP should provide a solid foundation for the lay summary 'lift-off'.

Postscript

I am currently conducting some research into the publication of CT results and would welcome any thoughts, comments, questions or information you have on this topic e.g. describing your experience of writing lay summaries, basic results, disclosure summaries etc., and/or whether you would be interested in participating in any short future questionnaires or interviews. Please feel free to contact me on this topic.

Conflicts of interest and disclaimers

The findings and conclusions in this paper are those of the author and do not necessarily represent the views of PAREXEL International GmbH.

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Package leaflets for medication in the EU: The possibility of integrating patients' perspectives in a regulated genre?

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Abstract

Package leaflets (PLs) have been legally required to accompany medicines in the EU since 1999. Despite the best intentions and efforts, however, they are generally not well-received by the public for whom they are intended. This paper picks up on the challenges that medical regulatory writers face in producing quality PLs using the official PL template when research indicates that patients would prefer a more personalised genre that incorporated their experiences and knowledge. This paper advocates greater inclusion of patients' perspectives, as this is currently achievable given the current legislation. The paper also notes the tantalising prospect of replacing the template with a set of recommendations that draws on knowledge of what works best for patients.

Keywords: Package leaflets, Regulatory writers, Template, Patients' perspectives, Semi-expert patients

Introduction

This paper addresses the question: how can medical writers, for whom best practice involves writing for the reader in a 'clear, accurate, and engaging' way,[1] accomplish this in a constrained, regulated genre such as the package leaflet (PL) which accompanies medications in the EU? The paper derives from my PhD dissertation,[2] which used discourse analysis to demonstrate how attention to patients' needs is possible in PLs; the primary focus of the present paper is on practical implications for medical writing professionals.

The dilemma: Between a rock (of regulation) and a hard place (of patients' expectations)

Since 1999, all medicines available to patients in the EU have been legally required to be accompanied by PLs, which provide information on medicines and how to use them. Although these texts are important for patients' health and safety, many patients do not value them. This is due to a number of factors, but the one that will be addressed here is patients' belief that PLs are not written with them in mind.[3] They deem PLs instead to be written for professional purposes, such as meeting legal requirements and avoiding litigation,[4] and consider their own perspectives and knowledge to be absent from these texts.[5]

Whilst genres are normally in a state of flux,[6] the PL is a particularly constrained genre and the scope that medical writers have for improving it is impacted in a number of ways. Firstly, the PL's status as a legal, regulated genre means that a conservative approach to genre development is most likely, as any delays to approving PLs due to alternative, unapproved wordings, for example, could delay the release of products and be expensive for pharmaceutical companies. Secondly, since 1998, a template produced by the European Medicines Agency (EMA) stipulates particular content, structure, headings, and statements for PLs. The template has been revised over the years: the most recent template, dated June 2015, is called *Version 9.1*.[7] Ostensibly, the template provides writers with a number of advantages. It helps to ensure that all information is present in a particular order, ensures linguistic consistency across PLs which is likely to facilitate regulatory processes, and essentially 'takes many decisions out of the hands of

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medical writers'.[8] However, this is also a potential disadvantage as 'templates tend to stifle innovation',[9] leading to very standardised texts. Moreover, the quality of the template has also been identified as problematic,[8] with the implication that texts that are based on the template reproduce its weaknesses.

The focus of this paper is on PLs that are regulated through centralised procedures by EMA. This is worth mentioning, as PLs in the EU may be regulated either nationally or centrally at European level. In Britain, for example, PLs regulated at national level by the Medicines and Healthcare Products Regulatory Agency (MHRA) are only required to follow the set content and order specified in the legislation,[10] whereas PLs that are regulated by EMA should adopt the content, order, headings, and statements of the template. If the set headings or statements of the template are not adopted by pharmaceutical companies seeking approval from EMA, each amendment is considered on a case-by-case basis and alternative headings may need to be argued for.[7]

What kind of audience do PLs address?

Berkenkotter[11] argues that writers write with an audience in mind, and that the best writers do this to a high degree. In this way, there are implicit, if not explicitly formulated, preconceptions of an audience, traces of which are evident in the texts themselves.[12] This begs the question: if patients feel that their perspective is missing, what is there then in PLs?

The answer to this question comes in part from the legal requirement that PLs, above all, be understandable. For example, Article 63(2) of Directive 2001/83/EC[13] states: 'The package leaflet must be written and designed to be clear and understandable, enabling the users to act appropriately, when necessary with the help of health professionals.' Moreover, a set of readability guidelines for PLs produced by European Commission[14] reminds PL producers that: 'Some people may have poor reading skills, and some may have poor health literacy. Aim to use simple words of few syllables' and 'Medical terms should be translated into language which patients can understand'. PLs, in other words, should be written with a lay audience in mind.

In a sense, this is eminently sound: as PLs provide information about medication, this information ought to be comprehensible, although Cutts,[15] for example, recently illustrated that attempts to employ plain language in PLs are not always successful. Further indication that PLs are intended for a lay audience is apparent in the representation of the patient in these texts, where patients are characterised as having a health condition, as needing treatment, as possibly being forgetful and needing clarification from medical experts such as their doctor or pharmacist. All of these representations reflect the lay patient of the biomedical model of health communication.[2]

This assumption of patient laity may not, of course, correspond with the actual reader of the PL, as patients are increasingly using the internet to equip themselves with information. Some chronic patients, in particular, gain knowledge of their condition to such an extent that they should be considered semi-experts, even experts, on their condition.[16] At the same time, however, there are also readers of PLs with low health literacy levels who need information to be expressed as simply as possible. In other words, patients exist along a broad epistemic spectrum, and although it is best practice to express information as clearly as possible, not everyone reading PLs is lay. The leaflet format as it currently stands does not make it possible to address various levels of health literacy.

At a more general level, there is lack of recognition in PLs of other aspects of patients' heterogeneity and humanity. Individual patients read PLs and find that the 'umbrella concept' of the audience does not reflect the intensely personal nature of their illness experience.[17] Perhaps patients have come to expect patient-centred communication not only in the clinical setting but also in written communication. In any case, this lack of focus on the patient in PLs must be taken seriously, not only to address patients' dissatisfaction, but also because of proven educational benefits: the more targeted and individualised medical leaflets are, the more motivated patients are to read them and the better they are at recalling their content.[18] The challenge for the regulatory writer is thus the following: given the template and the mass communication format of the leaflet format, how does one make PLs more personalised?

On meeting regulatory demands and demands from patients

The approach to improving PLs that is outlined in this paper is a pragmatic one. It proposes producing PLs in accordance with the template – which means that writers can more readily adopt these suggestions – whilst adding content couched in patient-friendly language that integrates patients'

perspectives in PLs. This content-related approach is in line with Billiones,[19] who, although no doubt mainly addressing a non-regulatory medical audience, urged the following: 'at the end of the day, templates do not guarantee quality documents. […] [W]e, medical writers, are still fully responsible for the content.' Interestingly, longer PLs are not necessarily off-putting: patients have stated a general preference for longer, more detailed PLs, provided the information is relevant for them.[3] Moreover, it is possible to produce better quality PLs whilst using the template. Pander Maat & Lentz,[20] for example, showed that PLs that met the template's requirements were improved (made more usable) using principles of document design.

For improvements to take place, however, there needs to be a context in which improvements *can* take place. The context that has impeded this genre's evolution can be addressed in two ways. The bottom-up approach involves pharmaceutical companies and regulatory writers making it a priority to include patients' perspectives to a far greater degree in the texts they produce. Such PLs would be better at engaging their publics, resulting in an increase in the safety of the medication, more ethical communication, and potentially improved customer relations. The top-down approach involves regulatory authorities such as EMA promoting more patient-oriented communication in PLs, with possible implications for changes in legislation. The integration of patients' perspectives in PLs would be an extension of EMA's growing focus on patient involvement, as is evident, for example, in EMA's use of feedback from user testing (comprehensibility tests) of existing PLs to refine the template[7] and the production of a webpage for patients and carers.[21] No doubt a combination of the top-down and bottom-up approaches would be the most effective for the bold changes required in this genre.

The following strategies can help support the production of PLs where patients' perspectives and knowledge are included and their needs are met:

- **Gaining familiarity with patients' experiences of PLs:** In order to integrate patients' perspectives in PLs, it is important to understand patients' experiences of PLs, particularly in relation to the various ways in which patients feel their perspectives are absent and their needs are not addressed. Well worth consulting in that regard, for example, is the study by Raynor et al.,[3] which synthesizes the findings of a comprehensive systematic literature review into the role and effectiveness of PLs with those of stakeholder workshops (including patients).
- **Considering choice of health communication paradigm:** When medical writers communicate with patients, they implicitly draw on health communication paradigms and their underlying assumptions. As stated earlier, the primary model of communication reflected in the current representation of the patient in PLs is the biomedical model of communication, but other models, such as patient centeredness and patient empowerment could be very relevant alternatives as they emphasise patients' perspectives, experiences and knowledge. Indeed, as shown in my PhD dissertation[2] which examined a dataset of 15 British PLs, three of which were regulated by EMA and 12 of which were regulated by MHRA, some aspects of patient centeredness were evident in a *limited* number of constructions of risk, trust and the patient (see Table 1), thus indicating that patient-centred communication, although rare, was nevertheless possible in PLs. Acquaintance with *alternative health communicative frameworks or paradigms* could provide the producers of PLs with inspiration regarding how to integrate aspects that reflected patients' needs, experiences and knowledge to a much greater degree.
- **Knowing the patient group:** In relation to meeting patients' needs, the recent paper by Lang and Esser[22] in this journal on how to incorporate empathy is very valuable. The point made about using *online self-help groups and patient forums* to acquire better understanding of patients' perspectives is particularly useful. *Patient organisations' websites* for particular conditions could also provide meaningful insights into the kind of content that would make PLs more focused on particular patient groups' needs, perspectives and experiences.

Whilst these suggestions can help to integrate patients' perspectives in PLs, there are clearly challenges involved in producing effective mass communication texts for individuals. Given the tension between mass communication texts and meeting individual needs, an exciting avenue that warrants further exploration is the possibility of supplementing the PL with online alternatives (e-leaflets), which could be tailored to the individual patient and which offered patients choice regarding preferred levels of detail and specificity.

Table 1: Aspects found in dataset of British PLs that reflect patient-centred communication

Discursive construct	Aspects that reflect patient centeredness	Example
risk	The risk information is constructed as having personal value and significance for the individual patient	Read all of this leaflet carefully because it contains important information for you. (Canesten Dermatological Spray)
trust	Information is provided on the benefits of the medication	Actonel changes the bone remodeling process back to normal, returning the strength to the bone structure. (Actonel)
trust	The patient's understanding of his/her illness/condition is promoted	The menopause is due to lowered levels of the hormones estrogen and progesterone. (Premarin)
trust	The patient's information-seeking on product is promoted	For UK residents only: if you have any questions or would like more information, call our Canesten Advice Line on 0845 758 5030. Calls charged at local rate. (Canesten Dermatological Spray)
trust	The patients' difficulties with his/her illness/condition are acknowledged	Because smoking is an addiction you may find it difficult to give up. (Boots NicAssist Fruit Fresh Gum)
trust	Awareness of the needs and wishes of the patient is projected	You can take Prozac with or without food, whatever you prefer. (Prozac)
trust	The medication is constructed as *assisting* the patient	The nicotine is sufficient to relieve the unpleasant withdrawal symptoms. It will also help to stop your craving to smoke but will not give you the "buzz" you get from a cigarette. (Boots NicAssist Fruit Fresh Gum)
trust	The patient is encouraged to deal positively with any setbacks	You might feel a sudden craving to smoke long after you have given up smoking and stopped using Boots NicAssist Fruit Fresh Gum. Remember you can use nicotine replacement therapy again if this should happen. (Boots NicAssist Fresh Fruit Gum)
trust	There is a commitment to the disabled	For information in large print, tape, CD or Braille, telephone 0800 7318450. (Vermox)
patient	The patient is constructed as having a social network	If your husband, partner or other family members smoke too, try to get them to give up with you. (Boots NicAssist Fresh Fruit Gum)
patient	The patient is constructed as having preferences regarding his/her medication	You can take Prozac with or without food, whatever you prefer. (Prozac)
patient	The patient is constructed as having emotions	If you are worried about any of these things, or if you have had a stroke in the past, talk to your doctor to see if you should take HRT. (Premarin)
patient	The patient is acknowledged as experiencing physical sensations	If any painful symptoms continue after this, you should tell your doctor immediately. (Chloramphenicol Eye Drops)
patient	The patient is constructed as potentially benefitting from resources other than pharmacological, such as psychological	Prozac should be offered to a child or young person with moderate to severe major depressive disorder only in combination with psychological therapy. (Prozac)
patient	The patient is constructed as being ruled by other motivations than health	The nicotine is sufficient to relieve the unpleasant withdrawal symptoms. It will also help to stop your craving to smoke but will not give you the "buzz" you get from a cigarette. (Boots NicAssist Fresh Fruit Gum)
patient	The patient is constructed as facing potential difficulties	Because smoking is an addiction you may find it difficult to give up. (Boots NicAssist Fresh Fruit Gum)
patient	The patient is constructed as having a past	You may have tried to stop smoking before and you know from bitter experience that it's not easy to give up cigarettes. However, you have now taken the first constructive step towards becoming a non-smoker. (Boots NicAssist Fresh Fruit Gum)
patient	The patient is constructed as having a future existence after the medication has been taken	After you have stopped smoking you might find that in times of stress, reaching for a cigarette is the only thing that will help you through. (Boots NicAssist Fresh Fruit Gum)
patient	The patient is constructed as needing, and being influenced by, positive affirmation	Easyhaler Budesonide is easy to use. (Easyhaler Budesonide)
patient	The patient is constructed as needing to be motivated	However, you will find that as time goes by, your willpower becomes stronger. (Boots NicAssist Fresh Fruit Gum)
patient	The patient is constructed as having a life outside of the illness	Do that job around the house or garden that you've been putting off, or take up a hobby. (Boots NicAssist Fresh Fruit Gum)
patient	The patient is acknowledged as an individual	Giving up is more difficult for some people than others. If you fail to stop first time, don't be disheartened. (Boots NicAssist Fresh Fruit Gum)

Conclusion

It is clear that PLs, as they are written *for* patients, ought to meet patients' needs, and that more should be done to ensure that these texts achieve that goal. The approach that has been outlined in this paper involves continued use of the template, while additional content is included to help reflect patients' perspectives and knowledge and meet patients' needs. However, given that the template has been revised many times and patients remain dissatisfied with PLs, it may be advisable in the long term to consider replacing the template with a set of recommendations that integrated the findings of research and patient feedback, and allowed regulatory writers greater freedom to respond to patients' needs.[20,23]

Improvements to PLs, however they take place, would help medical regulatory writers produce PLs knowing that these texts were appreciated by their recipients. Pharmaceutical companies could also benefit from more personalised PLs, as patients currently attribute poor communication in PLs to

'big pharma's' lack of interest in their well-being.[4] But the biggest beneficiaries would be patients who found that *their* needs were better met in PLs. This would lead to greater levels of satisfaction with these texts, as well as likely positive effects for patient empowerment, patient education, and patient health and safety.

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What do writers need to know about user testing?

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Abstract

Increasing amounts of information are being made available to patients – but how do we know if we are getting it right and meeting people's needs? In this article, we describe how we have employed user testing to test and improve not just information for patients, but also for professionals and others. This is built on the many years of using this technique, first at the University of Leeds and then through the spin-out company Luto Research (http://www.luto.co.uk).

Keywords: User testing, Information for patients, Health literacy, Package leaflets, Risk management plans, Clinical trial lay summaries

Writing for a lay audience is a particular skill which needs to follow established good practice guidelines.[1] However, even expert writers cannot rely on their expertise alone – they need the input of members of the public themselves. User testing is a unique way of engaging people to test and identify where documents have problems and need improving.

How is user testing unique?

User testing is 'performance based' and shows how a document actually performs when being used by the target audience. It is unique because it combines both quantitative and qualitative data gathering – often finding weaknesses in documents which expert writers could not have predicted themselves. It is very different from content based testing using readability formulae (such as Flesch or SMOG), which generally only test relatively minor aspects of readability i.e. word and sentence length. This means that a piece of information written backwards will have the same readability score as when written forwards.

In a user test (Figure 1), participants are first asked to find, and then explain, key pieces of information. Following on from this, they are asked general questions about the document – what they liked and didn't like and how they thought the information could be improved. The latter (asking for an opinion) is more typical of the 'user involvement' employed in the past – but it is different here. In user testing, the general views and opinions come from participants who have just had to use the document to find and explain information. This gives them a much more informed perspective on which to base their general views on the pros and cons of the document.[2]

User testing is also different because in user testing it is 'real' people who are testing the information. In the past it has been more 'expert' patients whose views have been obtained – people associated with patient groups, for example. Such expert patients can provide valuable input at the early stages of health information development but, because of their expertise, they are not the right people to test the information produced. What we need are real people to test whether the information actually works – can they find and understand the information they need? In a recent test at Luto Research, a university spin-out company which develops, refines, and tests health information materials, the participants included a retired cleaner, an unemployed person, a stand-up comedian, and a bus driver – representative of the real people who have to be able to use and understand the information we produce.

How is user testing performed?

User testing is a defined process originally developed in Australia by Professor David Sless,[3] and the key steps are described in Table 1. An important point to note is that the participants are *potential* users of the information. If the participants were already familiar with the topic the document is describing, they would have prior knowledge which they could draw on, and not just rely on the

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Figure 1: Typical user testing setting.

information in the leaflet to answer questions. User testing mimics the situation when someone first encounters a particular treatment or health issue, and receives information about it.

Also important is that, when applied properly, user testing is an iterative process (Figure 2). The document is drafted and then tested, generally with a 'round' of 10 people. The results are then assessed, bearing in mind that not all feedback from participants can be taken forward; indeed sometimes the feedback can be contradictory. After this careful analysis of the data, good practice in information writing and design is applied to amend the document – and it is then tested in another round of 10 people. Crucially, the testing itself does not improve documents; it is the application of good practice between rounds which is the key skill. The use of small numbers in the testing often raises the question 'How can you test something on just 10 people?' The answer is that user testing is a form of diagnostic testing – finding out where documents do not work, and remedying problems using expert information writing and design practice. Our experience, in over 20,000 individual user testing interviews that Luto has carried out, is that if there is a significant problem with a document, this will become apparent in the first two or three interviews. David Sless likens this to finding a 'creak' in a set of stairs – you do not need a large representative sample of stair users to find a creak.[4] Remember, though, that in user testing it is the people who are testing the information; we are not testing the people. This has to be stressed at

Table 1: Key steps in user testing

Step	Description
1	Identify the key points contained in the document – usually 12–15 points for an average health leaflet
2	Decide who to test the information with – potential users of the information, with a range of reading abilities and ages
3	Write a questionnaire which (a) tests finding and understanding of each point (b) gets participants' general views on the leaflet
4	Pilot the questionnaire on 2–3 participants
5	Administer the questionnaire individually to a 'round' of 10 participants
6	Analyse the quantitative and qualitative data to identify the strengths and weaknesses of the leaflet
7	Revise those parts of the leaflet where there have been shown to be problems, using good practice in information writing and design
8	Test again on a new round of 10 participants

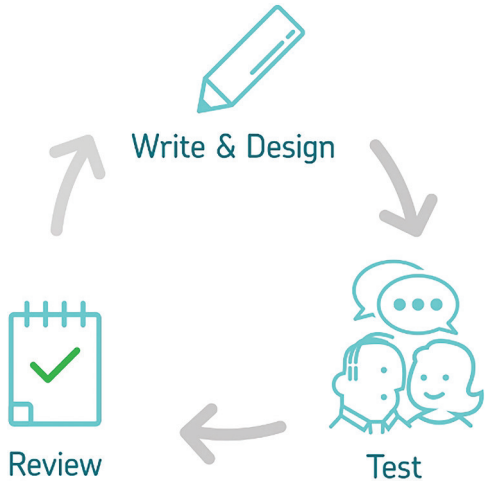

Figure 2: The virtuous circle: Write and design -> test -> review.

the beginning of each interview – we want them to find the weaknesses in the document.

How does this relate to health literacy?

It could be argued that the people least suited to assessing the suitability of lay information are the experts who write it. Medical writers, health professionals, and other people who work in regulatory affairs or medical information often have lives that are quite different from 'real' people. When writing for lay people, at the front of your mind should be that many people do not read too much and their literacy skills are much weaker than yours. Health literacy researchers often focus on identifying people with 'low health literacy' in order to provide particular materials or support to them. Our approach follows the 'universal precautions' approach promoted in the US, which accepts that all people would benefit from clear and well written information – not just the people with low literacy skills.[5] Indeed, health professionals themselves need clear and easy to read information – as shown by our user testing of the Summary of Product Characteristics (SmPC).[6]

What types of information can user testing be applied to?

User testing is the industry standard for testing Patient Information Leaflets (PILs) – indeed it is a regulatory requirement that such 'consultation with target patient groups' takes place. However, it is a powerful technique that can be applied to any type of health information – indeed any information at all. This means any format as well, including screen-based information and audio or video.

User testing has been applied to other medicines information such as educational materials accompanying Risk Management Plans (RMPs) in the EU or Risk Evaluation and Mitigation Strategies (REMS) in the US. Although not a legal requirement, successful user testing of such materials (for patients or for health professionals) has been welcomed by regulators. Other materials which have been improved by user testing include clinical trial patient information sheets[7] and lay summaries, which are becoming more prevalent, particularly in the EU. This includes European Public Assessment Report (EPAR) summaries[8] and RMP summaries. Our research shows that such testing can produce considerable improvements. However, it is not routinely applied. Even more significant is the new requirement for companies to produce lay summaries for all clinical trials. We have worked with a number of companies to maximise the readability of such summaries through applying good practice and user testing.

