

Volume 29 Number 4
December 2020

Medical Writing



Writing for patients

Also in this issue...

- Pharmaceutical clinical trials transparency and privacy
- Writing clinical trial summaries in plain language:
Some tips from patient education



EUROPEAN MEDICAL WRITERS ASSOCIATION



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ASSOCIATION

Medical Writing is the official journal of the European Medical Writers Association (EMWA). It is a quarterly journal that publishes articles on topics relevant to professional medical writers. Members of EMWA receive *Medical Writing* as part of their membership. For more information, contact mew@emwa.org.

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Medical Writing

Writing for patients

The first thing we must say is a huge “thank you” to **Dr Juan Garcia Burgos** and **Mr Paul Blake** for taking the time in an unprecedentedly manic year for the EMA to write a foreword for this issue of *Medical Writing*. The fact that they have prioritised this in the middle of the EMA relocation shows the huge commitment of the agency to engage with EMWA and the medical writing community in general, and the importance that the EMA places on transparency and providing quality information to patients and the general public. We are honoured and grateful to Juan and as a community look forward to continued communication and collaboration with the EMA on this crucial topic.

Using not only difficult to understand terms, but also different terms to mean the same thing, can be very confusing for patients.

When we started thinking about this issue, the hardest part for us was to consider what topics to leave out, rather than what to include. With limited space, it has been extraordinarily difficult to choose just 10 articles for the issue. Our aim has been to cover as wide a view of the theme as possible, to give a flavour of just how diverse writing for patients can be and how many different skill sets are needed (part of the joy of it, for us!). We thank all the authors who have put aside some of their valuable time to write their articles.

Using not only difficult to understand terms, but also different terms to mean the same thing, can be very confusing for patients. With this in mind, a new global initiative has begun to try to establish a set of plain language terms used commonly in clinical research. The group behind this initiative is extremely diverse, and includes representatives from industry, the medical writing community, patient representatives, and academic institutions, among others. It is a highly ambitious and very exciting initiative and we are proud to present an article from some of the group (**Sylvia Baedorf Kassis et al.**) explaining the project and its aims. On a related topic, **Neil M. Davis** offers an

interesting look at abbreviations that are used in multiple ways – potentially causing problems for professionals and patients alike.

Lisa Chamberlain James et al. discuss the issues surrounding writing for patients, including the new guidance and regulations instituted by regulatory agencies. The authors discuss the challenges and opportunities these pose and offer an insight into the possible future of writing for patients.

In the spectrum of information for patients, perhaps one of the biggest challenges is to provide fit-for-purpose, contextual information about Phase I clinical trials – when these involve healthy people, may not have a specific indication, and often involve medicines that never reach the market. With this in mind, **Clive M. Brown et al.** describe a template that the authors have developed to help writers to produce meaningful lay summaries of Phase I trials in healthy volunteers. The template ensures that study designs and endpoints are described in a consistent, lay-friendly manner across different types of Phase I trials.

Looking at patient information from a completely different perspective, **Alison Rapley** offers her insight into what makes a good (and bad!) participant information sheet. This is one of the documents submitted to research ethics committees for approval. Alison explains how to ensure that the document meets the necessary requirements by drawing on her first-hand experience as a research ethics committee member.

Development of a patient publication steering committee (PPSC) is an innovation in industry publication practices. **Linda Feighery et al.** describe how a pharmaceutical company plans to partner with patients to establish a PPSC and share insights on how medical writers could support such committees.

In a world increasingly overtaken by automation and artificial information, **Andrea Rossi** reminds us that although software can do word-to-word translation, there is much more to translation than just the words themselves. He explains the importance of communicating in a way that takes account of, and is sensitive to, the reader’s culture.

Writing for the internet requires a slightly different

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skill set than writing for print publications. Authors need to be aware of their potential audience's interests. To equip authors to write for the internet, **Diarmuid De Faoite** outlines the advantages that the Web presents and explains how to avoid mistakes.

Before the pandemic we are living with this year, most medical writers would have been right in thinking that writing for patients would be mostly limited to informed consents, laypersons summaries, and the odd patient engagement website. However, the events surrounding COVID-19 have brought the influence of social media under the spotlight. The WHO described the excessive amount of misinformation that bombarded media channels worldwide as an "infodemic". As if we needed another "-emic" this year... Nevertheless, **Sara Ferrão** explains how powerful social media has become in communicating healthcare information to the general public. She also makes some useful suggestions for health writers to keep in mind when reporting on peer-reviewed publications.

Along the same lines, **Amy Whereat** recounts a conversation she had with **Otto Spranger** following the 2019 spring conference in Vienna. Otto highlights the difficulties that patients still have in understanding the information that they need to make health decisions. He also suggests that medical writers, who understand the clinical trial process, can help patients to sift through the mass of clinical trial information that will soon become available with the mandatory publishing of layperson summaries.

We hope that there is something in this issue for everyone, and that you enjoy reading it as much as we have enjoyed putting it together and working with the truly inspiring authors. Even if regulatory writing is your one and only true love, we hope that this issue will give you an appreciation for the many facets of writing for other audiences and how worthwhile and rewarding writing for patients can be.

Stay safe, all.

Lisa and Amy

About the Guest Editors

Dr Lisa Chamberlain

James is a Senior Partner and CEO of Trilogy Writing & Consulting Ltd. She has been a medical writer since 2000 and has worked in the regulatory and medical communications fields. Lisa has a special interest in writing for the general public, is a member of EMWA's Educational Committee, teaches and reviews workshops for the American Medical Writers Association, is a member of TOPRA, DIA, and PIPA, initiated the EMWA PV Special Interest Group, is chair of the Geoff Hall Scholarship Committee, and is a Fellow of the Royal Society of Medicine.

Amy Whereat has been a freelance medical writer for over 10 years. She writes clinical research publications and review articles for industry, academia, and patient associations.



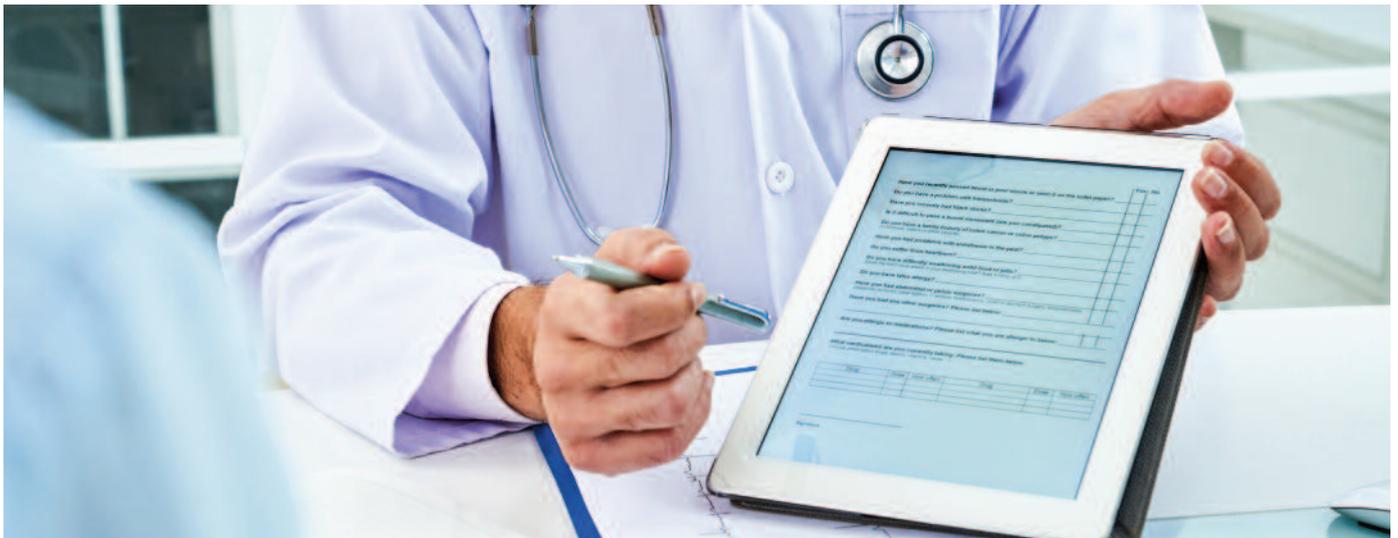
Save the date:

EMWA Conference in Latvia

RIGA

May 4-8, 2021

<https://www.emwa.org/conferences/future-conferences/>



Writing for patients: Foreword from the EMA

In recent years, regulators across the globe have improved the way they communicate to patients and the general public about their activities and how medicines are regulated.

In particular, how to best communicate the benefit and risk of medicines has been the focus of much debate and of many efforts, often involving different parties. Overall, this has resulted in an improvement of the information we offer to patients and citizens about their medicines. However, there is still a need to invest further in this field, as we navigate through an evolving landscape in medicines regulation, dominated by innovation and the explosion of new (digital) technologies.

For regulatory authorities to deliver our mission to protect public health, we need to address stakeholders' concerns and communicate the science behind our decisions. The main focus of regulators is to evaluate medicines for approval and to monitor their safety afterwards. To succeed in this important task, it is crucial that the public health recommendations that we issue are well understood and trusted by patients, healthcare professionals, and the public. However, as new methodologies and innovative treatments enter into clinical practice, it is increasingly more important to move from simply pushing out regulatory information, to explaining to society the scientific work of regulatory authorities.