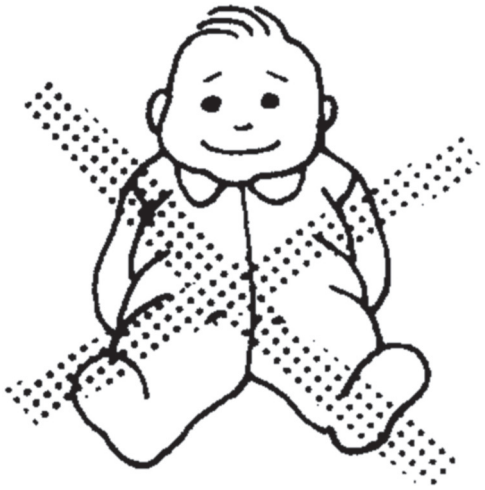

Figure 3: Keep out of the reach of children?

User testing can also be applied to pictorial information – indeed it could be argued that it is more important to apply it to pictorial information. If wording is not understood, the outcome is generally neutral – people just do not understand. With pictures, graphs, or other illustrations, people can get completely the wrong idea, which is more dangerous. This means that pictograms should always be tested. Take for example the pictogram in Figure 3. It was designed to be placed on medicine packs to put across a particular message: Keep out of the reach of children. However, our testing showed that some people gave three other meanings to it: 'Do not give to children', 'Do not use if you are pregnant', and 'This medicine is a contraceptive'.

User testing and usability testing

User testing is different from usability testing – but the two techniques can be complementary, and they can be combined into a single test. Usability testing is a term used typically to examine the usability of a set of instructions, such as the Instructions for Use (IFU) for a medical device. It is also used to determine how easy a website or app is to use. For medical devices with both a typical package leaflet and an IFU, we have developed a hybrid test which brings together the benefits of both techniques.

Key messages for medical writers

Writing for real people requires a different sort of writing. Many members of the public do not read too much, so their information needs to be written in a more conversational manner and needs to follow best practice for writing and design.

However, even following best practice cannot predict all of the problems that might occur. So, if you want to know if information works, ask the experts: the users themselves. However, finding out where the problems are is only half the battle. You then need to work with experts in information writing and design to work out how to iron out those problems.

Acknowledgements

We thank all those people who take part in our testing of health information materials – we depend on their expertise for user testing to work.

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Medical journalism: Another way to write about science

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Abstract

True journalism differs from public relations and uncritically reproducing press releases. It involves doing background research into the context surrounding the finding being reported, seeking comments from independent experts, and highlighting the negative as well as positive aspects. In this article, I pull together information for medical writers interested in journalism or science writing.

Keywords: Medical journalism, Medical writing, Science writing, Public relations

Ten years ago, I wrote an article on medical journalism for the *The Write Stuff,* the precursor of *Medical Writing*.[1] That article sought to define the differences between journalism and other types of scientific writing, and looked at prospects for medical writers (and others) wanting to make the move into medical journalism. At the time, I was working regularly as a scientific and medical journalist alongside my main job as a freelance medical writer. Then, for various reasons, medical writing took over, and a magazine that I'd contributed to for two years folded. So this article will be less of an account of my personal experience and more a pulling together of the information that's out there for someone interested in journalism or science writing. It is written from an Anglophone perspective; practices may be different in other parts of the world.

What is medical journalism?

Wikipedia defines medical journalism as 'the dissemination of health-related information through mainstream media outlets'.[2] However, this isn't wholly satisfactory as it ignores what many would see as an essential distinction between journalism and public relations (PR). According to the Institute of Public Relations (http://www.ipr.org.uk) in the UK:[3]

> *A PR specialist communicates with the target audience directly or indirectly through media with an aim to create and maintain a positive image [for their employer] and create a strong relationship with the audience.*

PR specialists may write press releases that end up being reproduced by the media, but they are not journalists. However, medical charities, non-governmental organisations, and universities all employ science communicators to publicise their research, and this is a way of being paid to write about science in a less commercial environment than corporate PR.

Perhaps a better definition of journalism would be 'Medical Journalism: Exposing Fact, Fiction, Fraud', which is the title of a 2001 book by Ragnar Levi.[4] The book includes 'information on pitfalls, stakeholders and their vested interests, telling facts from fiction, asking better questions and seeking betters sources'. A key difference between journalism and PR (or indeed medical writing) is that journalists aren't paid by the companies whose products they write about, and so are free to ask awkward questions and approach a subject from any angle they wish (within their own organisation's agenda, if it has one).

The UK's Medical Journalists' Association (MJA; http://www.mjauk.org) says 'we take pride in our autonomy and our motto: Independent and bloody minded.'[5] However, it's also common for newspapers and magazines to uncritically reproduce the press releases that flood into their offices, a practice that has been nicknamed 'churnalism' and is often the result of budget cuts. True journalism involves doing background research into the context surrounding the finding being reported, seeking comments from independent experts, and highlighting the negative as well as positive aspects.

What do medical journalists do?

So what do medical journalists do? According to the MJA,[5]

> *[Our membership] includes medical, health and pharmaceutical journalists, as well as doctors,*

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> *nurses, therapists and academics. We contribute to national and regional newspapers, professional journals, business and consumer magazines, radio, television and the web and between us we have written hundreds of books and reports.*

The Association of British Science Writers (ABSW) says:[6]

> *[Science journalists] use words, sounds, images, and graphics to create compelling stories about science that appear in newspapers, magazines, online, and on the radio, TV, and on the web in podcasts and video clips. Science journalists write about recent research discoveries; they also provide analysis, context, and perspective by exploring the social, ethical, and political implications of scientific advances and the scientific process.*

However, the ABSW goes on to say:

> *Journalists also hold scientists and the scientific process up to scrutiny. They examine questionable statistics or overinflated claims; they investigate scientific misconduct, conflicts of interest, and ethical breaches. They are often cool, dispassionate critics of science as much as they are champions of science.*

How to break in

How does one break in to medical journalism? Some medical journalists are full-time but others do it as a sideline to a medical or academic job. The rise of web-based communication and the decline in revenues earned by print publication has changed the job market for medical journalism, and has suppressed pay levels as readers and publishers increasingly expect content for free or for very low fees. Medical and scientific journalism is extremely unlikely to make you rich, and pay rates are lower than in medical writing. However, as the ABSW explains in its guide to being a science writer,[6] there are still opportunities. Blogging and tweeting are now standard parts of many science writers' work and are also suggested as ways to build up a body of writing as a way of getting noticed. Increasing numbers of science writers in the UK come through one of the various degree courses in science communication.

Freelancing as a medical or scientific journalist can be fun but is hard work unless you have someone who will regularly push work to you. Otherwise, freelancers must keep pitching ideas to editors. Each pitch takes time and effort to research, and editors receive far more ideas than they can use. Before approaching an editor, research the publication or website thoroughly and look at their guide for contributors.

According to the ABSW, the best way to decide whether science journalism is right for you is simply to have a go. Blogging, writing for your university, corporate or professional magazine or taking an evening or online writing class are all ways to get started. The World Federation of Science Journalists has put together a free online course, available at http://www.wfsj.org/course/index-e.html. Be wary of the heavily advertised courses that promise to refund your fees if you don't earn them back through writing. Courses from professional or academic providers are likely to be of better quality.

Box 1: Where to find out more about medical journalism

- Science writing: the basics. Association of British Science Writers. http://www.absw.org.uk/files/SYWTBASW_PDF_MB1_1.pdf
- Thirty-five Writers of SciLance, The Science Writers' Handbook. SciLance, 2013: http://pitchpublishprosper.com/science-writers-handbook/
- Council for the Advancement of Science Writing: A guide to careers in science writing available at http://casw.org/casw/guide-careers-science-writing
- National Association for Science Writers: FAQ for new and aspiring science writers available at http://www.nasw.org/faq-new-and-aspiring-science-writers

Can you be both a medical writer and a medical journalist? Yes, but it involves a change in mindset. For example, the information required in an academic conference abstract is very different from that needed for news story on the same study, and so is the style of writing. Many medical writers find it difficult to make the transition. However, in-depth knowledge of drug development and rigorous scientific training could give you a competitive edge if you can develop your writing and communication skills in the right way.

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Elements of storytelling in medical journalism

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Abstract

Medical journalists marry the techniques of technical medical writing and storytelling in their work. They need a high-level understanding of the science behind the story, but they must also skilfully employ techniques that draw in readers who may feel the topic is too complex for them. Journalists do this by hooking readers with the stories of the real people affected by the science and painting verbal pictures of hard-to-grasp concepts.

Keywords: Journalism, Medicine, Storytelling

I wanted to write before health and medicine ever entered my mind as my potential subject matter. They weren't even interests of mine. I had Bachelor's and Master's degrees in creative writing, and I wrote short stories and submitted them to journals while earning a very meagre 'living' teaching creative writing at a couple of colleges. I didn't feel like I had chosen that life. I felt like I had ended up in it. I meant to teach for a year or so, while I 'figured out' how to make a living as a writer. Suddenly I had been teaching for nearly ten. Teaching demanded more and more of my time, and writing got less and less. I felt that I was haemorrhaging wasted potential. I was extremely unhappy. I knew the next ten years teaching writing rather than actually writing would go by even faster than the first ten if I didn't plan my exit. I couldn't keep teaching while I waited for someone to publish my short stories. I needed to learn how to write something that people needed to read.

I wanted to learn a trade. I didn't want to get yet another Master's degree that was going to groom me for more academia. I already felt that my Master of Fine Arts in Creative Writing had made me a teacher, rather than a writer. I was teaching at the University of Georgia (UGA) at the time. The only graduate program at UGA's Grady College of Journalism and Mass Communication that was intended to prepare graduates for work in the field, rather than prepare them for a PhD, was the Master's in Health and Medical Journalism.

Health and medicine? Where was the poetry, the storytelling in that? I didn't want to write about biology. I wanted to tell stories, develop characters. I was a writer, not a scientist. I said all of this to the program chair, Professor Patricia Thomas, who assured me that health and medicine were rich with stories waiting to be told as she pushed a copy of Anne Fadiman's *The Spirit Catches You and You Fall Down* into my hands. 'Every story is a health story', she said. So I applied for the program and got in.

Everything I learned in journalism school and over the subsequent five years as a full-time independent journalist has refuted any preconceived notions I had about medical journalism – that it was dry, heartless, and devoid of storytelling and poetry. Medical journalists don't just have the opportunity to use the same literary devices taught in creative writing workshops; they *must* use these tools to engage lay readers in topics readers may otherwise think are too complicated to understand.

Human stories

Some readers will easily engage in a health story whose subject matter has a direct impact on them. Perhaps the reader is living with cancer, and the story describes a possible new treatment. To engage everyone else, however, reporters have to introduce readers to the people who live the stories – the characters needed to move any story along.

In a February 2014 story for *The Boston Globe*, Liz Kowalczyk reported on the risks of liver surgery for live donors.[1] A shorter story might have begun 'A Florida man died yesterday during live liver transplant surgery.' Kowalczyk, on the other hand, invests readers in the subject through the stories of Paul and Lorraine Hawks. Before readers learn of the risks of live liver donation that caused Paul Hawks' death, Kowalczyk paints a picture of a

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devout couple who pray together; a husband who shares in household chores with his wife; a couple who had a lot of living ahead of them. The reporter chooses carefully the details to reveal about the couple in a just a few information-packed lines:

> 'In that instant, Lorraine's world shattered. The Hawks, married for 35 years, had big plans. Now they wouldn't be building a new home in Tampa that summer, starting a small Christian ministry, or taking their road trip to North Carolina's Black Mountains.'

Readers who didn't have a personal interest in live liver donation now have an interest in this couple. They will read on to learn how a healthy man undergoing elective surgery could unexpectedly die.

Imagery

Reporters draw lay readers into scientific and medical stories by putting them at the centre of the action. This requires more than just a summary of the action. It needs images that appeal to the senses and give dimension to the scene. Kowalczyk doesn't simply tell readers that Mr Hawks died in surgery. She recreates the scene:[1]

> '[W]hen [the nurse] eventually led [Lorraine] and her family to a remote conference room, Lorraine began to weep, aware only of the nurse's heels clicking on the tile. […] As doctors and nurses in fresh white coats filled the room, she knew something very bad had happened.'

The images of heels clicking and fresh white coats make a lasting impression.

Metaphor

After a reporter has pulled the reader in with three-dimensional characters and scenes, there is still complicated science to explain. To help lay readers understand scientific and medical concepts, reporters might use metaphors. In her 2010 book-length work of journalism, *The Immortal Life of Henrietta Lacks*,[2] about the origin of HeLa cells, Rebecca Skloot creates an image of a cell that puts all readers at ease. Readers of the paragraph below, which falls early in the book, are made to feel that perhaps this subject matter isn't too complicated for them. With that, they press on to the next page.

> 'Under the microscope, a cell looks a lot like a fried egg: It has a white (the *cytoplasm*) that's full of water and proteins to keep it fed, and a yolk (the *nucleus*) that holds all the genetic information that makes you *you*. The cytoplasm buzzes like a New York City street. It's crammed full of molecules and vessels endlessly shuttling enzymes and sugars from one part of the cell to another, pumping water, nutrients, and oxygen in and out of the cell. All the while, little cytoplasmic factories work 24/7, cranking out sugars, fats, proteins and energy to keep the whole thing running and feed the nucleus. The nucleus is the brains of the operation; inside every nucleus within each cell in your body, there's an identical copy of your entire genome. That genome tells cells when to grow and divide and makes sure they do their jobs, whether that's controlling your heartbeat or helping your brain understand the words on this page.'[2]

While a cell biologist might not be completely comfortable with such a non-scientific description of a cell, by design this description makes readers quite comfortable. Had Skloot leapt right into the roles of the nucleus and the cytoplasm, she certainly would have lost some insecure readers. With the fried egg metaphor, she gives readers an image they can call up quickly in their mind. Then she zooms in on the cell, but she doesn't let go of the reader's hand. The image becomes more complicated, but no more so than a busy New York City street crammed with cars and factories. The image is as easy to conjure up as the fried egg. As Professor Thomas tells her journalism students, 'A good health story makes readers feel smart.' Indeed, readers can congratulate themselves at the end of the above paragraph: the author explained the inner workings of a cell, and they got it.

Numbers as images

Data and numbers can alienate the lay reader as much as a rote description of the anatomy of a cell. 'Infographics' are increasingly popular because they help readers to visualise data on countless topics. Journalists create these types of visuals with their words.

A common construct is 'that's enough to fill …'. A December 2014 story by the Associated Press visualised the amount of plastic in the world's oceans – 270,000 tons – as 'enough to fill 38,500 garbage trucks.'[3]

The numbers that may be hardest for readers to picture, however, are the seemingly smaller ones. When a particular condition strikes one or two per

cent of the population, should the reader be concerned? Is that a lot or a little? Take for example a public health story about rising teen birth rates. For an epidemiologist, '26.5 births for every 1,000 adolescent females ages 15 to 19' means something.[4] Many lay readers won't know what to make of this number. It's about two per cent of teen girls, which is easier to understand than 26.5 out of 1,000, but how does it apply to the reader? How does this statistic impact adolescent girls where the reader lives?

A reporter who wants to visualise this number for readers might think like this: In the U.S., there's about 12 or 13 girls in every classroom of 25 students. That's one pregnant teen in every four high school classrooms.

Science and storytelling

I never anticipated that reporting on medical research or the national impact of a particular disease would satisfy the same creative urges that writing short stories did. As a journalist, I still get to pore over how to unfold a story, choosing exactly the right moment to reveal each fact. I think and rethink which details about a character will portray her for readers exactly as I saw her. Which of her words will most accurately recreate her voice? How can I describe this microbe, tissue, or number so someone else can see it?

The storytelling challenges that I relished as a short fiction writer are the same ones that make my work as a medical journalist so satisfying. When I treat the work as storytelling – filling it with sympathetic characters and accessible images – I tell readers that this is a topic that anyone, even they, can understand.

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A stroll through the medical blogosphere

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Abstract

Medical blogs are a very popular way of communicating health-related information. They can be written by medical professionals or laypeople, and topics include diseases, procedures, health policies, and personal topics such as everyday experiences. In this article, we provide examples of medical blogs that illustrate the language used, which can be technical, semi-technical, or informal. Medical blogs need to be accurate and well written because they provide precious information about health-related issues.

Keywords: Medical blogs, Language, Form, Style, Lay audience

If you have a rash or fever, more often than not, you will consult the Internet before you visit your general practitioner. Once you open your browser and start searching for a medical topic, you will be flooded with links to many kinds of websites. Some will take you to online scientific journals, while others will take you to different wikis, question and answer portals (Q&A), or blogs. In this paper, we focus on medical blogs.

'Blog' is blend of the term 'Web log', a specific form of online diary. Blogs serve as platforms for voicing personal or professional views on a certain topic. Topics are listed in chronological order and may have photos and videos as well as hyperlinks to other web pages or blogs. Blogs are easily accessible, and anyone with a computer and access to the Internet can author one. Usually, users can subscribe to a blog, leave comments, and find references to other blogs and relevant pages. This interconnectivity and ability to provide feedback facilitates 'knowledge sharing, reflection, and debate, [and] they often attract a large and dedicated readership'.[1] Usually blogs appear as diaries expressing the author's feelings, opinions, and ideas. Some blogs, however, are educational tools used by students and education professionals, while others aim to serve as a forum for people who share similar opinions or professions.

Medical blogs

Medical blogs do not differ much from other blogs, although they focus, broadly speaking, on health and health-related issues. Their content varies from diseases, medication, health policies, health research, and nutrition to personal experiences.[2] Typically, medical blogs focus on one topic, but it is not uncommon for them to cover two or more.[3] Medical blog authors vary from physicians, nurses, medical students, patients, patients' family members, lawyers to journalists. The content can be considered as either informative or affective; informative content uses medical terminology extensively, while affective content uses an abundance of adjectives.[2] Three groups of bloggers are identified: physicians, patients, and nurses. It has been noticed that physicians tend to focus on illnesses, patients mainly focus on medication, and nurses focus on their everyday life and experiences.[2] Blogs written by physicians can be on a specific illness, procedure, or health policy, or they can deal with their everyday experiences or professional communication. Some bloggers are anonymous or write under pseudonyms, and for those who appear to be more transparent, it is usually impossible to check their credentials and identity with certainty.

This fact and the easy accessibility of blogs lead us to the question of the validity and relevance of the information disseminated on medical blogs. Not all of the authors reference the information on their blogs to a medical journal or traditional medical literature. Blog authors who publish scientific papers or books tend to mirror the conventions of scientific writing.[4] Some blogs (e.g. *Intensive*[5]) have more contributors who range in function from editors and section editors to consultants. These

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are often associated with official institutions, so they tend to be more credible.

The personal diary nature of blogs tends to make their writing a stream of consciousness. As Scott Plutchak[6] noticed while experimenting with blog writing, it takes less time to write a blog post than other types of documents; he observed that even with the time spent on revisions, blog writing is far less time-consuming than writing editorials. Writing editorials or scientific papers, in his opinion, is not the mere reporting of one's thoughts and ideas, but an exploration, a finding out of what one thinks about a certain topic. However, one of the advantages of this type of online publishing is the direct dissemination of information, knowledge, opinions, and ideas on a peer-to-peer level; blogs, Twitter, and e-mail discussions are far superior for this kind of exchange than online journals and traditional publishing.[7] A likely reason for this is the informality of blogs, which can also be a disadvantage.

Form and style

Patient-written posts tend to be longer than those of nurses and physicians. Nurses tend to use more adjectives and everyday language. Patients tend to avoid names of their diseases '(e.g. the beast instead of 'migraine') or use only abbreviations (e.g. Type 2 instead of diabetes type 2)'.[2] 'Abbreviations (e.g. CLL for chronic lymphocytic leukemia), enumerations, and citations of conversations as well as common speech, medical terms, and opinion-related words are used frequently in medical blog posts'.[2] The format of medical blogs seems to encourage a more conversational style and can sometimes even lead to online discussion boards. Sentences tend to be syntactically simple and correct. The language and the scope of medical terminology used, however, differ significantly according to the aimed or expected audience. The following randomly selected examples illustrate some of linguistic and content variants of medical blogs.

Example 1

Sinus bradycardia HR ~60 bpm with intermittent sinus arrest / sinus exit block, shown by 2 missing p waves followed by 2 ventricular escape beats at a rate just under 40 bpm.[8]

This particular example is an answer to a question in an educational post where readers (students or younger practitioners of medicine) are supposed to interpret a photo that contains rhythm strips of a fictional case-scenario. The answer is revealed after one click on the question of the post. This example is obviously aimed at professionals, not laypersons. The language is highly technical, abundant in noun phrases and abbreviations. An average person with no medical education would probably have difficulties understanding this.

Example 2

My dear readers, if you even exist anymore :-), I have neglected you. For that I am sorry. My last post was more than a year ago.[…]So, insert drum roll here, here it is! My first video lecture demonstrating how to use ultrasound to gain peripheral venous access. Hope you'll like it, because there are others following soon, and I intend to bore you with them as well;).[9]

This example is of a personal blog written by a doctor. The content is as diverse as the heading of the blog itself says: '*about medicine, science, internet, soap bubbles, design, imaginary friends, books, music for robots, uncreative taglines …*'[9] The language varies from very informal (use of emoticons, and idioms) to more specific or technical. The audience here is not specified, but there is a specific conversational or familiar tone as if talking to friends or peers. The posts vary from medical applications (Apps) to medical emergencies during football matches. The language is informal where possible and reverts to being technical where needed.

Example 3

In theory, all doctors should treat all patients equally. In practice, nice, friendly patients get better, quicker treatment. Queue shock, horror, outrage.[10]

This example is from the *British Medical Journal*[11] which has various direct links that can take you to diverse blogs dealing with myriad of topics. This one comes from a doctor's blog. The main audience is patients as indicated by the title, *Inside secrets to getting the best hospital care.*[10] Thus, the language used is far from technical. It is conversational, yet borderline formal, with frequent informal intrusions (e.g. *rubbish care, stroppy, demanding, impatient arse*[10]). The style of the post is very humorous, one might even say satirical, if, say, the reader is a doctor. If you are a patient, you might find it a bit offensive, yet practical.

Example 4

This year, there has been a major resurgence of measles, a dangerous disease that for decades had been virtually unknown in the United States. And it's become clear that measles has re-emerged as a public health issue in this country because large numbers of individuals remain unvaccinated.[12]

Figure 1: A well-organized medical blog.

As a part of the blog *Well*[12] of the *The NewYork Times*, this post is written in journalistic/column style. The post itself begins with a more personal touch with the author introducing the story from her private life but then it goes on to be more factual and narrative. The terminology is in the sphere of plain language (*Confronted with a patient suffering from a fever, red eyes, runny nose, cough and blotchy rash, we don't even think of measles[…]*[12]). The language is adapted for the broadest audience possible.

Writing a medical blog

People who decide to write a medical blog should pay attention to the type of information they provide, accessibility and readability of the blog, and the language used.

Since blogs are a personal view on any issue close to authors' heart, they undoubtedly portray their views, opinions and attitudes. Medical blogs, however, usually provide the readers with facts about health-related topics and should, therefore, be more objective. The credibility of the information is achieved through mentioning the sources either by referencing them or by inserting a hyperlink to a research/article. Another way to achieve credibility is for the authors to clearly display their credentials, to respect patient's confidentiality and disclose any potential conflicts of interest (e.g. *KevinMD*[13]).

Blog posts, as was mentioned before, appear in chronological order, thus writers should strive to make blogs more organized in order to make the navigation through the site easier. This could be achieved either by organizing the blog topically (by adding different sections: physician, patient, health policy, health tips, audio, video etc) or by adding 'tags' that serve as keywords for the post (e.g. *Better Health*[14], see Figure 1).

The language of the posts depends on the readership, but more often than not, the audience are laypersons. With this in mind, authors should try to avoid technical language and rely on plain language (where possible). Instead of saying that herpes zoster is caused by varicella-zoster, it would be

Table 1: Useful links for future medical bloggers

Topic	Links
Plain language	*Plain Language Medical Dictionary.* http://www.lib.umich.edu/plain-language-dictionary *How to write medical information in plain English* https://www.plainenglish.co.uk/files/medicalguide.pdf *Medical Translator* http://www.iodine.com/translate
How-to guide	*How to Start a Blog* http://www.wikihow.com/Start-a-Blog *How To Start a Blog – Beginner's Guide for 2015* http://www.bloggingbasics101.com/how-do-i-start-a-blog/
Blogging platforms	*Blogger* https://www.blogger.com/ *WordPress* https://wordpress.com/
Medical search engines	*MedWorm* http://www.medworm.com/ *iMedisearch* http://www.imedisearch.com/ *WebMd* http://www.webmd.com/

better to say that shingles are caused by the chicken pox virus. If the author wishes to retain the technical terms, one can do so by adding them in parenthesis. This makes the posts more readable and also provides the audience with information for further research. Sentences should be clear and syntactically simple. Authors should avoid clusters of noun phrases, abbreviations, impersonal sentences, and reduce the use of passive. The language should be accessible to everyone, but not colloquial (avoid jargon).

For some useful links that could help you start a medical blog, see Table 1.

Conclusion

There is an abundance of medical information on the Internet. The most common are medical blogs, which come in diverse forms. The general idea behind these blogs is to familiarize different types of audiences about various medical topics (both professional and personal). The main challenge in writing a medical blog is to adapt the technical language in an understandable way for lay audiences. People who decide to use the Internet in order to find health-related information expect to find medical information in plain language. Since this type of information is of great importance to readers it is paramount to make those sources trustworthy and authentic, both in the form and content.

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Writing narrative style literature reviews

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Abstract

Reviews provide a synthesis of published literature on a topic and describe its current state-of-art. Reviews in clinical research are thus useful when designing studies or developing practice guidelines. The two standard types of reviews are (a) systematic and (b) non-systematic or narrative review. Unlike systematic reviews that benefit from guidelines such as PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement, there are no acknowledged guidelines for narrative reviews. I have attempted to define the best practice recommendations for the preparation of a narrative review in clinical research. The quality of a narrative review may be improved by borrowing from the systematic review methodologies that are aimed at reducing bias in the selection of articles for review and employing an effective bibliographic research strategy. The dynamics of narrative review writing, the organizational pattern of the text, the analysis, and the synthesis processes are also discussed.

Keywords: Narrative review, Systematic review, Search methodology, Review writing

Introduction

A periodic synthesis of knowledge is required because of the huge amount and rapid rate of publications. The need for a review of literature may arise from the abundance of information, divergent views, or a lack of consensus about a topic.[1,2] Although synthesizing the literature is a challenging task, the interest in reviews is ever-growing. Unlike original articles, literature reviews do not present new data but intend to assess what is already published,[3,4] and to provide the best currently available evidence. For this reason a review is defined as a 'secondary research' study, meaning that it is based on 'primary research' studies.[1]

The two standard types of reviews are (a) systematic (SR) and (b) non-systematic or narrative review (NR). NRs are aimed at identifying and summarizing what has been previously published, avoiding duplications, and seeking new study areas not yet addressed.[3,5,6] While PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) provides reporting guidelines for SRs, no acknowledged guidelines are available for NR writing. The task of review writing is frequently assigned to medical writers, for example, on new or completed research projects, synthesis for editorial projects. However, training opportunities on writing literature reviews in the biomedical field are few. The objective of the present study is to identify practice guidelines to improve NR writing on topics related to clinical research.

Comparison of narrative and systematic styles of literature reviews

A recent report stated that NRs form the basis of medical literature synthesis, and their number per year in MEDLINE significantly surpassed that of SRs.[7] Although NRs and SRs differ in objectives, methods, and application areas, both may include several kinds of studies with different levels of evidence: randomised clinical trials, observational case-control or cohort studies, and case reports. Nevertheless, since NRs and SRs are written retrospectively, both are prone to bias.[8]

The main objective of a SR is to formulate a well-defined question and provide a quantitative and qualitative analyses of the relevant evidence, followed or not by a meta-analysis. The SR strengths are: focus on a unique query, clarity in retrieving articles for review, objective and quantitative summary, and inferences based on evidence.[9] Nevertheless, SRs have several limitations: heterogeneity in the selected studies, possible biases of single studies (patients selection, performance evaluation, measurement), and even publication biases.[8,10] Moreover, SRs cannot be continuously updated; the median validity of an SR has been estimated as 5.5 years, but it is 3 years for 23% of reviews and 1 year for 15%, depending on the

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therapeutic area.[10,11] According to some reports on SRs, significant shortcomings of SRs were the lack of: assessment of biases, reporting of key methodological aspects, especially in non-Cochrane SRs,[12] and inclusion of adverse assessments.[8] Standard methods of collecting data for SRs can be complicated, for example, if the patient and disease characteristics are not well reported,[7] and it might be difficult to draw conclusions that would be applicable in daily practice. Moreover, there are no rules regarding the sample size requirements.[8]

In contrast to SRs, NRs can address one or more questions and the selection criteria for inclusion of the articles may not be specified explicitly. Subjectivity in study selection is the main weakness ascribed to NRs that potentially leads to biases.[8] An historical NR is irreplaceable to track the development of a scientific principle or clinical concept; as in fact, the narrative thread could be lost in the restrictive rules of a SR; some issues require the wider scoping of a NR. On the other hand, the rigour of an SR is needed to evaluate, for example, the efficacy of diagnostic or treatment interventions, and the outcomes of natural or therapeutic exposures.[9] Although these are the key sources of evidence, their technical language and the time needed to identify the key results may deter their application.[13] Table 1 summarizes the hallmark differences between NRs and SRs.[14]

In reality, neither the SRs with their restricted focus, nor the NRs with their distinctiveness completely satisfy the wide range of topics to review.[9] Hence, new approaches are currently in development such as meta-narrative reviews[15] and realistic syntheses.[16] Once the need for an NR is identified, a glance at the expert opinions on this particular topic may be useful in improving the method of literature selection and reducing the risk of a suboptimal reporting.

Preparation of a narrative review

As yet there is no consensus on the standard structure of an NR. The preferred format is the IMRAD (Introduction, Methods, Results, Discussion), but an NR may be organised in a chronological order, with a summary of the history of a research when clear trends are identified, or presented as a 'conceptual frame', where the contents are separated according to dependent or independent variables and their relationships.[2,17] However, the NRs structure should respect, apart from the author preferences, the journal style, and the conventions followed in the particular field. Table 2 visualizes the general framework of an NR. In this model the central body is partitioned in units (sections), each composed by concepts (key variables), which are discussed and evaluated.[2]

Literature search

Unlike SRs, the Methods section is not mandatory for NRs (depending on the journal style), but if included, it adds clarity to the key messages of the NRs.[2,18–20] The literature search (the 'Methods') is a critical step in determining the selection bias. If the review query is well-defined, for example, a clinical question, then it would be possible to design an appropriate search strategy in a form suitable for search engines. Hence, a structured approach on the lines of that used for SRs is advisable in literature search for NRs.

Table 1: Main differences between narrative and systematic reviews

	Narrative reviews	Systematic reviews
Main Features	Describe and appraise published articles but the methods used to select the articles may not be described.	The query is well defined [review question, secondary question(s) and/or subgroup analyses]. Clearly defined criteria for the selection of articles from the literature. Explicit methods of extraction and synthesis of the data. Comprehensive research to find all the relevant studies. Application of standards for the critical appraisal of the studies quality.
Uses/applications	General debates, appraisal of previous studies and the current lack of knowledge. Rationales for future research. Speculate on new types of interventions available.	Identify, assess and synthesize the literature gathered in response to a specific query. Collect what is known about a topic and identify the basis of that knowledge. Comprehensive report with explicit processes so that rational, assumptions and methods are open to examination by external organizations.
Limitations	The assumptions and the planning are not often known. Selection and evaluation biases not known. Not reproducible.	The scope is limited by the defined query, search terms, and the selection criteria Usually reader needs to reformulate the alternative questions that have not been answered by the main query.

Table 2: General framework of narrative reviews

Introduction

- Content: describe the rationale
- Structure: organization of the collected information
- Limits: define the objective(s) and scope

Literature search

- Searching strategy: databases, keywords
- Inclusion/exclusion criteria: types of studies, languages, time periods, others
- Verify the availability of all the selected studies
- Citing and listing the researched references

Central body/Discussion:

Section 1
First key concept:
- discuss and evaluate
- summarize in relation to the research query

Section 2
Another key concept:
- discuss and evaluate
- summarize in relation to the research query

Added sections
- following the same pattern

Conclusions
From each summarised section:
- highlight the main points
- connect with the research needs
- repeat the meaning for the research design

Abstract
- According to the journal style
- Descriptive or structured (IMRAD pattern)

Search terms

As the search terms (keywords) define the limits and the nature of the literature search, these should be established in a comprehensive way in order to permit selection of all the related articles, and at the same time, eliminate those that are not relevant. The key concepts are transformed into keywords, choosing only the most distinctive terms.[2,18] Thesaurus systems such as the MeSH (Medical Subject Headings) terms of the National Library of Medicine, which are used to index articles for PubMed, may be referred to for selecting the appropriate keywords directly related to the topic of interest.[1,3,18]

Selection criteria

Defining the inclusion/exclusion criteria for literature selection can be helpful in focusing on the relevance of the studies to the topic. The exclusion criteria may be identified according to the pertinence of the search objective, whereas the inclusion criteria may define the fundamental factors of the review.[2]

In the first step it is useful to mark the date, keywords, and their combination with the number of records retrieved during each search. The process may continue selecting manually other publications that are cited in the articles retrieved during the first search. Then the cycle can be repeated till reaching a 'saturation point'.[17]

It is advisable to include a variety in the information sources, for example consult different databases, and limit citations of the same research group or the same journal, even though these may be authoritative.[18] Original articles are preferable over other NRs on the same topic. In addition to reports of randomized clinical trials and observational studies, editorials by key opinion leaders may also be included.[1]

Once a primary bulk of articles is obtained, the selection may be refined and process may be recorded in a 'Summary table' or using 'Reference cards';[18] it is useful to sort the articles and file these with the bibliographic references in an appropriate citation style.

Critical assessment

Evaluating the fitness of an article for the review may prove to be a complex task that concerns different issues related to the journal, author's(s') reputation, accuracy of methods, analysis and coherence.[6] In general, each article should be critically evaluated according to the following:[3]

- key results
- limitations
- suitability of the methods used to test the initial hypothesis
- quality of the results obtained
- interpretation of the results
- impact of the conclusions in the field

The studies with the best contributions should be synthetized[3] highlighting the possible

inconsistencies among the results. Moreover, it may be opportune to integrate new articles in case of missing evidence.

Crafting the text

Drafting an NR text rarely follows a linear pathway, as it is a dynamic process.[1] The starting point is the data retrieved – visualized in figures and tables – which are the cornerstones of the NR; in fact, each section should refer to the gathered data.[21]

In the preparation of the NR, the Introduction should be written after the Results and Discussion sections are finalised; in fact, the NR analysis of the retrieved articles allows a better understanding of the results, and facilitates a meaningful discussion and conclusions.[2,21,22] Moreover, retracing the text backwards enables elimination of points that may be redundant or irrelevant to the main discourse.[21] The drafting of the Discussion should follow the critical assessment process: the previous sections are re-assessed, the results are evaluated and interpreted referring to the initial query, highlighting the meaning and validity of the conclusions.[18]

The writing of conclusions, title, and abstract of an NR follows the criteria of other manuscripts.[2,18,19,23] A particular attention should be paid to the title and keywords since these are used by databases for indexing the article. The title may include text from the abstract, and should mirror the essence of the whole article. The title should also be attractive enough to persuade readers to read the abstract and then the article.[18,21,22] Informative titles, which state the relevant elements of the manuscript conclusively are considered better than indicative titles. Definitions such as 'A review' or 'Clinic review', 'Updated review', 'Clinical evidence' in the titles do not add value,[18] whereas the indication 'literature or narrative review' or 'review of the

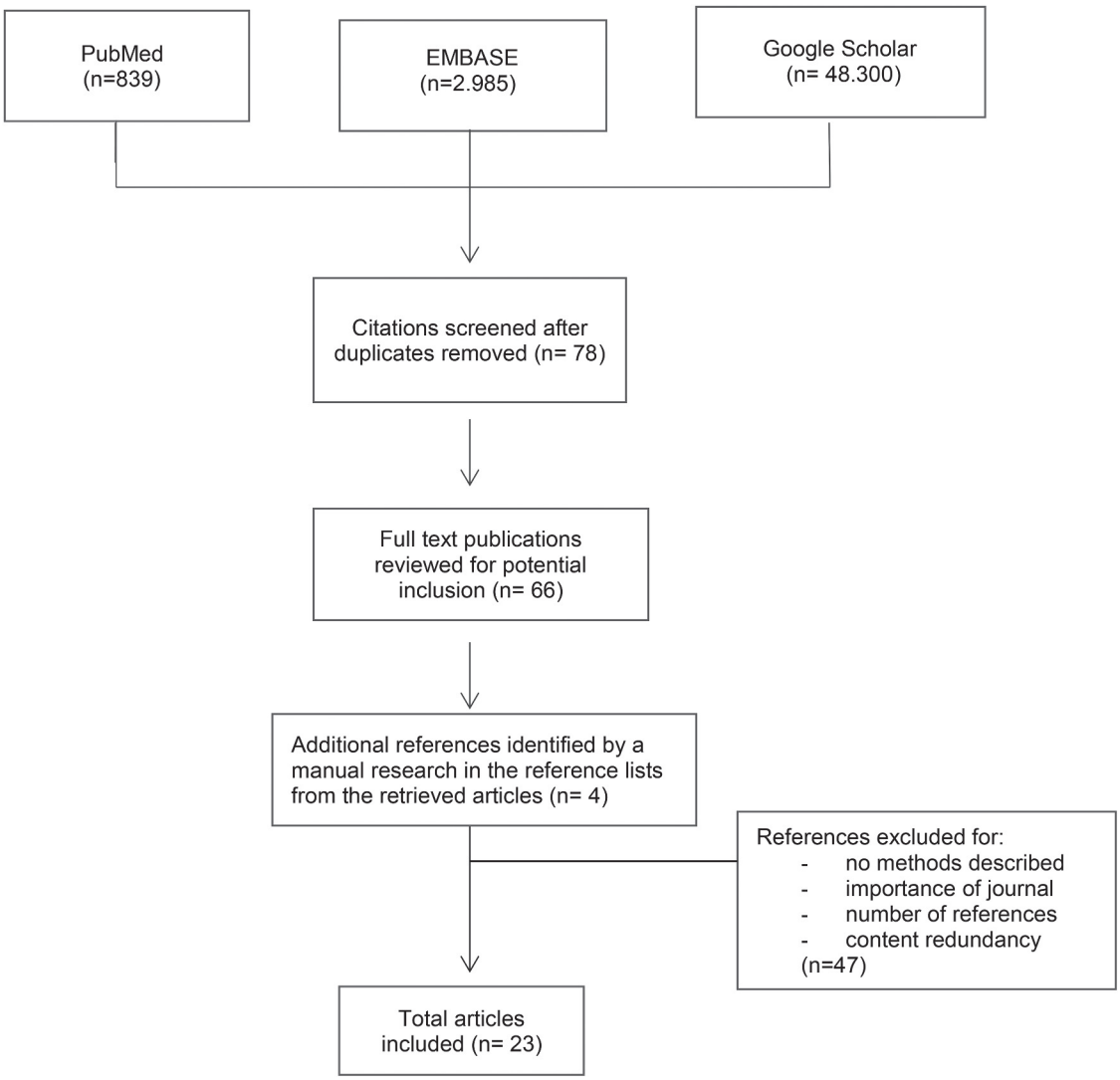

Figure 1: Flow chart of the literature selection process for the present article.

literature' is helpful in clarifying the research design. An example of good title is: *Injuries Associated with Soccer: A review of Epidemiology and Etiology*.[2]

Literature search for the present article

As an example, a literature search was performed for the present study on the lines of searches for an NR, but including features of SR methodology (Figure 1). The electronic search included three databases, PubMed, EMBASE and Google Scholar, and used three search terms: 'medical literature review writing', 'medical narrative review writing', and 'medical systematic review writing'. The inclusion criteria were: all types of articles, articles published in PubMed, and related only to humans. The exclusion criteria were: articles for which full text was not available, were not in English, or were grey literature. From the articles retrieved in the first round of search, additional references were identified by a manual search among the cited references (Figure 1).

Conclusions

The international debate over reviews is far from being dampened. However, NRs are still the cornerstone for synthesis of medical literature, with functions and applications different from those of SRs. The preparation of NRs can benefit from applying the methodological rigour of SRs. As suggested here, restricting the focus on well-defined issues, establishing clear inclusion and exclusion criteria for literature search, concentrating on a specific set of studies and establishing a relevance criteria of selection would help improve the quality of NRs. A methodological approach to NRs is essential because inadequate reporting influences the interpretation, the translation and the application of published research.

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News from the EMA

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The articles included in this section are a selection from the EMA's news and press release archive for June–August 2015.

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

Updates to product information templates for all medicines for human use

10 June 2015 — Changes will enhance presentation of information for patients and healthcare professionals

The European Medicines Agency (EMA) has introduced a number of changes to the templates of the product information that accompany all medicines authorised for use in the European Union (EU). These changes are expected to improve the way information is presented on medicines.

The product information is part of the marketing authorisation of all medicines. It provides objective and up-to-date information about the quality, safety and efficacy of the medicine. The product information consists of the package leaflet with information for patients and the summary of product characteristics (SmPC) that is intended to guide doctors, pharmacists and other healthcare professionals in prescribing, dispensing and administering medicines. It also includes the labelling, information to be included on the outer packaging of medicines or on the immediate packaging.

The changes to product information templates are detailed in the updated guidance for the pharmaceutical industry published on June 10: http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500004368

The main modifications are:

- the printed package leaflet for patients may only contain the address of the local representative of the marketing-authorisation holder in the Member State where this particular medicine is sold, instead of the contact details of all local representatives in all EU Member States;
- all strengths of the same pharmaceutical form of a medicine can now be combined in one SmPC, whereas until now a separate SmPC was required for each strength of the same pharmaceutical form.

EMA publishes video and presentations from the 24 June webinar on the implementation of its transparency policy

29 June 2015 — The European Medicines Agency (EMA) has published today the video recording of its webinar held on 24 June to provide an update on the implementation of its policy on the publication of clinical data, as well as the slides of all the presentations given.

The video and presentations are available on the EMA website at http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2015/06/event_detail_001163.jsp&mid=WC0b01ac05800 4d5c3.

EMA's policy on publication of clinical data entered into force on 1 January 2015 and applies to clinical reports contained in all marketing-authorisation applications submitted on or after this date. The first reports will be published as soon as a decision on the application has been taken, currently foreseen for mid-2016.

To help stakeholders anticipate the requirements and prepare for the publication of clinical reports, the Agency explained the work processes which are foreseen. The topics covered by the webinar included an explanation of the principles for the submission of redacted clinical reports, the redaction consultation process, as well as guidance on redacting commercially confidential information in clinical reports and on the anonymisation of clinical reports for the purpose of publication.

During the webinar, participants had the opportunity to comment interactively on these topics and share their views.

A face-to-face meeting will be organised on 6 July 2015 at the EMA to allow more detailed discussions on the draft guidance on anonymisation of clinical reports for publication and on redacting commercially confidential information in clinical reports. Stakeholder organisations have been contacted to nominate experts as participants in this meeting. The guidance is expected to be finalised and published after the summer.

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Regulatory information – Electronic application becomes mandatory today

EMA application forms should be used for all human and veterinary centralised procedure applications as of 1 July 2015

1 July 2015 — Companies are obliged to use electronic application forms provided by the European Medicines Agency (EMA) for all centralised marketing authorisation applications for human and veterinary medicines. Forms are available for initial marketing authorisations, variations and renewals and can be downloaded from the electronic Application Forms (eAF) at http://esubmission.ema.europa.eu/eaf/index.html.

The electronic application forms reflect and capture the same content as the previous paper-based versions, but offer a more structured application process for users. Their use is expected to reduce the administrative burden for both the regulatory authorities and pharmaceutical companies.

Since their initial release in 2012, the forms have been significantly improved following feedback received. Further testing exercises will be conducted prior to new releases of the next versions in the coming months to collect user comments and further improve user experience.

From January 2016, the use of electronic application forms will also be mandatory for all other EU marketing authorisation procedures for human and veterinary medicines, i.e. the decentralised (DCP), mutual recognition (MRP) procedures and for national submissions.

Further information on the new requirements can be found on the eSubmission website (http://esubmission.ema.europa.eu/eaf/index.html) and in a new information leaflet (http://esubmission.ema.europa.eu/eaf/docs/eAF%20communication%20-%201%20pager%20-%2017.02.15.pdf).

FDA, European Commission and EMA reinforce collaboration to advance medicine development and evaluation

US and EU regulators aim to enhance trust in quality, safety and efficacy of medicines

14 July 2015 — Senior leaders from the United States Food and Drug Administration (FDA), the European Commission and the European Medicines Agency (EMA) reviewed their ongoing cooperative activities and discussed strategic priorities for the next two years at their regular bilateral meeting held on 19 June 2015, at FDA Headquarters in Silver Spring, Maryland, USA.

Over the past years, EMA and FDA have significantly increased their level of collaboration and sharing of information to advance regulatory excellence worldwide. There are now daily interactions, most of them structured around scientific and regulatory working groups or "clusters". The focus of the cluster reviews during this bilateral was pharmacovigilance, biosimilars, paediatrics and veterinary medicines.

Strategic priorities

Looking ahead, EMA, European Commission and FDA decided to establish a new cluster on patient engagement to share experience and best practices regarding the involvement of patients in the development, evaluation and post-authorisation activities related to medicines.

Participants also agreed that communication on the ongoing successful cooperation should be enhanced and that efforts to support communication activities and align core messages should be strengthened.

They also agreed to further strengthen their collaboration in inspections and data integrity, safety monitoring of medicines, biosimilars, paediatric medicines, rare diseases, timely access to new medicines and veterinary medicines. This will help EU regulators and FDA increase efficiency on a global level and avoid duplication.

Planned focus for each area includes:

Patient engagement: In the US and in the EU, patients are well informed and expect that their voice is heard by regulators when it comes to the way studies are designed and the assessment of the benefits and risks of specific medicines. Involving patients in the evaluation discussions adds meaningful perspectives to the process. EMA and FDA aim to expand patient input during the regulatory process, for example to better understand how medicines and the availability of treatments affect patients and how patients approach quality, safety and efficacy of medicines.

Safety of medicines: The long-term collaboration between EMA and FDA in pharmacovigilance has facilitated the exchange of critical information and the coordination of communication to patients and healthcare professionals in the EU and the US. The participants agreed to further strengthen collaboration in the International Pharmacovigilance cluster with a more strategic focus on, among others, the assessment of everyday use of medicines.

Biosimilars: Activities in this cluster will continue to support the global development of biosimilars. The agencies are interested in aligning their scientific approaches to biosimilars to avoid regulatory divergence that may delay patients' access to medicines.

Paediatric medicines: Regulatory collaboration is of vital importance for the development of paediatric medicines. Because the development of paediatric medicines is largely driven by legislation in the EU

and the US, EMA and FDA will continue to align their scientific approaches including through "common commentaries" and development plans which help to achieve a rational approach to the conduct of the necessary clinical trials. A workshop to share EU and US experience under their respective regulatory frameworks may be organised in 2016 to further support these efforts, resources permitting.

Rare diseases: Collaboration in the area of rare diseases is of growing importance. Medicines developers can already use a common template to request orphan designation of their medicine in the EU and the US. Building on this success, and the Paediatric Cluster's work on rare diseases, EMA and FDA will establish a joint working group, the Team of International Global Rare Disease Experts (TIGRE), to better support the development of safe and effective medicines for children who suffer from rare diseases.

Timely access to new medicines: Improving timely access to new medicines to treat serious diseases has been at the core of the collaborative endeavours of EMA and FDA. By sharing information to facilitate joint approaches, e.g., in scientific advice or the evaluation of medicines, and by building on the best available regulatory practices the two regulators aim to minimise divergence and support patients' early access to new treatments.

Veterinary topics: Recognizing that the One Health concept is a worldwide strategy for expanding interdisciplinary collaboration in all aspects of healthcare for humans, animals and the environment, FDA and EMA continue pathways for effective communication and information sharing activities. Cooperation is particularly strong in the area of novel veterinary therapies such as stem cells, oncology products and cytokines. EMA and FDA are focusing their efforts to further encourage the development of novel veterinary medicines and to further reduce antibiotic resistance.

Inspections: Progress was also made for the mutual reliance on inspections of drug manufacturing sites. EU regulators and FDA are evaluating how their respective inspectorates, in addition to their regulatory and procedural frameworks to inspect manufacturers of human medicines compare. This is an essential prerequisite to relying on each other's inspection findings, avoiding duplication of efforts, and enabling wider inspection coverage. Both agencies are working expeditiously towards a plan for a final framework for an agreement and an implementation plan.

Data integrity: Both agencies stressed the importance of data integrity as a cornerstone to establishing and maintaining confidence in test results and agreed to work on communication and training to help increase the awareness of manufacturers.

The European Commission, EMA and FDA organise in-person bilateral meetings routinely to monitor progress and ensure that their collaboration delivers on agreed strategic priorities that promote the safety, efficacy and quality of medicines to the benefit of global public and animal health.

Fast track routes for medicines that address unmet medical needs

Launch of two-month public consultations on revised guidelines on accelerated assessment and conditional marketing authorisation

27 July 2015 — The European Medicines Agency (EMA) has revised its guidelines on the implementation of accelerated assessment and conditional marketing authorisation, two key tools in the European legislation to accelerate patients' access to medicines that address unmet medical needs.

The public consultations on the revised guidelines are open until 30 September 2015. Comments should be sent using the forms provided.

Accelerated assessment and conditional marketing authorisation are intended for innovative medicines that target a disease for which no treatment is available, or that provide patients with a major therapeutic advantage over existing treatments.

Based on the experience gained in implementing accelerated assessment and conditional marketing authorisation in recent years and taking into account discussions on the optimisation of the use of these tools at the European Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP), EMA has revised its guidelines to improve these existing frameworks. The updated guidelines are expected to optimise the use of these tools by medicine developers and consequently allow more medicines that address unmet medical needs to reach patients earlier.

Accelerated assessment

EMA's accelerated assessment procedure allows for a faster assessment of eligible medicines by EMA's scientific committees.

The main changes included in the proposed revision of the guideline are detailed at:

http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500190554

They include:

- more detailed guidance on how to justify fulfilment of major public health interest, which is the basis for a request for an accelerated assessment;

- optimisation of the assessment timetable by better balancing evaluation phases to reach a CHMP opinion within the 150 days after the start of a marketing authorisation application procedure (compared to 210 days in non-accelerated procedures);
- emphasis on the importance of early dialogue with EMA so that accelerated assessment can be planned well ahead of the submission.

EMA highlights that the eligibility criteria laid down in the accelerated assessment guideline are also being considered for a new scheme, currently under development, that is designed to facilitate the development and accelerated assessment of innovative medicines of major public health interest, in particular from the viewpoint of therapeutic innovation.

Conditional marketing authorisation

Conditional marketing authorisation allows for the early approval of a medicine on the basis of less complete clinical data than normally required, if the medicine addresses an unmet medical need and targets a seriously debilitating or life-threatening disease, a rare disease or is intended for use in emergency situations in response to a public health threat.

While less complete, the available data must still demonstrate that the medicine's benefits outweigh its risks and the applicant should be in a position to provide the comprehensive clinical data after authorisation within a timeframe agreed with the CHMP. In addition, the benefit to public health must outweigh the risk due to the limited availability of clinical data at the time of marketing authorisation.

The revised guideline emphasises on the importance for medicine developers of planning a conditional marketing authorisation prospectively and engaging in early dialogue with EMA and other stakeholders, for example through parallel scientific advice with health technology assessment bodies. This is expected to help translate conditional marketing authorisations into early access to medicines for patients.

In addition, the revisions include:

- clarification on fulfilment of unmet medical needs, i.e. medicines providing major improvements in patient care over existing therapies can be eligible in certain cases;
- clarification of how a positive benefit-risk balance is to be substantiated where there are less complete data, with further guidance on the level of evidence that must be provided at the time of authorisation and the data that can be provided after authorisation;
- updated guidance on the extent and type of data required to be included in annual renewal submissions.

An overview of the proposed changes to the two guidelines is available on the EMA website (http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500190556).

Updated guidance on good clinical practice released for consultation

Comments on the ICH E6 addendum are invited until 3 February 2016

21 August 2015 — The European Medicines Agency (EMA) has released an addendum to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) E6 (R2) guideline on good clinical practice (GCP) for a six-month public consultation.

Stakeholders are invited to send their comments using the template provided by 3 February 2016. The completed template should be sent to ich@ema.europa.eu.

GCP is an international ethical and scientific quality standard for designing, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and wellbeing of trial subjects are protected and that clinical-trial data are credible.

The current ICH E6 guideline provides a unified standard on GCP. It describes responsibilities and activities of sponsors, monitors, investigators and ethics committees.

Since the finalisation of this guideline in 1996, the scale, complexity and costs of clinical trials have increased. Developments in technology and risk management processes offer new opportunities to increase their efficiency by allowing sponsors to focus on relevant activities. With this in mind, the guideline has been amended to:

- encourage implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, recording and reporting while continuing to ensure the protection of clinical trial participants, and data integrity;
- update standards regarding electronic records and essential documents intended to increase the quality and efficacy of clinical trials.

Updates have been made to several sections of the guideline and are highlighted in the document.

Profile

An interview with Laura Carolina Collada Ali: On the peculiarities of working for independent research organisations

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Laura C Collada Ali wears different hats: she is a medical writer plus a medical translator, and has extensive experience delivering multilingual authoring and translation services across a wide range of independent research organisations. She is a translator by education, yet has worked for many years in the fields of independent clinical research, regulatory affairs, and logistics. Based on her background, she has a large portfolio of services to offer: scientific writing and translation, proofreading, regulatory writing, medical communications writing, project management, and training. Additionally, she served as Public Relations (PR) officer for EMWA from May 2013 to May 2015. In this profile, we turn to Laura to better understand the peculiarities of working for independent research organisations.

(Note from the MEW Editorial Board: For MEW readers, Laura is also well-known for her profile interview series. She recently took over the translation section of MEW of which she is now the new section editor. She handed over the interview series to Beatrix Doerr who is the current EMWA PR officer. It is only fitting to feature Laura as our profile interviewee in this issue, with Beatrix as interviewer. Thank you, Laura and welcome, Beatrix).

MEW: About your professional career: You have 15 years experience in clinical research and regulatory affairs based on what we call 'independent research or not-for profit research'. In how far do you think this experience helps you in your current role?

Laura C Collada Ali (LCCA): Indeed, I have worked at the European Organisation for Research and Treatment of Cancer (EORTC) in Brussels for two years where I was responsible of coordinating the scientific review of new protocols. Integrating evaluations from subject matter world experts and opinion leaders can be a challenge sometimes! I have also worked for many years for the Italian Group for Adult Haematological Malignancies (GIMEMA) Data Centre in Rome. I was in charge of logistics and regulatory affairs, coordinating a team of five colleagues and dealt with the logistics and start-up procedures of more than 30 clinical trials.

This broad hands-on experience in the independent clinical research field is particularly useful for small organisations looking to gain international audiences for medical and scientific subject matters. I really think this helps me a lot because I fully understand what their particular needs are and I am able to render them in target documents that fulfil their expectations. On the other hand, when I decided to go freelance, I already had quite a big portfolio of potential clients. Today, indeed, I often work with different independent organisations, both as writer and as translator.

MEW: Do you think it is essential for newcomers to gain first experience in the field of clinical research and regulatory affairs or will it taking training courses in this field be sufficient? How did you gain the necessary medical knowledge?

LCCA: Well, all roads lead to Rome, but some may be harder to travel … Probably, a combination of the two is the right answer. Yet, in my opinion, experience in the field cannot be equalled by theoretical training, unless a given training course comprises a final 'hands-on' stage that is sufficiently effective.

Experience gives you a broader view and the possibility to fully understand the intricacies of what you are doing. It enables you to put in practice what you've learned by training, and having actually 'practiced' or done something leads you to a better understanding of the given topic.

When you fully know your subject matter, you are able to be proactive and to propose solutions when identifying a potential problem. Such an approach is highly appreciated by clients, of course.

That said, professionals who have long experience in medical writing or translation and did not start hands-on on clinical research may also be able to have such an approach.

MEW: You offer quite a big portfolio of services. What advice would you give somebody who is new to freelancing–specialise or diversify?

LCCA: Personally, I would say both.

In my experience, the best option is to be able to give a broad range of services within a highly specialised domain. Indeed, I am somewhat diversified because I do not focus only on translation, but also do lots of writing, editing, and even training,

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and thanks to my experience as project manager, I am also able to manage projects that involve different languages and specialisation domains, collaborating with expert colleagues in different languages and domains.

On the other hand, I am also somewhat specialised because most of what I do is based, first on medicine, and secondly, on the fields of oncology and haematology.

This strategy may have several advantages: your learning curve in the subject matter is less steep, as you focus on one single area. All your projects are likely to be similar and you may apply what you've learned in one project to the next one. You target a single segment, which is far easier from a marketing point of view than targeting several ones.

On the other hand, you need to bear in mind that by specialising you may be economically tied to one specific segment, which means that you may have decreased opportunities for sales, it may be harder to increase your customer base, and you may get tired of focusing on the same topic project after project.

MEW: Of all the different services you offer, which one would you deem the most challenging and why?

LCCA: To be honest, in my experience, I would not be able to say that writing is more challenging than translating, or the other way round. What I do sometimes find 'challenging' is interacting with the author of a given text that needs to be either edited or translated. And you may wonder why? It is not always easy to explain to a physician that what he/she has written is:

- ambiguous and needs clarification,
- grammatically incorrect,
- semantically incorrect,
- not coherent with other parts of the text,
- does not respect typographical rules of the given language,
- etc.

Very often, authors consider their texts as their own creation and do not happily accept criticism, even the constructive ones. You need to find an appropriate way of communicating and, of course, you always need to have references at hand to support your thesis. This may sometimes be tiresome, yet with experience you learn to approach such situations in the best way possible.

MEW: Writing for non-profit organisations is no different than writing for the industry, right?

Well, yes and no. Although some may argue that the difference is not in what not-for-profit research does, but in why it is done – increasing shareholder value versus addressing patients' needs, often conducting research for neglected diseases and orphan drugs. In many European countries, there is a particular regulation that applies only to independent research by lowering the amount of bureaucracy needed to run a clinical trial. This means that documentation requirements for not-for-profit studies may be less complex and stringent compared to those of a pharma company trial. And, of course, independent trials usually being not aimed at registering a given drug, will not lead to any regulatory registration-driven documentation.

Conclusion

Laura shared with us the great wealth of opportunities in medical writing and communications–from translation to writing, including project management and training. I hope this interview will particularly be useful for newcomers, showing how to build on previous experience to further career paths and business ventures. For freelancers, Laura gave some food for thought on specialising versus non-specialising. We also thank her for her candid views about potential difficulties with authors. It is certainly reassuring for newcomers that even experienced people like Laura face resistance and her tips can help to master such situations.

In conclusion, medical writing is a wide field and with enthusiasm and commitment, everything is possible. So start exploring new horizons. As Laura says, 'all roads lead to Rome' and since she lives in Italy, she must know it!

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The Webscout

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Lay audiences

Are we aware how different from each other presentations for lay audiences and those for professional experts are, even if they cover the same subject? Check these publications on pirfenidone, a drug against idiopathic pulmonary fibrosis:

http://ow.ly/RkeoZ and *http://ow.ly/Rket3*

Whereas the former is a detailed publication for the scientific community the latter is a concise summary aimed at the public. These examples illustrate that presenting or talking to a lay audience necessitates specific considerations regarding language, style, and depth of detail.

But what exactly is a lay audience? You can check thefreedictionary.com for a definition of the term 'lay person': someone lacking specialised or professional knowledge of a subject. In a lay audience there will be people with varying degrees of health literacy due to differing educational backgrounds or different occupations. Some will be non-experts who have gained quite a bit of insight because they have been engaged with the subject, e.g. in patient working groups. For others the subject might be completely new.

There are some simple rules regarding language, style, and grammar to keep in mind when presenting to a lay audience. Let me start with language. Use simple words and short sentences and avoid acronyms and disciplinary jargon whenever possible. The use of plain language eases understanding. Check an earlier edition of the Webscout for a reflection on plain language.[1] You may also find this YouTube webinar on how to address a lay audience helpful:

https://www.youtube.com/watch?v=cafNRpb3vtM

The webinar illustrates how to communicate complex science effectively to a wide range of audiences and contains useful recommendations regarding the focus of such presentations. If technical phrases have to be used they should be explained, e.g. by analogies (a receptor binding a signalling molecule is analogous to a keyhole into which one particular key fits). Whenever there is a simpler word or phrase for a technical term go for the simpler option ('cells proliferate' could be phrased as 'cells grow and multiply'). An excellent presentation about Herceptin illustrates these recommendations:

http://www.breastcancer.org/treatment/targeted_therapies/herceptin/how_works

The above-mentioned YouTube webinar also addresses the structure and style of presentations. The first sentence is important to elicit the listener's or reader's curiosity. Furthermore, it can help to explain the rationale for an investigation and to outline why the work is important. Before going into detail, present the overall picture and the context. Starting with details is the best way to confuse the audience.

Whenever you summarise the existing evidence on a specific topic be sure to emphasise the logical connections between thoughts, paragraphs, or citations using simple conjunctions to accentuate congruence or contrast. This webpage elaborates on conjunctions and their use:

http://www.smart-words.org/linking-words/conjunctions.html

Grammar also contributes to ease of understanding. Long complicated grammatical structures e.g. double negations, should be avoided. Writing and talking in the active voice helps to keep the attention of the audience. Check this page for more advice and several very helpful links:

http://www.dcc.ac.uk/resources/how-guides/write-lay-summary

When it comes to describing results it is important to elucidate their meaning. Again, check the YouTube webinar. Diagrams are helpful only if they are explained well to allow the audience to understand them. Offer an interpretation of the results and an answer to the initial research question. And summarising the results, providing conclusions, and explaining the impact on, for example, clinical care nicely brings the presentation full circle.

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

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Reference

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Design and interpretation of clinical trials: An online course offered by John Hopkins University

There has been a lot of discussion about massive open online courses (MOOCs) over the last few years. This prompted me to investigate a few of these to see if they could be useful learning tools for EMWA members. Courses are available to anyone via the web. In addition to traditional course materials such as filmed lectures, readings, and exercises or quizzes, most MOOCs provide interactive user forums to support interactions between students and lecturers. The subject matter of most courses is not directly related to medical writing, and the quality of the few I have tried varied significantly.

There are three main providers: Udacity, edX, and Coursera. With over 660 courses (approximately 85 of which are active at any one time), Coursera is by far the biggest provider and provides the greatest variety. Coursera acts as an education platform and partners with top universities and organisations worldwide. I reviewed their offerings via their web site (https://www.coursera.org) and, after looking at a couple of courses, I identified one on Design and Interpretation of Clinical Trials which seemed relevant to medical writing. This is a 6 week course requiring approximately 2–3 hours' commitment per week and is run at set times of the year. This means that everyone enrolled is doing the same thing at the same time so the user forum works better. There is currently no date for future sessions but the course has previously run in the first quarter of the year.

The official summary of the course states that it will explain the basic principles for design of randomised clinical trials and how they should be reported, and it does just that. There are two to four lectures each week and weeks 4 and 6 also include selected reading material. Each week there is a quiz with up to 10 questions to check your understanding. The instructors, Janet Holbrook and Lea T. Drye, speak clearly and informatively without the background distractions and self-consciousness seen in the lectures from some courses.

In the first part of the course, students are introduced to the terminology used in clinical trials as well as the most commonly used designs. The advantages and disadvantages of the different designs and the effect on sample size requirements are discussed. Types of trials covered include parallel, cross-over and factorial, equivalence and non-inferiority, group allocation, and adaptive design trials. The concepts of randomisation and selection bias, including a discussion of the different types of randomisation schemes and the importance of blocking and stratification, are covered in week 2, as is the process of blinding or masking. Week 3 covers the different types of clinical trial outcomes, the difference between objective and subjective outcomes, and how to select an appropriate primary outcome variable. It also addresses how clinical trials are analysed and interpreted, including a discussion of the role of subgroup analysis as well as the principle of intention-to-treat. Week 4 covers ethical issues with a review of the essential ethical considerations involved in conducting experiments on people and why these are important. This area is covered mainly by suggested readings followed by quizzes and, in my opinion, is less successful than the lecture approach used in the other parts of the course. Week 5 covers reporting of results from clinical trials and introduces the Consolidated Standards of Reporting Trials (CONSORT) guidelines. Week 6 looks at how to rate the quality of evidence provided by different types of studies. It discusses whether randomised clinical trials should be seen as the gold standard with examples from a couple of areas where results of clinical trials and observational studies provide different results.

The multiple choice quiz questions are particularly useful for ensuring that you have fully understood the topics. These are graded and used to evaluate student performance. You have three attempts at each quiz and are given a clear explanation of the correct answers once you have submitted your final quiz for assessment.

In order to successfully complete the class and receive a Statement of Accomplishment (SOA) signed by the instructors you must complete each quiz and achieve an overall average score of 70% or more. Coursera offers two tiers of SOA, one free and one for a fee. The free SOAs are 'honor system' certificates that don't verify your identity. Verified SOAs require you to use a webcam and an ID to confirm your real identity and that it was you who did the work. This is called Signature Track and costs around $40. You can opt in to it a couple of weeks after a course has started, so you can wait until after you've experienced some of the course before committing.

Periodically questions that highlight different issues in clinical trials are posted on the discussion forum and students are encouraged to participate in the forum. I did not find this particularly useful and stopped looking after a couple of sessions. The majority of students participating came from backgrounds outside of clinical research and had

limited knowledge of clinical trials, and so questions and comments were at a fairly basic level.

Although I did not learn anything new, for me this was an enjoyable refresher on the concepts involved in clinical trial design and interpretation. I would definitely recommend it to medical writers who are new to the area of clinical trials or protocol design.

There has been an enormous expansion in online courses in the last few years and it would be useful to get feedback from EMWA members, both positive and negative, on other online courses relevant to medical writers. If you have experiences you would like to share with other members via Medical Writing, please send your feedback to Karin Eichele at info@mediwiz.de.

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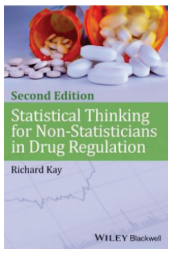

Statistical Thinking for Non-Statisticians in Drug Regulation (Second Edition)
By John Wiley & Sons, 2014. ISBN: 978-1-118-47094-7 (hardcover). 59.99 GBP. 368 pages.

George Bernard Shaw is believed to have said that *'It is the mark of a truly intelligent person to be moved by statistics'*, and it is clear from this book that author Richard Kay is such a person.

In 2014, this well-known lecturer and consultant to the pharmaceutical industry released a second edition of *Statistical Thinking for Non-Statisticians in Drug Regulation*. This book provides a comprehensive overview of statistical methods used within clinical drug trials and is targeted towards readers with a basic understanding of statistics and trial design. It will be beneficial to a range of non-statistician professionals in the clinical trial field, including but not limited to medical writers, data managers, programmers, and investigators. As a medical writer, I found this book particularly useful to both strengthen my current understanding of statistics and introduce new and unfamiliar terms.

The book is well-structured, with successive chapters giving the reader a step-by-step introduction to statistical procedures used in clinical trials. For this reason, I recommend that the book be read cover-to-cover, as many sections in later chapters refer back to earlier chapters. The author has clearly tailored the content well and, where necessary, each chapter is accompanied by relevant sections of the International Conference on Harmonisation (ICH) E9 guidelines, EMA guidelines, FDA guidelines, or Committee for Medicinal Products for Human Use (CHMP) guidelines, which help to present the statistical procedures from a regulatory standpoint.

The author has divided the book into 21 chapters. Chapters 1 through 4 introduce the reader to concepts including the use of control groups, placebos and blinding, randomisation strategies, sampling, the normal distribution, and the pitfalls of ensuring reduced error, before focusing on some of the basic statistical tests. Although a seasoned medical writer may find the content of these chapters all too familiar, it is a useful refresher to some of the fundamentals of trial design.

Chapter 5 has been restructured from the previous version and is now titled '*Adjusting the analysis*'. This chapter looks at why investigators might want to adjust an analysis due to imbalances in baseline factors such as age and explains that without such adjustment the means of two datasets may not be directly comparable. Methods described include two-way analysis of variance for continuous data and the Cochran-Mantel-Haenszel test for binary categorical and ordinal data. This chapter also discusses how to evaluate treatment homogeneity and the benefits of multi-centre trials. Chapter 6 extends chapter 5 by discussing how to adjust for several factors simultaneously with the use of simple, multiple, and logistic regression and analysis of covariance. Chapter 7 introduces the reader to the types of population analysis in trial design, focusing on the intention-to-treat (ITT) population and the per-protocol population. This chapter highlights the dangers of compromising the randomisation of patients at the analysis stage and the importance of using the ITT analysis (or full analysis set) to ensure the statistical comparison remains valid. It also discusses how to deal with the '*missing data*' caused by patients who fail to complete the study in line with the protocol. These approaches include but are not limited to: (1) Complete case analysis, (2) Last observation carried forward, (3) Success failure classification, and (4) Worst-case/best-case imputation. Each approach is accompanied by relevant guidance from ICH E9, the FDA, and the CHMP. Chapters 8 and 9 discuss further basics of clinical trial statistical considerations such as the importance of power and sample size in preventing type I and II errors and how statistical significance relates to clinical significance.

In the second half of the book, chapter 10 looks at how to deal with, and the regulatory view regarding, multiplicity or multiple testing, which occurs when a trial has multiple endpoints, multiple comparisons of treatments, or multiple subgroup comparisons. Such cases may require methods of adjustment such as Bonferroni correction, Hochberg correction, or interim analyses. Chapter 11 explores the advantages and disadvantages of using non-parametric tests when parametric tests are not applicable and discusses examples such as the Mann-Whitney U test and Wilcoxon signed-rank test.

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From a hypothesis perspective, clinical drug trials are broadly divided into three categories: superiority, equivalence, and non-inferiority. Chapter 12 focuses more on equivalence and non-inferiority studies, including how to define confidence interval (CI) margins and the need to use two-sided CIs for equivalence studies and one-sided CIs for non-inferiority studies. Chapter 13 looks at the analysis of survival data, including considerations for censoring, Kaplan-Meier curves, event rates, the use of median instead of mean survival, and constant and non-constant hazard ratios. This chapter extends chapters 6 and 8 by discussing adjusted analyses and sample size in the context of survival data and would be particularly useful for writers who work predominantly on oncology trials. Chapter 14 discusses the use of interim analyses and provides useful guidance on being compliant with data monitoring committees (DMCs).

In addition to the restructuring of several chapters, this second edition sees the addition of five new chapters: 15, 16, 17, 19, and 20. Chapter 15 focuses on Bayesian statistics and compares this methodology with classic and frequentist methods. It also introduces the concepts of prior and posterior beliefs, their role in Bayesian statistics, and the viewpoint of regulatory authorities on their use. Chapter 16 discusses adaptive designs, where aspects of a clinical trial can be changed based on accumulating data. This chapter also describes how to minimise bias in these designs and maintain the validity of the results. It further discusses various types of adaption and describes the regulatory guidance regarding the use of adaptive designs in exploratory and confirmatory studies.

Non-randomised (observational) designs offer an alternative to the '*gold standard*' of randomised controlled trials, but should only be considered when prior belief in the superiority of the test therapy is extremely strong and where the disease course is highly predictable. Chapter 17 focuses on non-randomised designs, discussing the types of bias they are affected by, such as selection, attrition, detection, and performance bias, and the regulatory guidelines concerning their use. Chapter 18 looks at the statistical considerations of meta-analysis such as methods of combination, CIs, and detecting heterogeneity. This chapter has been restructured since the first edition to include additional statistical methodologies, a case study example, and further regulatory aspects.

Chapter 19 looks at the various aspects of safety data analysis and the role of DMCs, including quantification of the benefit-risk balance for regulatory submissions. It also explains the importance of pharmacovigilance and the use of proportional reporting ratios in evaluating safety signals. Chapter 20 looks at statistical methods for evaluating diagnostic methods, including the use of receiver operating characteristic curves, regression models, and method comparison (e.g. use of the *kappa* statistic to measure agreement between two diagnostic tests).

The book concludes with chapter 21, which discusses the role of the statistician in designing trials and the essential role statistics plays in ensuring that a trial remains unbiased and provides valid results from which to draw meaningful conclusions.

In summary, this book gives a well-structured overview of the statistical procedures used in clinical trials. Statistics is not an easy subject to comprehend; most writers will have a basic understanding, but the relevance and the rationale behind the choice of statistical procedures may often be overlooked. In this book, the author has taken a complex subject and produced an invaluable resource that is straightforward to follow. The content and structure of the book provides a step-by-step overview of the design process; complex terms are well defined, and the abbreviations list, comprehensive reference list, and index add to the ease of understanding. Furthermore, the principles discussed in this book are applicable to a range of professions in the clinical trial field and numerous therapeutic areas. I would strongly recommend this book to any medical writer who compiles clinical study reports or clinical manuscripts on a regular basis.

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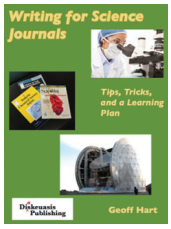

Writing for Science Journals: Tips, Tricks, and a Learning Plan
By Geoff Hart , Diaskeuasis Publishing, 2014, ISBN: 978-1-927972-01-4 (paperback). 22.00 GBP. 639 pages.

Most of us will be familiar with the sensation of sitting down to write in a new area with a blank page on the desk and a host of unformed questions that crystallise into 'How do I begin …?'

If that new area is manuscript writing, reading *Writing for Science Journals* (available in paperback,

e-published, and pdf versions) is a good beginning. This guide to writing for journals is subtitled 'Tips, Tricks and a Learning Plan' and presents the entire process of planning, preparing, writing, revising, and publishing a paper in a peer-reviewed science journal.

Geoff Hart is a Fellow of the Society for Technical Communication and has worked as a scientific editor for more than 25 years. He estimates to have edited more than 6000 works. He has helpfully distilled his experience into this book, including what he refers to as 'dirty secrets'–the inside knowledge on how papers are reviewed and assessed for publication. Although the book is evidently addressed to research students, there is plenty of information here to benefit medical writers.

Writing for Science Journals has 24 chapters that describe the entire manuscript writing process. Chapter 1 is an introductory chapter. Chapter 2 covers ethics and Chapter 3 covers choosing a journal. Chapter 4 discusses the outline of the manuscript (see below). Chapter 5 covers using a word processor. Chapters 6 to 13 cover the different sections of the manuscript in detail, after which Chapter 14 addresses experimental design and Chapter 15 explores numerical and statistical considerations. Chapters 16 and 17 cover figures and tables, respectively, and Chapter 18 covers online supplemental material. Chapters 19 and 20 address writing format and style. Lastly, Chapters 21 to 23 cover the process of review and publication, and conclusions are offered in Chapter 24.

Hart advocates the use of a strong outline (Chapter 4). He says 'it is difficult to review an entire manuscript, but easier and faster to review a short list of concise points to confirm that each is clear and that their sequence effectively tells your story'. Rather than take the journal article section headings and attempt to fill in a plan under them, Hart suggests summarising the following for the outline:

- 'The problem I investigated
- What questions remain unanswered
- Which of those I tried to answer
- Methods developed by previous researchers that I will use in my research
- New methods that I developed to solve problems other researchers did not solve
- Details of the statistical analysis required by my methods'

He explains that by extending this rationale to the plan for the results and discussion sections, one can ensure that 'each result in the results section has a method used to produce that result, and that every key interpretation in the discussion is supported by data described in the outline of the results section'.

In my view, this outline could be used as a check for much of the work that we do, as it can be all too easy to get distracted from the fundamental purpose of the research by the details of it. As with all the chapters, Hart uses examples throughout to illustrate his points.

The subsequent chapters on the sections of a journal article each finish with a summary of learning points. The style is narrative and approachable, with tips, notes, and asides. The chapters on experimental design (including how to choose a standard of comparison, how to eliminate bias, and how to replicate results), numbers and variables, figures, and tables contain a host of useful information that provides food for thought. Hart emphasises that there is considerable variation among journals; the guidelines in this book are delivered with the caveat that there should be thorough research into the specific requirements of the journal that you wish to target.

To some extent, information can feel hard to find. A note on the use of abbreviations is buried in Chapter 7 ('The First Pages'), whilst acronyms are dealt with in detail in Chapter 9 ('Materials and Methods'). It is also true that some chapters should be little needed by the medical writer (Chapter 5, 'Using Your Word Processor Efficiently', for example). However, read as a whole and using the index to navigate back to points of interest, this is an approachable and entertaining manual. Most interesting for me is that by being directed towards research students, the book provides awareness of the context of research writing outside of the medical writer's office. This, together with the clearly presented strategy for constructing a paper, makes this book well worth consulting.

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Regulatory Writing

TTIP: Good or bad for the pharmaceutical sector?

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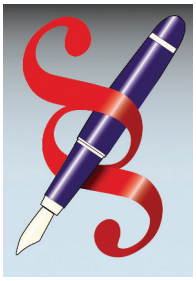

The Transatlantic Trade and Investment Partnership (TTIP) has attracted increasing controversy, particularly in Europe. The TTIP is a trade agreement under negotiation between the United States and the European Union, and affects three main areas: market access, specific regulation, and broader rules and principles and modes of co-operation. The aims therefore go well beyond simply eliminating trade tariffs (which are already fairly low), with harmonisation of regulations and business approaches also in the scope of the agreement.

According to one report, an 'ambitious and comprehensive' transatlantic trade and investment agreement could bring economic gains of €119 billion euros a year[1]. The authors claim that this translates into up to €545 per year in the pocket of an average family of four in the unlikely assumption that the gain is distributed equally. Inevitably, there will be winners and losers in any policy change, but the suspicion of many is that large corporations will stand to benefit most and that their gain will be societýs loss. The idea that the agreement will be made-to-measure for corporations has been strengthened by the perception that negotiations are conducted behind closed doors and shrouded in secrecy (more on this later).

TTIP and the pharmaceutical sector

The pharmaceutical sector is one of the most heavily regulated sectors there is and the need for alignment of regulatory practices in a global market was already recognized more than 25 years ago, with the launch of the International Conference on Harmonisation (ICH). Since its inception, the ICH has steadily driven a convergence of pharmaceutical regulations throughout the world. In recent years, the Food and Drug Administration (FDA) in the US and the European Medicines Agency (EMA) in Europe have been working together increasingly closely, with greater information sharing and numerous staff exchange programmes. Despite this convergence, many pharmaceutical companies are still frustrated by differences between the constituent regions of ICH and between the US and Europe in particular.

Paediatric medicines

For example, in the case of pediatric medicines, an approved paediatric development plan is now required on both sides of the Atlantic — a Pediatric Study Plan in the US and a Paediatric Investigation Plan in Europe. Not only are there differences in the structure of these two documents, but there are often differences in overall interpretation, with the result that companies may not be able to implement a single global paediatric development programme. The consequent duplication is not only costly for the companies but also potentially harmful to children as they may be unnecessarily exposed to investigational medicinal products. Duplication may also make it more difficult to conduct properly powered and scientifically meaningful trials if the patient pool is limited, particularly in indications where a number of new drugs are coming through (for example, multiple sclerosis) and competition for patients is already strong. In paediatric development, greater harmonisation would therefore seem desirable.

Scientific advice and GMP inspections

Harmonisation of scientific advice is also proposed. Currently, companies can go to either the FDA or the EMA for scientific advice, which although not binding, will usually shape the clinical development programme. Discrepant scientific advice may generate conflicts for the pharmaceutical companies. As for the paediatric plans, unification (or mutual recognition) of scientific advice would help eliminate some of the many uncertainties and duplication from drug development. The agencies too would be able to free up resources, which are often stretched. Duplication of effort may also be reduced by introducing mutual recognition of Good Manufacturing Practice inspections. Both these proposals seem like a natural extension of the climate of greater cooperation and sharing of information alluded to above.

Biosimilars

One final example of an area that may benefit from greater harmonisation is biosimilars. The patent protection (or data exclusively) of many blockbuster monoclonal antibodies has either expired or is due

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to expire soon. The coming years are therefore likely to see a huge growth in the number of biosimilars, with corresponding cost reductions. Given that everyone is on a steep learning curve with biosimilars, the agencies have been forced to develop the regulations rapidly and there are certain divergences between the US and Europe. Unlike generics, which often only require a relatively small (and cheap) bioequivalence study, demonstrating bioequivalence is more complex (and costly). Therefore, any divergences in the regulations are likely to magnify the uncertainties for the biosimilar companies and hinder the development of their products.

Wider impact on healthcare

As outlined above, although considerable progress has already been made in harmonisation of the regulations for drug development on both sides of the Atlantic, further convergence would seem potentially beneficial in some areas. So far, so good. As it stands, however, the TTIP would not just be limited to drug development but to the wider healthcare sector. This is where the main concerns start to appear. Clearly, healthcare provision is very different on each side of the Atlantic. European countries pride themselves on having universal healthcare systems, in stark contrast to the US, where private healthcare is the norm and any attempt to introduce universal access (e.g. Obamacare) is fiercely resisted. The greater commoditisation of healthcare in the US is also reflected by, for example, direct advertising of prescription medicines to consumers.

The main fear of many opponents to TTIP is that the agreement could give too much power to corporations to guide public health policy and impose a US-style approach to healthcare policy, in particular through the controversial Investor-to-State Dispute Settlement System (ISDS). This supposedly gives corporations the opportunity to take national governments to a tribunal of arbitration about legislation that leads to loss of profits. Examples of legislation that may impact corporate profits include banning logos on cigarette packets or campaigns to reduce soft-drink consumption by children. Although industry advocates claim that the ISDS would not provide a mechanism for companies to influence national health policy, some claim that the threat of legal action may lead to a 'regulatory chill', whereby governments are discouraged from passing health protection laws.

A transparent process?

Although TTIP could be beneficial for pharmaceutical companies and patients alike, it is hard to assess potential impacts if there is a lack of transparency in the process. Measures have been taken to improve transparency but these largely seem reactive (after high-profile leaks followed by protests) rather than proactive. For example, the TTIP texts have been made available to all Members of the European Parliament (MEPs) in a reading room (and it seems that material will also be made available to other 'selected individuals' outside Brussels). However, members are not allowed to remove restricted material from the reading room and they are not allowed to have specialist support to help them understand the complex technical material. No doubt, the TTIP negotiators have access to expert legal and technical opinion.

Proponents of the process are also at pains to point out that public consultations have been made. Again, these also appear reactive measures and anyway, without transparency, it is impossible to know the extent to which the opinions aired in these consultations are assimilated. Although the FDA and EMA are major stakeholders, the TTIP negotiations are hardly mentioned on their websites. Are they participating? And if so, why are they not communicating more about the negotiations? Overall, the sudden embrace of transparency feels rather superficial and the negotiators could do much more to reassure the public that the overall wellbeing of European citizens is being taken into account.

On balance...

In short, it is very difficult to determine whether TTIP will be a force for good or bad in the pharmaceutical sector. Certainly, greater regulatory harmonisation could benefit pharmaceutical companies and some of that benefit might trickle down to the end patient in terms of faster approvals and cheaper drugs (if the development costs are lower and these saving are passed on). Despite reassurances from participants in the process, the details of the deal are opaque, making a judgement on their impact difficult. And even if the full details were known outside the select circles involved in the negotiations, predictions of impacts would be difficult as the law of unintended consequences would likely apply in the face of the complexity of the issues. On perhaps the most contentious issue, the ISDS, it looks like the European Parliament will push back on its full implementation in the health sector. That is probably a good thing.

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Lingua Franca and Beyond

Section Editor:

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Lingua Franca and Beyond–working together

Knowing that the main theme of this issue of *Medical Writing* is writing for the lay audience, I was thinking hard about what would be the most relevant topic to discuss in the *Lingua Franca and Beyond* section. My thoughts went to a topic that bridges the lay audience with medical and regulatory writers (regardless of native language). A couple of months ago, I attended an investigator meeting; at the end, one of the Danish investigators congratulated the organisers, and said: 'The meeting was just perfect; the only remark, we couldn't really follow all acronyms'. This made it clear for me that abbreviations and acronyms widely used in clinical development language and in medical publications are something that must be a problem for the lay audience, if it was a problem for medically educated people. Here we go – I have an excellent topic! Therefore, I asked Art Gertel to share with us his views on the use of abbreviations and acronyms. Many of us know that Art is an expert in regulatory affairs, medical writing, and bioethics; he was also President of AMWA (the American Medical Writers Association). Art naturally presents the American point of view but, at the same time because of his close connections with EMWA, he understands very well the European, multi-language perspective. In his very interesting overview, he also draws our attention to this multi-language perspective and the fact that acronyms and abbreviations don't always translate into other languages. This reminds me of a family story. I used to spend quite a lot of time in Warsaw together with my husband, who does not speak Polish. When he needs to take a taxi, and no person with a good command of English and Polish is around, I write down the address … just to be on the safe side. Once, he was to go to the office of the Technical Institute; the well-known acronym of this Institute was NOT (**N**aukowa **O**rganizacja **T**echniczna), and everybody knew it! Obviously, my husband didn't. So I gave him a piece of paper with the text: 'NOT Czacki Street'. What happened? Guess? He considered me to be completely insane. 'There are hundreds of streets in Warsaw, and she wrote down one of them I should *not* go to, instead of writing the one I should go to. On top of everything in capital letters' – he thought. Well, acronyms do not translate into other languages and are not obvious for foreigners.

I had the pleasure of attending John Carpenter's excellent classes in medical writing and will never forget his examples of the overuse of acronyms – some of them even to the point that they make whole sections of text impossible to understand. A parody of such overuse was published more than 15 years ago in the *New England Journal of Medicine*. Read and try to understand what Steven Mann wrote and the Editor answered:

Steven Mann's letter to the Editor:

"There is a recent trend (RT) in the medical literature (ML) to abbreviate previously unabbreviated phrases for the sake of efficiency (PUPSAE). Although it makes good sense (GS), the frequency with which it is used can tax the inexperienced reader (IR). Sometimes repetition can actually be beneficial (RCABB) by allowing the reader to retain words he does not constantly have to refer back to (WOHCREBT).

I would like to suggest to the *Editor* (ED), that for the IR who doesn't wish to have PUPSAE, he have the GS to change the ML so that RCABB and he can eliminate WOHCREBT."

Steven G. Mann
NEJM, April 27, 1989

The Editor's reply:

"We agree with Dr. Mann, but protest our innocence (POI). We do not ordinarily abbreviate PUPSAE because we also believe RCABB and we know that the IR needs WOHCREBT. But it makes GS to allow some previously abbreviated phrases (PAPS) when they are in widespread use (WU), and we occasionally even allow abbreviations of PUPSAE when repeatedly spelling them out would be unusually cumbersome (STOWBUC). We admit, however, that WU of PAPS and PUPS in the ML, even when

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STOWBUC, often raises the IR's and the ED's BP and HR."

NEJM, April 27, 1989[1]

Finally, I would like to invite you to check your familiarity with acronyms and abbreviations – see the short quiz. Do you know what the following acronyms and abbreviations stand for? AERS, CHMP, CORE, CTA, CTD, DSMB, DSUR, EEA, EMA, GCP, GLP, GMP, IND, IRB, MAH, MR, NDA, PRO, SmPC/SPC, SUSAR.

If you don't know, don't worry; you will find the answers on page 253; but if you know at least half of them, you are very well equipped for the regulatory world.

Enjoy! HAINRE – MKH
HAINRE – HAve an INteresting REad

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Acronyms and abbreviations — enigma machine required?

As someone who came of age in an era before Twitter, Short Message Service (SMS), emoticons, and even (GASP!) the Internet, I have an inherent bias against overuse of acronyms and abbreviations. That being said, I am also part of a culture (the Pharmaceutical Industry) that thrives on the use of these short-cuts. As the vectors of communication continue to place pressure on us to convey concepts using fewer and fewer characters, and when speed is of the essence, we tend to fall back on the use of these time-and-space savers. Unfortunately, their use may actually result in message confusion and longer elapsed time, given the need for the recipient to figure out what the sender meant.

In many respects, the use of these acronyms and abbreviations (let's call them '*A&As*') represent admission into a 'Secret Society', comprising only the *cognoscenti*.

First, some definitions:

An **acronym** is an **abbreviation** formed from the first letter or the first few letters of each word in a phrase. Usually these components are individual letters (such as sonar, created from '**SO**und **N**avigation **A**nd **R**anging'), or parts of words or names (as in *Benelux*–the customs union formed by Belgium, the Netherlands, and Luxembourg.).[1] The American Medical Association (AMA) *Manual of Style* further cites a distinction regarding the latter as an initialism: 'a name or term formed from the initial letters of a group of words and pronounced as a separate word.'[2]

An **abbreviation** may be any type of shortened form, such as words with the middle omitted (for example, 'Rd' for Road or 'Dr' for Doctor).

Fowler's *Modern English Usage*[3] appears to take a dim view of *A&As*, categorising them as 'curtailed words'. 'Some of these establish themselves so fully as to take the place of their originals or to make them seem pedantic; others remain slangy or adapted only to particular audiences.' Going further in seeming to disparage American usage, Fowler states: 'Another way of forming curtailed words is to combine initial letters, a method now so popular, especially in America, that a word – *acronym* – has been coined for it.'

Likewise, the editors of the AMA's scientific publications discourage the use of abbreviations, acronyms, and initialisms in their journals, with the exception of internationally-approved and accepted units of measure and some well-recognised clinical, technical, and general terms and symbols. '*Overuse of abbreviations can be confusing and ambiguous for readers – especially those of another culture or those outside a specific specialty. However, since abbreviations save space, they may be acceptable to use when the original word or words are repeated numerous times.*'[2]

Use of *A&As* has become so ubiquitous that users often are unaware of the source term. When asked what the letters stand for, too often the response is a blank stare and a shrug of the shoulders.

There are several classes of *A&As*:

- Those that are used across general society: e.g. FYI, FAQ
- Those that are used across the medical and scientific community: e.g. therapeutic areas: CNS, CV, OB-GYN; diseases and associated measurements: AML, MS, HIV, HbA1c, LFT, ALK PHOS, SGOT; measures of frequency: BID, QD, QID (which, by the way, may or may not separate each letter with a period); diagnostic technology: PET Scan, CAT Scan
- Those that are used in a regulatory context: e.g. FDA (United States **F**ood & **D**rug **A**dministration), EMA (**E**uropean **M**edicines

[1]From Letter to the Editor. N Engl J Med 1989;320:1152; Copyright ©1989 Massachusetts Medical Society. Reprinted with permission from Massachusetts Medical Society.

Agency), EudraCT (**Eu**ropean **C**linical **T**rials **D**atabase), PMDA (Japanese **P**harmaceuticals and **M**edical **D**evices **A**gency)

- Those that are used across the pharmaceutical industry: e.g. NDA, IND, ISS, ISE, ICH, CTD
- Those that are used within a particular pharmaceutical company, including research programs:
  - **TOPCAT-G** (A **T**rial of **O**ptimal **P**ersonalised **C**are **A**fter **T**reatment for **G**ynaecological cancer)
  - **EURECA** (**E**uropean **R**esearch on **E**lectrochemotherapy in head and neck **CA**ncer)
  - Including those where they couldn't even get the acronym correct: **PROTECT** (**P**redicting **R**esponse to Standardized Pediatric **C**olitis **T**herapy)

But, of course, there are not universal standards of use, either across institutions or in terms of rules of usage:

Examples of non-standard use across institutions include:

- Clinical Study Report (CSR) vs. Clinical Trial Report (CTR)
- Institutional Research Board (IRB) in the USA vs. Ethics Committee (EC) in Europe vs. Research Ethics Board (REB) in Canada

Examples of inconsistent rules of usage include:

- When a multiple-letter abbreviation is formed from a single word, periods are in general not used, although they may be common in informal usage. *TV*, for example, may stand for a *single* word (*television*), and is, in general, spelled without punctuation (except in the plural). Although *PS* stands for the single word *postscript* (or the Latin *postscriptum*), it is often spelled with periods (*P.S.*).

There are also documents that serve the same purpose; however, they may have a different name and structure:

- Investigational New Drug application (IND) in the USA *vs.* Clinical Trial Application (CTA) in Europe and Canada

Perhaps this speaks more to the issue of a lack of a global standard. While we certainly have much conformance in *structure* in the context of the ICH (International Conference on Harmonisation) CTD (Common Technical Document), there are still many differences among nations and languages, with respect to how *A&As* are accepted and used. In addition, these variations in standards often result in 'reinventing the wheel' forcing creation of multiple documents to meet the requirements of multiple authorities when a single, universal, document should suffice.

One of the problems with using *A&As* is that they quickly become jargon. I have experienced the disorientation upon changing jobs within the industry and finding myself in my first meeting at the new company, completely baffled by the *A&As* used by the meeting participants. I felt as if I had forgotten to bring my decoder ring! I clearly remember a situation when, back in my graduate school days, I was working in the pathology/toxicology laboratory and, when reviewing one of the necropsy reports, came upon the notation: '*MDYPPT*'. Having no idea what that represented, I tracked-down the laboratory technician who had submitted the report and he stated that it was obvious that it stood for 'Moderate Dark Yellow Precipitate', with an expression on his face that implied that even an idiot should have known that.

I recently saw a road sign directing drivers, as follows:

S.I. Thwy Nxt Rt

Even for a *native speaker*, it was not intuitive that the sign meant: *Staten Island Thruway Next Right*

The same is true for documents. It is now standard practice to include a list of acronyms and abbreviations in documents such as protocols and study reports. These are usually provided early in the document. This is especially valuable when the terminology used is esoteric and may not be readily known to the reader. In addition, I would never use an acronym or abbreviation without spelling-out the term at first use. Thereafter, it is acceptable to use just the acronym or abbreviation, without the 'decode'.

Another complication is that *A&As* don't always readily translate into other languages. Unfortunately, their use often represents arrogance on the part of the *native speaker*, conveying the assumption that anyone who is competent and reasonably intelligent should readily understand their secret code.

One should also consider whether there is a difference between using *A&As* in written vs. spoken language. Is it any more or less confusing when one uses them in speech? I would say that it

is more confusing, as there is greater potential for confusion associated with accent, pronunciation, and letters that may sound alike (e.g. 'c' and 'k') which, when spoken, do not allow clear association between the letter and its source word.

Use them or lose them?

In reviewing the pros and cons of *A&As*, I find it difficult to identify too many advantages in unbridled use. While *A&As* certainly present opportunities to save space, the benefits are quickly outweighed by increasing potential for confusion and, worse, misinterpretation. These, in turn, result in increased time to comprehension, and obfuscation. I tend to agree with the AMA editors in selective use of *A&As*. I would also encourage anyone who is attending a meeting where there may be participants who are not familiar with company-specific *A&As* to deliberately define the terms when using them in the meeting conversation. I have prepared 'decoder sheets' for distribution to new employees when they first join the company or department. The sheets are a valuable aid in making these colleagues more comfortable with the culture of their new environment and avoiding the embarrassment of having to ask for a 'translation'.

As long as definitive publications and documents associated with our profession (e.g. peer-reviewed journal articles and filings to regulatory authorities) are less driven by saving incremental space and time, I would reserve frequent use of *A&As* for those media that ARE so-restricted (e.g. TWEETS). At least we haven't regressed to using emoticons ☺!

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Abbreviations & Acronyms – Quiz answers

Question	Answer
AERS	Adverse Event Reporting System (FDA)
CHMP	Committee for Medicinal Products for Human Use
CORE	Clarity and Openness in Reporting: E3-based
CTA	Clinical Trial Application (Canada and EU)
CTD	Common Technical Document
DSMB	Data and Safety Monitoring Board
DSUR	Development Safety Update Report (ICH)
EEA	European Economic Area
EMA	European Medicines Agency
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
IND	Investigational New Drug Application (USA)
IRB	Institutional Review Board (USA)
MAH	Marketing Authorisation Holder
MR	Mutual Recognition
NDA	New Drug Application (USA)
PRO	Patient Reported Outcome
SmPC/SPC	Summary of Product Characteristics
SUSAR	Suspected Unexpected Serious Adverse Reaction

Gained in Translation

Editorial

Section Editor:

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Welcome to the Translation Section editorial!

What we call 'lay-friendliness' is a key characteristic of Patient Information Sheets (PIS), which are tightly regulated on a European level to guarantee a comprehensible document that contains usable information for patients. It is clear that we, as translators, need to make an effort to improve language access as a means of empowering patients in decision-making about their own care. Strategies to support patients play an important role in understanding the causes of illness, protecting their health, and taking appropriate action. Yet, professional translators often primarily focus on the faithfulness of the translation to the original document rather than on the comprehensibility of the translated version, forgetting that often messages that work well with one language-speaking audience may not work for audiences who speak another language.

In the following article, Lorenzo Gallego Borghini gives an overview of lay-friendliness of PIS translations in Spain. Enjoy the article!

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Literality of translations is affecting the quality and readability of research patient information sheets in Spain

Background

In Spain, clinical research is a source of a great deal of work for biomedical translators. In 2013 alone, the Spanish Agency of Medicines and Medical Devices (AEMPS) approved 759 clinical trials, of which 74% were international multicentre studies, a percentage which has risen from previous years: 58% in 2012, and 60% in 2011.[1] The conduct of international multicentre studies means, of course, that many clinical research documents are being translated into Spanish. The law no longer requires the research protocol to be translated into Spanish,[2] but many ethics committees still request a copy in Spanish. On the contrary, the patient information sheet (PIS) and the informed consent form (ICF) must be written in the subject's 'own language' (*lengua propia*), and therefore translation of the PIS/ICF has become a mandatory legal step in the approval process of any multinational research study. The final recipients of these texts, i.e. patients, are lay persons, and with this in mind, the translations should be written in clear and understandable language; at the same time, however, they should be accurate and adapted to the target legal and social framework. However, in reality, some things are not being done properly.

Problems in informed consent documents

What clinicians are saying

In a study of 101 sequentially selected PIS/ICF documents, a good percentage of which were likely translations as the sample included all clinical trials approved in the previous two years, it was found that 97% of these documents require readers to possess secondary to higher education levels; the authors concluded that the PIS/ICF documents analyzed were unacceptably difficult for readers, a situation which might even affect the validity of the consent process.[3] Other experts in Spain have also questioned the quality of PIS/ICFs with complaints such as the following (in Spanish originally):

- 'Many information sheets are (poor) translations from English, done by people who lack the necessary clinical experience; ethics committees are forced to review and rewrite them';[4]
- '[…] informed consent documents are usually literal translations […]; they are too long and have too many technical words, which make them difficult for patients to understand;'[5]
- '[…]one of the problems with terminology may be related to translations that are too literal or not adapted to our local culture. In the current era of globalization, a new approach is needed to produce accurate translations, based on a multidisciplinary approach, taking into account the

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> specific context and the local characteristics while being faithful to the source texts.'[6]

Bhutta[7] has pointed to a key question: 'The informed consent forms are […] translated and then back-translated to ensure that they retain their original meaning. This emphasis on literal translation serves largely to satisfy the legality of the process rather than the information and comprehension needs of the community or individuals who may potentially participate in research.'

The objections of research ethics committees

I recently studied a sample of 100 review letters from Spanish research ethics committees (RECs) to learn more about quality issues in PIS/ICFs potentially related to translation. I found that almost a third of all the objections raised to the PIS/ICF document could be related to the translation from English. In addition, Spanish RECs criticize the translations of these documents in harsh terms and replicate the remarks cited above: they find them too long and dense, they consider the style to be awkward, confusing and cumbersome, and they point out many terminological and cultural pitfalls.[8] When analyzing them in detail, it becomes clear that poor — often too literal— translations are behind many of the issues noted by RECs.

Examples of issues found in literal translations

Literality affects all levels of language but most notably aspects such as the following:

Repetitions

Informed consent forms in English are full of repetitions. For instance, the word *study* is used preceding all the elements related to a clinical trial and is repeated every time these elements are mentioned: the *study doctor,* the *study personnel,* the *study drug,* the *study treatment,* the *study site,* the *study visits,* etc. The English language tolerates these repetitions much better, perhaps because English words tend to be shorter and fewer articles and prepositions are used. For instance, *study doctor* (four syllables) literally translates into Spanish as *médico del estudio* (seven syllables), and *study drug* (three syllables) can be *medicamento del estudio* (nine syllables — three times as long!) if translated literally.

In Spanish, lexical repetitions are considered a sign of poor style. When translating into Spanish, there are alternatives to using the term *estudio* every time. For example, the *study doctor* can become *el investigador,* which sounds less like a 'big word' in Spanish than *investigator* in English, and the *study site* can simply be *el hospital.* The term *research study* itself is best translated as *ensayo clínico*, as many RECs demand,[8] or as *investigación*, which does not mean the same as English *investigation*. Other times, the word *study* can be left out in the translation, as it adds no significant meaning in the communicative context.

Univocality

One of the features of literal translations is univocality — the notion that there must be an exact correspondence between one source word and one target word. Univocality is certainly desirable for scientific terms, especially in highly technical contexts. However, in PIS/ICFs, many terms are not actually scientific or technical, even if found more often in this genre, and some variation may benefit readability in a target language like Spanish, which does not tolerate repetition well, even within the same document. It is the case of terms like *visit,* which can be rendered as *visita,* yes, but can also be *cita* or *control.*

A troubled client once got back to me about a translation and asked me to amend it by introducing the term *procedimiento* exactly every time *procedure* appeared in the original. I could not make them understand that this word is utterly meaningless and that it can be translated not only as *procedimiento* but also as *actividad, prueba* or *estudio* (as in *assessment*), and can sometimes even be left out; indeed, the common sentence *You will have the following procedures* can be *Le harán lo siguiente,* where the notion of *procedure* is carried by the verb *hacer* (*to do, to perform*).

Discourse

As mentioned above, Spanish tends to repeat less. One of the reasons for this is that the traditional Spanish discourse relies more on what has already been said and what readers already have in their heads. For this reason, literal translations of English into Spanish tend to 'grow' by 15% to 20% regarding the source text. However, a good use of more traditional Spanish rhetoric can keep this 'growth rate' at about 5% or 10% maximum, and this is especially true for these texts, considering the number of lexical repetitions which can be suppressed easily in Spanish with no loss of meaning. This phenomenon was explained very well by López Ciruelos in what I believe to be a landmark article for Spanish translation.[9]

Abbreviations and acronyms

Acronyms are not used equally in English as they are in Spanish. In fact, In Spanish, abbreviations and acronyms are used less frequently than in English and different shortening procedures are used, most notably the selection of one stronger

element in a compound. For example, whereas in English the abbreviation *MRI* is widely understood, Spanish has chosen the stronger word in the compound to shorten the name of this diagnostic procedure, and so *resonancia magnética nuclear* becomes *resonancia* in colloquial Spanish, much more often than the abbreviation *RM* or *RMN,* which are confined to technical jargon and the written language. Therefore, why not translate *MRI* as *resonancia* in informed consent forms if that is the term that patients are using in Spain? And the same can be said for names of diseases, such as *systemic lupus erythematosus,* which in Spanish can be shortened as *lupus,* using the core word instead of the acronym *LES.* Yes, there are other types of lupus, but again, Spanish relies more on what has already been said and on the communicative context, and the specific form of the disease will be clear earlier in the text and of course on the patient's mind. However, many clients demand to see an acronym in the translation exactly where there is an acronym in English, and otherwise they seem to think the translation is missing something.

Grammar and syntax

Many grammatical and syntactical problems are caused by interference with English in these translations. One of them is the excessive use of possessives, which again are used far less in Spanish; when translated literally, these can lead to clearly ungrammatical expressions, such as *su médico del estudio* for the *your study doctor* (but literally, *your doctor of the study*). There are also marked differences in the use of demonstrative pronouns, and thus many sentences which begin with *this is* or *these are* in English need to be rephrased in Spanish for clarity, such as *This is a randomized study,* which should be either *Este ensayo es de tipo aleatorizado* or *El ensayo es de tipo aleatorizado*.

Other problems are found in adverbs ending in *-ly,* which correspond to Spanish adverbs with the *-mente* ending. However, in Spanish these endings produce longer words and are used less frequently (these do sound more like 'big words' than in English), in favor of other expressions. For example, we do not use *-mente* adverbs for frequencies, and thus *daily* and *weekly* are better translated as *todos los días* or *una vez al día* and *todas las semanas* or *una vez por semana* instead of *diariamente* and *semanalmente;* we do not use these adverbs either for administration routes, so we prefer to say *por vía intravenosa* instead of *intravenosamente* (*intravenously*).

It is also worth mentioning that Spanish has a much freer word order within sentences thanks to its preserved verbal system. When the rigid word order of English is kept in a translation, the result can read artificial, awkward, and clearly foreign. For example, a simple sentence such as *A total of 100 patients will take part in this study* can be best translated into Spanish placing the verb at the beginning and the subject at the end: *Participarán en esta investigación 100 pacientes.* This also enables us to remove *a total of,* as the figure is no longer placed at the beginning of the sentence.

Legal and cultural adaptation

Choosing cognates for translating legal terms can be a bad idea, not only because the target text can sound poorer but also because it can have legal implications. For example, literal translations usually include the word *divulgación* for *disclosure* in the context of data protection, but *divulgación* in Spanish has the meaning of public dissemination rather than disclosure between two authorized parties — which is far beyond the scope of the use approved by patients when they sign an ICF. The terms used in the Spanish Data Protection Act[10] are *comunicación* and *cesión.* RECs systematically complain about this.[8]

Cultural problems arise when paragraphs concerning different healthcare systems are translated without proper adaptation. For instance, in texts from the US, anything to do with payment, co-pays, payers, medical bills, etc., should be adapted to our free-of-charge universal-access system; trademarks and USANs or BANs should be changed for Spanish trademarks and INNs; and Anglo-Saxon volume measures should be transformed into decimal units (such as the number of *teaspoons* of blood to be collected, which in Spanish should be expressed in milliliters).

The reasons behind this situation

Summed up, all of these issues clearly affect the quality and the readability of these all-important documents in clinical research. One of the main reasons may be, as pointed out by Bhutta,[7] that literal translation serves largely to satisfy the legality of the process, and less attention is paid to the actual adaptation to the target culture and the comprehension needs of the readers. Sponsors seem to be very fond of literality, perhaps because it is easier for them to monitor these texts if they find recognizable cognates in the same place as in the source text. Indeed, many translators in Spain are subject to what has been called 'monitored translation' (*traducción vigilada*),[11] i.e. translation that is assessed for quality using non-professional criteria such as cognate correspondence or symmetrical punctuation, even by individuals who are not speakers of the target language, which is relatively feasible

with Spanish given its relative transparency, its closeness to English and their shared roots.

In fact, another reason for this fondness for literality is that many sponsors use backtranslation as a quality control procedure; of course, a literal translation will translate back into English more easily, and the review process will be smoother and require less effort. But is this real proof that the translation is good? In my opinion, of course, it is not.

The renowned legal translation scholar Anabel Borja[12] has suggested that literality has traditionally been conceived as being equal to fidelity. However, as this professor points out, fidelity can also be understood to mean fidelity to the meaning, and excessive literality can have the opposite effect. The source language structures do not need to be replicated to obtain the same effects, including legal effects.[12]

Finally, but very importantly, the translation market in the clinical research sector in Spain, and in Latin America also, has been taken over in the last few years by large multinational agencies employing computer-assisted (and even automatic) translations tools. These companies apply an industrial approach to what is fundamentally intellectual work and are driven more by increasing their profits at any cost than by an actual interest in translation. The cost reduction frenzy also leads them to employ very junior translators who are eager to get started and are ready to accept their aggressive discounts for matches and their unfair work conditions, but have little expertise in such a sensitive field as human research. The predominance of these companies is seriously affecting the quality of medical translations in Spain and in Latin America.

What can be done

A radical solution to the problem with ICF translations in Spain would be not to translate them at all but to write them from scratch in Spanish and cap the maximum number of words at around 2,500. Indeed, in Spain the Coordinating REC Centre has proposed a sample PIS/ICF to be used by sponsors,[13] but in reality ICFs are almost always translated from English, and some of the latest ones I have seen had more than 10,000 words.

How to tackle the trends in industrial translation is a different question altogether and one that specialized translators should take up very seriously. Ideally, sponsors should understand that literality is not a guarantee for legality or a sign of quality in translation, especially in the English to Spanish pair and in such a sensitive context as this one — important information to be read by lay persons, many in stressful situations. It should be understood that literality is not a synonym for fidelity or accuracy. It is up to us translators, and also up to language service providers, to convey this message to the industry.

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English Grammar and Style

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In this issue

- We continue Michael Schneir's fascinating series on distractions in medical and scientific writing, this time concentrating on non-pronoun-induced backtracking with adverbs, verbs, and nouns. This sounds a little fearsome, but the concepts are straightforward and, as ever, Michael gives us elegant solutions.
- Sirisha Bulusu provides sound advice on the preparation of congress abstracts. This will be followed up by a second part in our next issue.

Revising medical writing: Reasons not rules Backtracking, non-pronoun-induced Part 4 – Syntactic position revision, juxtaposition

Introduction

Previous articles in this series have examined the causes of, and solutions to resolve, backtracking arising from ambiguous use of pronouns. Backtracking can also be induced by adverbs, verbs, and nouns. Just as for pronoun-induced backtracking, non-pronoun-induced backtracking impedes immediate comprehension.

Part 1 – Adverbs

The adverb 'respectively' is widely used in research writing, probably for concision; however, 'respectively' induces backtracking. The reader has to match each member of one set of words (usually nouns) to each member of a prior set of words.

Example 1: 'Respectively'

This example is from a Results section, data verbalisation.

> *The mean specific radioactivity in lungs and plasma of the rats was 16 and 18 DPM/ng,* ***respectively****.*

'Respectively' elicits an inter-set matching between the pair of coordinated DPM/ng values and the pair of coordinated tissues, necessitating extra cognitive effort to backtrack. Alerting the reader by using 'respectively' does not excuse the writer from facilitating comprehension. The suggested revision involves juxtaposing the individual coordinated DPM/ng from the 2nd pair to the individual coordinated tissues in the 1st pair. The order of the words in the listed pair '16 DPM/ng (lung)' is in the same order as in the forecast: 'mean specific radioactivity … in lungs and plasma'.

> *The mean specific radioactivity of the rat tissues was 16 DPM/ng* ***(lung)*** *and 18 DPM/ng* ***(plasma)****.*

Example 2: Misuse of 'respectively'

This example is from a Results section, data-based trend.

> *The data showed that the plaque index and gingival bleeding index were significantly reduced,* ***respectively****, over the 6-week period in the test group.*

The presence of the set of indexes 'plaque index and gingival bleeding index' probably elicited the mistaken use of 'respectively'. However, there is no 2nd set for an inter-set match up, thereby negating the need for 'respectively'. The suggested revision is to use the determiner indefinite pronoun 'each' to refer to each index.

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*The data showed that the plaque index and gingival bleeding index were **each** significantly reduced over the 6 week period in the test group.*

Example 3: 'Vice versa'

'Vice versa,' a Latin term meaning 'conversely' (i.e., 'with the order reversed'), necessitates backtracking into the sentence to ascertain what sequence of constituents is being interchanged.

Example 3 is from a Results section, data-based trend.

*Few women reported using a diet low in folic acid but high in vitamin A, or **vice versa**.*

How difficult is the cognitive effort to complete the induced interchange of the adjectives 'low' and 'high' between the vitamins 'folic acid' and 'vitamin A'? In the example, 'vice versa' initiates an interchange of the adjectives (i.e., 'low' to 'high' and 'high' to 'low'). Although there are no other logical possibilities for the converse meaning of 'vice versa' except 'high in folic acid and low in vitamin A', an explicit statement eliminates the extra conceptual effort involved to complete such an interchange.

The suggested revision is to replace 'vice versa' with the exact meaning.

*Few women reported using a diet low in folic acid but high in vitamin A or, **conversely, high in folic acid but low in vitamin A**.*

Notes

(a) Because of its concision, the use of 'vice versa' is difficult to resist; however, without knowledge of the science, selection of the correct meaning of 'vice versa' may be difficult.
(b) In addition to 'the converse', another marker equivalent to 'vice versa' is 'the reverse' as in 'Few women reported using a diet low in folic acid but high in vitamin A, or the reverse.'

Part 2 – Verbs

Example 4: 'To do'

To avoid verb repetition in a comparison, 'do' is often used; however, the casualty as with other such concision techniques is that the exact meaning may be uncertain. As with 'vice versa', replacement with the intended meaning will avoid the uncertainty of backtracking.

This is an example from a Results section, data-based trend.

*The PAOLL vaccine induced a more increased FN-gamma and IL-2 secretion than **did** the SAOLL vaccine.*

Although the use of 'did' avoids the repetition of 'induced', it necessitates an inversion of the subject 'vaccine' with the verb and usage of the verb 'do' to facilitate this inversion. However, 'did' induces a backtracking. Three suitable revisions are suggested.

(i) Thematic-focussed subject

Revise the sentence so that 'IFN-gamma and IL-2 secretion' become the subject necessitating a shift in voice from the active to the passive ('was induced').

A more increased IFN-gamma and IL-2 secretion was induced by the PAOLL than by the SAOLL vaccine.

(ii) A variant of thematic-focused subject

The thematic focus is a combination of the subject in revision (i) and the verb 'induced'.

The induced IFN-gamma and IL-2 secretion was more increased by the PAOLL than by the SAOLL vaccine.

(iii) 'There' descriptive pattern

In an extension of revision (i), the sentence is changed from a narrative style 'was induced' to a descriptive format 'there was a more increased' involving the linking verb 'was' and the participle adjective 'increased'.

There was a more increased IFN-gamma and IL-2 secretion induced by the PAOLL than by the SAOLL vaccine.

Notes

(a) In all three revisions, subject-to-verb inversion and backtracking are avoided. In addition, comparison of the constituents 'by the PAOLL' and 'by the SAOLL' occurs at the sentence-end position, simplifying and emphasising their comparison.
(b) Another way to look at the revisions is the underlying principle of juxtaposition. That is, juxtaposing the compared constituents at the end of a sentence elicits the 3 revision transformations (i to iii) shown above.

Part 3 – Nouns

Example 5: 'Former and latter'

The backtracking and the revision induced by 'former and latter' are similar to the backtracking and revision induced by 'respectively'.

This example is from an abstract: experimental approach plus results.

> *For the two categories of dietary usage included in this study, namely, multi-vitamins without folic acid and multi-vitamins with folic acid, the incidence of neural tube defects for the* ***former*** *was 4% and 1% for the* ***latter****.*

Revision involves juxtaposing each member of one pair (the diets) with their appropriate constituent in the other pair (% neural tube defects), thereby precluding backtracking.

> *For the two categories of dietary usage included in this study, the incidence of neural tube defects was multi-vitamins without folic acid* ***(4%)*** *and multi-vitamins with folic acid* ***(1%)****.*

Summary

Backtracking induced by adverbs, verbs, and nouns can be eliminated by juxtaposition of a pertinent member of one set with a pertinent member of another set. To avoid backtracking by 'vice versa', an exact statement of the reverse meaning is recommended.

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Writing abstracts for congresses (1)

Publishing data in congress abstracts often provides the first opportunity for physicians and pharmaceutical companies to present data from clinical trials. However, congress guidelines usually stipulate strict word count or character limits for these abstracts. Although a simple solution would be to publish two (or more) abstracts, many congresses discourage this practice, or actively forbid submitting multiple abstracts from one study. Consequently, medical writers may find themselves under pressure from authors and study sponsors to include as much data as possible in a single abstract, whilst keeping within the congress restrictions. Unless great care is taken, the resulting abstract can be very data-heavy, making it difficult for the reader to understand the key data and messages presented.

Writing abstracts for congresses therefore presents a unique challenge for medical writers, who must strike the right balance between adhering to congress guidelines and meeting requests from authors. An excellent two-part article discussing techniques to shorten abstracts was previously published in *Medical Writing*, focusing on abstracts for manuscripts.[1,2] In this two-part series, we discuss good writing practice for congress abstracts, to clearly convey results whilst respecting congress limitations.

Abbreviations

The use of abbreviations should be considered carefully when writing congress abstracts.

On the one hand, abbreviations are a simple way of significantly reducing the number of words or characters. Some abbreviations that are not acceptable in manuscript abstracts are frequently used in congress abstracts: for example, abbreviating 'patients' to 'pts' and 'weeks' to 'wks'. Depending on the audience, consider whether it is strictly necessary to define commonly used abbreviations in abstracts. Constantly defining abbreviations can detract from the overall flow and may not be helpful when the reader is likely to be familiar with the abbreviation. Some congresses publish a list of acceptable abbreviations which may be used without definition.

On the other hand, overuse of abbreviations (especially uncommon ones) can make the abstract difficult for the reader to follow. For congresses with word count limits, abbreviating words may not always help to shorten the abstract. Abbreviating 'methotrexate' to 'MTX', for example, does not save any words (in fact, one extra word is used to introduce the abbreviation!). However, this abbreviation does significantly reduce the character count. Always try to bear the reader in mind and use abbreviations when appropriate, rather than just as an abstract-shortening device.

Punctuation

Considered use of punctuation such as brackets, colons and semicolons can be a useful tool for presenting data in abstracts concisely. Consider the following example:

[1] At Week 24, remission rates in treatment arms A and B were 55% and 45%, respectively.

Rephrasing this as follows conveys the same information in a much more digestible (and shorter) form:

[2] Week 24 remission rates: Arm A = 55%, Arm B = 45%.

Example 2 saves characters and also helps to avoid use of the dreaded 'respectively' as in Example 1, which forces the reader to backtrack to understand what is being referred to[2] (see also the article on Revising Medical Writing, above, by Michael Schneir). For congress abstracts with word limits, strategic use of a slash without subsequent spacing may also be used to conserve words (within reason), eg. presenting results as 'responders/non-responders' and the corresponding values as '−2.8/−0.5' may count as one word. However, it is easy to overuse this approach, and it might not be appropriate to present all data in this format. Too much punctuation in an abstract also runs the risk of not appealing to the reader's eye. Avoid placing brackets within brackets, eg. instead of (56.6 vs 78.2 [$p < 0.001$]) use (56.6 vs 78.2, $p < 0.001$).

Referencing

Unlike manuscript abstracts, where references are usually not permitted, many congress abstracts include references to other publications. References can be very costly in terms of word and character counts, therefore only key references should be included. If references are necessary, consider how much information the reader really needs to understand which publication is being referred to. Using abbreviated journal titles and including only the final page number of the reference (eg. 1234–5 instead of 1234–1235) cuts characters, while still allowing the reader to identify the publication being referenced. It may also be appropriate to remove 'et al.' from the reference, which saves two words (or five characters) per reference.

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Out On Our Own

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Editorial

In this issue, Satyendra Shenoy, a member of a few years from Mumbai tells us about the tribulations – if not trials – of realising his lifelong ambition to settle in Germany. What eventually made this possible was discovering, as a benchside scientist, how rewarding scientific and medical writing is, which enabled him to set up as a freelancer in Cologne. Although it is relatively easy as an EU citizen to work as a freelance writer in Germany, it is not quite so straightforward for non-EU citizens, and there is no shortage of advice in Satyen's article.

Another new member, Uwe Kollenkirchen, also working as a freelancer after a long career in research, gives us his personal opinion on one of the blocks in the Expert Seminar Series (ESS) introduced at the Dublin Conference in 2015 for experienced colleagues looking for in-depth exploration of topics. Sam Hamilton responds to his comments. The ESS was generally very well received, although both Uwe and Sam – and other attendees – felt that there should be much more opportunity for discussion and questions.

As a new freelancer, Uwe is also acutely aware of the cost of attending conferences and has some interesting comments on the cost effectiveness of attending conferences in an article he prepared based on a questionnaire about conference attendance cost.

A year ago, Janet Davies reported on setting up business as a freelancer in the Azores. In this issue, she takes stock one year on, and things are still looking very positive!

We wish you all the best for 2016 and look forward to seeing you in Munich in May.

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Freelancing in Germany – Oddventures of a non-EU guy

In a few months, it will have been five years since – in a moment of serendipity – I ventured into medical writing. Throughout my career as a benchside researcher, writing has been a part of the job, be it sections of manuscripts or research proposals or conference posters, and yet I had never thought I'd take up writing as a full-time occupation. I believe that mine is not a unique case since most medical writers have in one way or the other taken this road after coming from diverse backgrounds. However, in the context of medical writers freelancing in Germany, I presume that I am one of the very few who are citizens of a non-EU country and who moved here to establish themselves in this profession. This piece is my account of the experiences and findings, the trials and tribulations, and ultimately hanging up my shingle in Germany.

Germany? Really? But why?

I have been asked this question one time too often to count; by friends, family, colleagues, immigration officials, the lot. And I can list many a reason, professional and personal:

- Germany is the second-largest market for medical writing in Europe after the UK.
- German immigration laws allow non-citizens to practice their trade as self-employed persons (*Selbständige*) or freelance rs (*Freiberufler*).
- I had lived in Cologne, Germany, since the end of 2011 and had some idea of the lie of the land.
- In Germany, writing – even technical and medical – comes under the category of arts, and writers are classified as artists. This is a bonus in terms of social security and insurance (I won't go into details here but one can look up '*Künstlersozialkasse*', the KSK). Moreover, various financial and tax incentives make it a less bumpy ride for business start-ups.
- Germany is diverse and cosmopolitan, and while English may not be as widely spoken as in Scandanavia or The Netherlands, life is fairly easy despite no knowledge of German (but learning the language of the land one wishes to reside in is practical, after all).

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These are some of the many reasons that can bolster one's confidence to set up one's writing shop here. However, for me, the one that was at the heart was a deep desire since childhood to live in Germany. So, when towards the end of 2013 I came to the proverbial fork in my career path, I hung up my lab-coat and took the road that beckoned the medical writer in me.

To job or not to job, that is indeed the question

The decision to freelance was not an easy one to take. After all, a steady 9-to-5 in the employ of an organisation, regular entries in the bank at the end of the month, paid vacations, and the comfortable security of all these are indeed desired by most of us, myself included. And yet, one must consider what one can bring on board while applying for a job; after all, that is what the person hiring is looking for. My plus points were a background in academic and pharmaceutical research and a proficiency in English. However, I was (and still am) a newbie with a limited track record and no experience in certain types of medical writing viz. regulatory, which are more sought after. In other words, not the ideal candidate most employers advertise for. It was at this juncture, after a few unsuccessful interviews, that I was reminded of a meeting I had walked into while attending the EMWA Spring conference in 2012 – the Freelancer Business Forum. It was here that I first got to hear the stories and experiences of fellow EMWA members who were freelancers and running their own enterprises. As fascinating as well as insightful this meeting was, my thought at the moment was "This is too bold and fanciful an idea for me". However, the seed had been sown. And after a fruitless wait to hear back from potential employers, I finally decided to do myself a favour and employ myself. This may appear to have been somewhat epiphanous; in reality, it was anything but. The decision to set up my own shop was made after a lot of hard thinking, weighing the pros and cons of such a venture, and yes, plenty of research on the feasibility of turning this bold and fanciful idea into a reality.

Well researched is half begun (and I daresay, a quarter done)

Just type in key words like *freelancer, medical writing, Germany, etc.* in Google search and one is presented with a few dozen pages of hits. Of course, as with any general search, one has to separate the chaff from the wheat. There are a number of private websites and forums that offer specialised advice for those wishing to move to Germany; however, I must note here that most have the same information, possibly cut and pasted from other sites (and since there is no way of tracking where the original info came from, I am not providing references). What these sites do provide is a general idea on what is required to work as a freelancer in Germany, the procedure to follow, the governmental agencies involved, the paperwork required for the application, etc. Yet other community websites like Toytown Germany (http://www.toytowngermany.com) that are managed by resident expats (and there are plenty of them) give plenty of useful insights in and advice on life in Germany, down to city and town level.

With reference to freelancing as a medical writer in Germany, most helpful to me were two comprehensive back-to-back articles[1,2] by Stefan Lang (Scientific & Medical Writing, http://www.scientific-medical-writing.de), published in Medical Writing (formerly The Write Stuff), the quarterly journal of the European Medical Writers Association (EMWA). Alistair Reeves (Ascribe Medical Writing and Translation, http://www.ascribe.de) and Sam Hamilton (Sam Hamilton Medical Writing Services Limited, http://www.samhamiltonmwservices.co.uk), veteran medical writers based in Europe and senior EMWA members, have also penned a few insightful articles that address specific issues dealing with running a freelance writing business. In addition, the Out On Our Own section of Medical Writing features useful information, experiences, and pointers from EMWA members who work freelance in Germany and other EU countries. All in all, thanks to the present Internet age, a lot of useful information is just a click away.

Visa – for anywhere you want to be

So what is the first requirement for a medical writer from outside EU to freelance in Germany? As in any other country, a non-national requires authorisation to reside and be employed in Germany, including those who are self-employed or work freelance. Of course, citizens of EU (including those in the European Economic Area or with Swiss citizenship) are free to start up a business in Germany but for those who are not EU citizens, the first step is to procure an 'Aufenthaltserlaubnis' (residence permit). And the governmental agency that provides this is the 'Ausländeramt' (Foreigner's Office, henceforth referred to as The Amt). This august bureaucratic office is not to be confused with the Auswärtiges Amt, the German Foreign Office, which operates at the federal level and among other things governs Germany's foreign missions. The Amt, on the other hand, is a part of the

Interior Ministry of the respective states in Germany and is responsible for all decisions regarding resident foreigners in that particular state. So this is the agency that decides on an applications made by non-EU persons; it may consult other local and national agencies regarding such an application, but it is the one that has the final say. I must add a corollary here – since applications for residence permits have to be made at the offices of The Amt in the city where one wishes to set up their business, one must have decided on the location (and the rationale behind it, e.g. close to the pharma belt near Frankfurt) beforehand. It is acceptable to change one's residence after moving to Germany but one won't be granted a 'general approval' to arrive in Germany and then choose a city/town/hamlet/cave to work from.

So how exactly does an aspiring freelance writer from outside the EU make an application? Well, if one is already in Germany with a valid residence permit, then they put together an application packet. Alternatively, they can consult the pertinent case officer at or refer to the website of The Amt on what goes in this packet. Generally speaking, the application has all their details and credentials, financial documents, and a business plan that explains how and why they want to run their venture in Germany, and submit it to the local offices of The Amt. If one doesn't have an existing residence permit (and presumably isn't in Germany at that point), then one has to make the application at the nearest German foreign mission in the country of one's citizenship. An important point to note here is that a person who is in Germany on a temporary visa (tourist, business, etc.) cannot make a direct application for a long-term visa (be it for freelancing or even with a job offer from a German company) while in Germany. An exception to this rule has been made for non-EU nationals from the USA, Canada, Australia, New Zealand, Japan, Republic of Korea, and Israel; citizens of these countries are allowed to arrive in Germany on a temporary visa and then apply for a residence permit. Whilst applying from outside Germany, another important point to keep in mind is that German foreign missions do not issue residence permits, the authority to do so lies only with The Amt. So once an application has been submitted to an Embassy or a Consulate, it will be forwarded to the pertinent office of The Amt where the applicant wishes to live. The Amt will then review the application (very carefully, and in consultation with other agencies like the local Chamber of Commerce and Industry, Federal Employment Agency, etc) and make a decision. Once the mission receives an approval of the application, it will issue a temporary visa lasting three months. Thereafter on arrival in Germany, one has to visit The Amt in person (of course, after having made an appointment) with other documents like city registration (Anmeldung), health insurance, local bank statement, etc. in order to apply for a residence permit.

I would like to add an extra paragraph here to remark on an important aspect of this procedure – the time frame. In my case, my Aufenthaltserlaubnis was at the point of elapsing by the time I had decided to apply for a permit to freelance, and hence I had to return to India, my native land, to submit my application. All my research, as well as discussions with a couple of other freelancers I knew, told me that the process took between six weeks and three months. I had submitted my application in October last year and it was April, a good seven months later, before I received an email from the German Consulate, telling me that my application had been approved. It was a long and hard wait, especially since I had submitted every possible document and proof The Amt had asked for, and was already in the 'Go' mode as far as setting up my consultancy, Describe, in Germany was concerned. Especially since I could think of not one valid reason for the decision to be delayed by so long. It was a period of uncertainty and self-doubt, of frustration and incredulity with the cogs of bureaucracy, of plodding through time, of watching my eagerness and resolve dissipate. It was also a lesson in surmounting these negative emotions and keeping hope, being patient, and having a positive outlook.

The reason to share this snippet is to highlight the fact that despite being well-prepared and meeting all the requirements, there are elements that are simply beyond one's control, that exist in Murphyland, governed by his laws. My case was fairly straightforward and I was not asked by the The Amt or the Consulate to provide anything else in support of my application. Despite this, it took a while before my application was greenlighted. While visiting The Amt after arriving in Germany, I asked my case officer why it had taken so long and if it was because of shortcomings in my application. She was most sympathetic, as was her shrugged response, "It happens sometimes." Such are the machinations of bureaucracy, I suppose, and not just in Germany.

The current page…

Things have come to pass, ever since, and mostly in my favour. I have now completed all the requisite

paperwork pertaining to residency, gotten my tax ID from the Finanzamt, etc. and Describe is now open for the exciting business of medical writing. Of course, it is still early days and the challenges have not ended with being granted the approval to work as a freelance writer in Germany; au contraire, they have just begun. It will take some time and work to establish my business and to achieve the two main goals behind this fanciful dream of mine – to develop myself as a good writer and to help propagate medical writing as a career in Germany. But my best efforts are definitely underway.

"No man is an island" is a cliché, I agree. But it is also very true. I may have driven this dream of mine, and in return, been driven by it; but in achieving it, I have also received help and support from many a people. Being an EMWA member allowed me to seek advice from fellow members who have walked this path before and have graciously shared their experiences, either in print or via emails and personal chats. A special thanks to Sam Hamilton for her encouraging words when I first gave this 'oddventure' serious thought, as well as for referring me to other EMWA members. And last but not least, my heartfelt thanks to my family, friends, and loved ones for all the support they rendered me in bringing my dream to fruition.

Today, as I draft this article about my experience as a freelance medical writer trying to make his way in Germany, I am reminded of a poem I learnt in school as a child, Robert Frost's *The Road Not Taken*. "Two roads diverged in a wood, and I– I took the one less travelled by, And that has made all the difference." A wonderful difference at that, I must add, since for the first time in my life, I have a deep sense of satisfaction about my job.

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Useful links

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Expert Seminar Series: A new-style session at EMWA conferences? A personal view

So far, the programme of the EMWA conferences has consisted of workshops (mainly for continuous education and EPDP certification), a full day symposium (for in-depth coverage of selected topics) and of some other pow-wows, e.g. welcome lecture, brief lectures on generic topics, short seminars, and the Freelance Business Forum.

Recently, a new type of session was introduced at the 40th EMWA Conference in Dublin earlier this year. The Expert Seminar Series consists of two consecutive independent sessions per seminar and is intended to supplement the educational conference portfolio.

I took the opportunity of attending two sessions of the new expert seminars. The first was on MedDRA coding and the second on the client-freelancer partnership. I wanted to get a first impression of what these seminars offer. I started my preparation for the sessions with looking at the information that is usually available in the online conference agenda. There I found a short description of the content, but, unfortunately, neither a participant profile, nor an objective, nor a slide set. I was actually a bit relieved because I didn't need to prepare at all with no pre-workshop assignment, and no post-workshop assignment either, as for the workshops. And – no credits had to be earned.

Both sessions were presented largely in lecture style. In one session, group exercises were used to support

the understanding of the rather dry field of MedDRA coding, which definitely helped to digest the large body of information. Particularly outsiders (like me) will have had difficulties in following the content. The second session was much more interactive, which might be attributable to the topic of the client-freelancer partnership, but also to the auditorium. This seemed to consist almost exclusively of members of both groups, which most likely triggered the vivid discussion. The way both sessions were presented was strikingly similar to that of the regular workshops which form the bulk of the conference content.

The Expert Seminar Series events that I attended did not offer anything new in content and style – perhaps the other series did. In addition, the two topics were so different that it seemed inappropriate to combine them in one series. Why not introduce a new kind of session at the annual conferences with a focus on *discussion* of specific medical writing topics? This would add value to the current programme and be likely be very welcome. The Expert Seminar Series could certainly serve this purpose, but would need to focus on important up-to-date topics maximising the interaction between presenter and audience.

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Response from EMWA Executive Committee

The target audience for the ESS was experienced medical writers, heads of medical writing departments, and industry leaders from other disciplines who want to learn about the latest developments affecting the medical writing industry and play a role in shaping the world of medical writing. The inaugural Dublin ESS focussed on developments in the field of regulatory and clinical medical writing, and featured sessions led by invited presenters, all recognized leaders in their field, on a broad range of topics of interest to medical writers.

ESS sessions – each comprising two topics – were held on Wednesday morning, Wednesday afternoon and Friday morning. Uwe attended the Wednesday afternoon ESS.

The post-conference survey revealed that 25.7% of conference attendees attended at least one ESS, so the participant profile could reasonably be expected to be the experienced group we had targeted. However, Uwe says 'Particularly outsiders (like me) will have had difficulties in following the content'. Advice on who should attend was given with the expectation that experienced medical writers would have the most to gain from the ESS programme.

The post-conference survey asked respondents to rate each ESS individually. No ESS scored less than 4.19 out of a maximum possible score of 5 when rated for content or less than 4.27 out of 5 when rated for format. The Wednesday afternoon session that Uwe attended was rated 4.36 for content and 4.42 for format – the highest scores of the three ESS sessions.

I led a team of 3 Executive Committee (EC) members in organising the Dublin ESS programme. I personally attended two of the three ESS sessions (4 topics of the 6 offered) and reviewed the feedback forms for all 6 topics whilst still in Dublin when the sessions themselves were fresh in my mind. Although comments were overwhelmingly positive, I felt that further benefit would be gained through format refinement. I will ensure that lessons learned in Dublin are carried forward to the Munich 2016 ESS programme which I am leading with 2 new team members, Raquel Billiones and Kathryn White. My team's aims for the Munich ESS include more discussion time and speaker-audience interaction, a room set up that facilitates easier audience participation and better audio quality. The Munich abstracts are with us for review and the programme will be finalised in Q3/Q4 2015. I am therefore unable to comment on content at this stage.

The ESS programme will inevitably continue to develop. Future ECs may well decide to pre-designate ESS topics, but for the first couple of years, and under the current EC, we have decided to solicit content suggestions direct from members.

Uwe, I thank you for your comments and your views on the inaugural ESS programme.

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Contemplations of a freelancer on the 2015 EMWA Spring Conference: Was it worth the money? An attempt at a cost-efficiency evaluation

I don't know which factors drive your decision to attend a symposium when you do not have time to be away from your desk or you only have very limited funds in your budget to finance such an enterprise – or both. Certainly, the benefits of a conference like the EMWA annual meetings are obvious: networking, learning and discussing what's new in the field and what has changed, and acquiring new contracts.

After attending my first EMWA conference in autumn 2014 in Florence, I was waiting eagerly for the next one where I could continue learning more about the different disciplines in medical writing and engage in further networking with colleagues in the field and possibly companies. That was the plan.

After the programme for the 2015 spring conference in Dublin came out, I assiduously prepared my conference calendar. More than 60 workshops, lectures and social events had to be checked, sorted and prioritised. I tried to squeeze as many as possible into the three-and-a-half-day schedule. The hardest part was making the decision as to which workshops were important and should be in the shopping basket and which might be only a 'nice to have' and kept as an alternative. After finishing my favourites list, I realised that my basket had to be re-arranged. Second choices needed to be included because some of the first choice workshops ran parallel or were already sold out at an early stage. After all these decisions were made, I calculated the cost for the conference.

I discovered that the total cost of the conference summed up to approximately €2700 – quite a bit of money. The only potentially reducible cost was that for accommodation because I had chosen to stay in the pricey conference hotel in order to be directly on location. But I wanted to make the conference as effective as possible and not lose time by commuting back and forth to the conference venue.

Looking at the expected cost, I remembered our last family vacation and realised that two adults and two kids could easily spend at least one week at the beaches somewhere in southern Europe for that money. This made me rather hesitant and caused me to postpone my final decision to some time in the future. But finally, help with decision-making came unexpectedly only a few weeks later when I was asked whether I would like to write about the cost-efficiency of the next EMWA meeting. Obviously, I could not resist.

I immediately started contemplating how to approach the task and asked myself: 'What does cost – efficiency actually mean? And how can you measure it?' I looked up the term in Wikipedia and got a totally insufficient and inconclusive explanation. Other sources were more helpful. For example, in a good old thesaurus, it is described as 'reduction in cost' or 'being effective without wasting time or effort or expense'.[1] If 'effective' is translated here as 'to get more of something', like a product or hardware, then one gets an idea of what cost-effective means. But in the case of a conference we don't get hardware. The product we pay for is 'software' and it even depends on one's personal perception of it, which is highly variable. The perceived value for which we pay a certain amount of money can range from very little to enormous. In addition, even the value of money is subjective. But enough about the philosophical evaluation of the meaning of cost-efficiency, let's get to the facts.

Assuming that the cost efficiency evaluation of only one conference participant must be irrelevant, it was clear that, for a meaningful analysis, I needed data from other participants. Thus, I decided to use a questionnaire with which I collected the responses of 9 other conference participants who work as freelancers. The questionnaire focussed on information on expenditure for the conference and the perceived quality. In addition, free text comments were allowed. The results are shown in Table 1.

Most of the 10 freelancers who contributed to the poll participated in all conference days (four days);

Table 1: Cost and quality rating by freelancers attending the 40th EMWA conference in 2015. Ten freelancers from 8 European countries who had attended between 0 and 13 earlier EMWA conferences provided data and evaluations. Results are presented as median and range (in brackets)

Number of conference days attended	Number of workshops attended	Number of social events attended	Overall cost (€) of the conference[a]	Average cost (€) per conference day[b]	Conference quality[c]
4 (1–5)	3,5 (1–7)	2 (1–4)	2781 (970–3790)	734 (470–2320)	2 (1–4)

[a]Overall conference cost include travel, accommodation, food, fees for conference, workshops, seminars, symposium and social events.
[b]Median of overall cost divided by number of conference days attended per participant.
[c]Rating of conference on a scale between 1 (excellent) and 6 (waste of money).

in some cases, one day of travel was added. Altogether, they attended a median of 3.5 workshops (including seminars and symposium) and two social events. Seven attendants participated in the entire conference, while three only stayed for one or two days. The attendance of workshops, seminars and symposium was variable, about one half signed up for four or more workshops out of a maximum possible of seven (two per day on Wednesday, Thursday and Friday, and one on Saturday).

The median cost for the conference was € 2781 (all participants). Eight of ten attendees paid more than €2300. The overall cost included travel, accommodation, food and beverages, extras and all conference fees. A median of €734 had to be paid for every conference day.

The quality of the workshops was rated as good. Four participants perceived them as excellent, and only two felt that improvements were necessary (four on the rating scale).

Compared to an evaluation of the EMWA spring conference in 2009 in Ljubljana,[2] this conference appeared to be considerably more expensive. The median cost per conference day back in 2009 was €580 and hence the cost had increased by approx. 27% in 2015. Total cost increased from median €1970 (Ljubljana) to €2781 (Dublin), a plus of more than €800.

What about quality? Seven out of ten participants rated the quality of the conference as good or excellent. The main strengths of this conference were seen as the possibility of networking and getting up-to-date information on important medical writing fields, such as regulatory procedures, information sources, writing skills. Content and presentation of the workshops, seminars and symposium were largely rated as good and adequate, although some workshops were considered as needing improvements. A careful evaluation of the attendee feedback, which is usually collected at the end of each single workshop, will most likely help to identify where corrective actions are needed.

The open text feedback returned with the questionnaire mainly referred to critical aspects – in other words, where room for improvement is seen with regard to cost-effectiveness. Major concerns were raised on the price of the conference. Although the conference fees were perceived as justified overall, the participants would appreciate less expensive conferences in the future. Most of them thought that finding less expensive European cities that are easy to reach would help lowering the overall cost. Cities like Lyon, Barcelona and Berlin were mentioned, but there are many more options. Less expensive hotels should also be considered instead of big hotel chains like the Hilton, which are usually rather costly. Fundraising through corporate sponsorship should be used to aid the reduction of conference fees.

Some participants raised the question of whether the workshop fees were appropriate and criticised that the advanced workshops were more expensive than the foundation workshops. More room for sessions with no extra charge would be welcomed. There was a big difference at this conference between the availability of open (no charge) and closed (extra charge) sessions (7 vs. 57). The introduction of more lectures or other type of open sessions would provide the opportunity for further learning, networking and exchange of ideas particularly when workshops are full and alternatives were not available at time of booking. An increased number of no-charge sessions would potentially attract an audience that does not want to participate exclusively in workshops, but likes to take advantage of the conference's other benefits. A more diverse program along with increased options to individually tailor spending would serve the needs of newcomers and senior writers alike. Newcomers could keep their costs low and seniors could take advantage of an increased number of 'advanced' sessions.

The proposals that were made by the freelancers who participated in this poll are in line with some of the suggestions for cost reduction which were made by participants of the Ljubljana conference (e.g. cheaper conference rates, cheaper hotels, more sponsoring of workshops).[2] Both groups were also quite consistent in their appraisal of the good quality of the conference: largely good workshops, good organisation, good opportunities for networking.

Finally, allow me a personal note: I think that the concept of charging for the conference admission (€580) and for the attendance of the workshops (up to €950) should be revisited. The conference itself, outside workshops, expert seminars and symposium, does not offer much to justify the relatively high registration fee. It is appreciated, however, that lunch and boarding during the breaks are included, which is very convenient and supports networking. Consider re-evaluating the importance of the workshop and seminar program and possibly select workshops with low frequency of attendance to be offered free of extra charge or substitute them with different types of sessions, e.g. lectures or discussion forums at future conferences.

Special thanks to those freelancer colleagues from Italy, France, Germany, Poland, Finland, The Netherlands and Austria who shared their conference costs and opinions with me. I appreciate your openness and support. In addition, I thank Lauren

Franklin-Steinmetz for proofreading and correction of the article. It substantially increased my level of comfort with it.

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Out on the ocean: A year of freelancing in the Azores

Last year, Janet Davies left her job in the Netherlands, moved to Faial Island in the Azores, and became a freelancer.[1] Here she gives us an update on the ups and downs of freelancing on a volcano!

Although often I may prefer to be gardening or swimming rather than doing paid work at the computer, on the whole I am thoroughly content with the freelance lifestyle, especially here in such a gorgeous environment. I love living here. I am looking forward to moving into our restored house in the next 2–3 months, and then to start work on our newly acquired *atafona* (more below) next year. It is good to have plans. I have completed a beginner's course in Portuguese and will continue taking lessons in the autumn. It is a slow process.

I still don't have a website for the business. The question is, do I really need one? I have a more-or-less up to date LinkedIn profile and am listed on the EMWA and BELS (Board of Editors in the Life Sciences) sites. I remain reluctant. Not only because I don't like the idea of being so public but also because I have a perfectly manageable number of clients (and hence workload) right now. I'd be interested to know what other freelancers think on the pros and cons of a website.

Here are some thoughts on issues I have faced during the past year or so as a new freelancer. I'm sure many of these issues will be familiar to all freelancers, seasoned ones as well as newbies like me.

Paying taxes

This was my first year of paying Portuguese taxes. I was pleasantly surprised by how much less than expected I had to pay in business tax. We even got a refund on our personal taxes. So far so good. But there is yet the form to complete on our worldwide income for the Dutch tax authorities. And my Dutch accountant has left the office and is not responding to emails. This is one issue that is now languishing near the bottom of my to-do list but comes to the fore at 4 a.m. I am glad to have a reliable accountant here – Sandra – it is money well spent. Earlier this year I received an unexpected visit from the tax inspectors because they said I had underpaid my social security contributions by about 3 euros. I referred them to Sandra. All sorted, no problem!

Importance of networking

I do miss one aspect of employment: interactions with and the support of colleagues. This year I was invited to a Medical Writers' Spring Retreat run by Kathryn White (Cathean Ltd) and held in Nettlebed, Oxfordshire. It was an inspiring, informative, and fun event: one of those activities that are essential for isolated freelancers like me, because it provided an opportunity to discuss with other freelancers those tricky tasks such as negotiating fees and, for example, how to deal with clients who ask you to keep time free for future projects that either don't materialise or are horribly delayed.

One thing I learned at Kathryn's Retreat is that we all need *good* clients. That is, those who like what we do and don't quibble about fees, those with whom we have a friendly yet professional relationship, those with whom we have a rapport and open communication. That may be one reason to create a website: to attract more good clients. 'Bad' clients are those who make unreasonable demands yet are not willing to pay reasonable rates.

Several of my clients have wanted me to work faster and thereby cost less. I have been wondering whether I am slow. After talking to a couple of writer friends who had similar experiences I have decided I am careful and thorough but not slow. I think I need to steer clear of those clients.

Indemnity insurance

One of the difficult issues I faced in this first year was a requirement (by a new client) for professional indemnity insurance. Rather stupidly, I took out some insurance (though I have no idea whether the coverage is appropriate) before looking for information on this topic on the EMWA website and on LinkedIn. I am not a big fan of insurance in general, which I see as something of a scam, preying upon our insecurities, and I believe that indemnity insurance should not be necessary for medical writers or editors. We work with material that is either provided by our client or already published, and any piece we

submit to our clients undergoes several more rounds of checking and approval (and probably alteration beyond our control once we are no longer involved in the project). The second time a new client required indemnity insurance I asked what risks were to be covered. I have not received a reply.

No IT support

This week I have been bemoaning my lack of IT support. Some keys on my desktop's keyboard stopped working. And now I can't even start up the computer because my password contains one of the non-working letters. I'm hoping it has to do with the high humidity here and the keys will work again in drier weather… Or perhaps I do now have to splash out on a whole new desktop. The computer is now 13 years old and I can no longer update the operating system because there isn't enough memory, but the computer still works (bar the keyboard) perfectly well. I don't know about you, but I resent the perpetual software updates computers need and vehemently object to the built-in obsolescence of modern gadgetry. But perhaps I am giving my age away!

My "office"

The timing may not have been perfect – we are still restoring our cottage while living in rented accommodation – but when the *atafona* (barn-like outbuilding) adjoining our land came up for sale last year, we had to buy it. Not only because we wouldn't want to be overlooked by an ugly modern house (a likely fate for this structure if we didn't own it) but also because it will be very useful. We can use the ground floor for its original purpose (food storage, animal housing) and as a workshop and the upper floor as guest accommodation and an

Figure 1: The former ruin, now a house with roof, doors, and windows.

Figure 2: The *atafona* (right), with a small cart house (left).

office for me. Eventually. Which leads me to another freelancer issue: my office.

In our rented accommodation my desk is in the middle of our living space. Not ideal. It will not be

Figure 3: The helpful cats, Mouse (tabby) and Pico (black).

much better in our house: my desk will probably be in a corner of the bedroom. To be fair, it is a large bedroom on the ground floor and overlooking the sea, but still it will not be ideal. I now know I really need a place where I can concentrate, away from interruptions. So I look forward to the time when we can convert the upper floor of the *atafona*. I forgot to mention that the business bought it, so it will be a nice big tax-deductible expense for this year!

The sedentary nature of our work means it is important to exercise. Since I now have only a two-second commute from bedroom to desk and lack the self discipline to take myself out for a walk every day, I am thinking about using a standing desk. Several people have told me that after a brief period of getting used to it, they love their standing desk. If you use one, please do let me know what you think of it. Does it also deter helpful cats? (We now have two.)

Self discipline

Did I mention that I had left my alarm clock behind in the Netherlands? It is lovely to wake when I am ready, but it tends to be a little late. Even in the summer, sunrise here is around 6:30 a.m., and as there is a large volcano between us and the sun rising in the East (we are in the south-western corner of the island, overlooking the Atlantic Ocean to the south west), it doesn't get properly light until 8:30 to 9:30, depending on the weather. So my working day starts quite late. Generally that isn't a problem, but I do like to get out to see (and harvest) whatever's growing in the garden, and perhaps do a spot of therapeutic weeding. So if I could arrange my workload to get all my project work done in a couple of hours a day that would suit me fine. Trouble is, of course, as I'm sure every freelancer knows, the workload doesn't flow so conveniently!

Attending the next EMWA meeting

I really do want and need to attend the next EMWA meeting. I hope to see you there!

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Interesting that 'topless' has entered the Spanish language and seems to have disappeared from English. And let's hope there are no 'deadguards' on duty!

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