One good example of an area where regulators must strive to engage and communicate better with society, and a major focus of public attention, particularly in view of the current

pandemic, is vaccines. Over the past years we have seen how vaccination, an incredibly successful medical intervention that has not only saved millions of lives but eradicated some deadly diseases, is put into question, not just by anti-vaccine groups, but by parents who develop genuine concerns following harmful narratives in social media and elsewhere, and even by academics and members of the medical profession. The unavoidable challenges of bringing new vaccines for COVID-19 in a shorter timeline may be seen by these groups as a further opportunity to raise levels of scepticism, which will need to be counteracted with high-quality, evidence-based information, and transparency.

**To be trusted,
we need to
explain the
science and
facts in ways
that the public
can understand.**

Digitalisation is becoming an increasingly routine aspect of our daily activities. New technologies have prompted new ways for society to communicate, share, and gather information. And the speed at which information – and disinformation – can travel implies additional challenges for regulators and providers of authoritative information, who aim at ensuring that our voice and messages are heard through the platforms that people use.

Accompanying this technological revolution have been many changes in the nature of our society, making it more critical of any type of authority than ever before. The term 'fake news' has become part of our daily conversation. With so many voices, people find it hard to distinguish reliable information from unreliable, and communities of belief often found through social media can sustain people in following harmful narratives. In such an environment, regulators

must work harder than ever to win public trust and to remain a reference source of reliable information.

We have seen over the years an increasing demand from civil society for the rationale underpinning our decisions. Regulators are becoming more open and keener to collaborate with those challenging accepted ideas and asking for the evidence on which decisions were based. Regulators and decision makers should be prepared to explain why we have acted in a particular way and provide the evidence and reasoning behind our decisions.

But it is not enough to be transparent about our decisions. As explained before, to be trusted we need to explain the science and facts in ways that the public can understand. If we fail to explain and connect with the EU citizens whom we serve, other less trustworthy sources may fill the gap with misinformation and inaccurate facts. High-quality, and clear information becomes a critical element of the regulatory process, an essential one to deliver our mission to protect the health of EU citizens.

**Juan García Burgos
Paul Blake**

Author information

Juan García Burgos is Head of Public and Stakeholders Engagement Department, Stakeholders and Communication Division, European Medicines Agency.

Paul Blake is Scientific Communication Officer for the same department.

Passing the torch: The sequel

Phillip Leventhal
Outgoing Editor-in-Chief

For the last 8 years, I have been serving as Editor-in-Chief of *Medical Writing*. I feel that it's time to pass the torch to a new person with new energy and fresh ideas. As I wrote in 2012, "This is yet another step in the evolution of the journal."¹ But first a little about the journal's evolution so far.

Medical Writing began life in 1993 as a newsletter produced by EMWA's predecessor, the European chapter of the American Medical Writers Association.² With EMWA's establishment as an independent association, the newsletter continued under the appropriate name of *The EMWA Newsletter*, produced by Keith Veitch. Five years later, in 1998, under the direction of Barry Drees, the newsletter expanded to become a "real" journal, *The Write Stuff*, a play on the title of the book and film about the beginning of the US space programme. Barry passed the responsibility for running the journal on to Elise Langdon-Neuner in 2014, as he said, "with great satisfaction."¹ For 8 years, Elise almost single-handedly produced the journal as it grew, which became a rather large job. Just before passing the torch to me in 2012, to reduce the load, she



arranged to move production of the journal to a publishing house and give it the more professional name *Medical Writing*.³

After about 2 years, it became clear that we were off course and that I and the rest of EMWA would be better off bringing the journal back in-house. This was tricky, but we managed to take back control and begin producing the kind of journal that our members wanted. To reduce the work, we added Victoria White as Managing Editor, expanded the Editorial Board, and created

a very successful Guest Editor programme. Thanks to the work of these people and our many contributors, we now have a high-quality, attractive, practically useful, and professional journal.

Now that the journal is operating smoothly, it is with "great satisfaction" that I pass it on to a new Editor-in-Chief, Raquel Billiones. Raquel has already brought her energy and ideas to the journal as a frequent contributor and Guest Editor, as well as to EMWA as a workshop leader, Executive Committee member, and Special Interest Group chair. I am pleased that she has volunteered and look forward to the next step in the

evolution of *Medical Writing*.

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1. Leventhal P. Passing the torch. *Med Writ*. 2012;21:265.
2. Drees B. The history of the Write Stuff: 10 years of bringing European medical writers together. *The Write Stuff* 2008;17:408.
3. About the Medical Writing journal. *Med Writ*. 2012;21:3.

Filling big shoes

Raquel Billiones
Incoming Editor-in-Chief



I have small feet. With shoe size 35, I will never be able to fill the shoes of Elise or Phil. But I am comfortable in my own shoes, I love running and walking in them, always with a direction and a goal in mind.

The EMWA journal and I have a long history that goes back to the time when I got my little foot in the door of medical writing. Somehow Elise saw the potential in a fledgling medical writer, published my first article in *The Write Stuff* in 2007,¹ and encouraged me to write more. I became a convert. Several articles later, I moved on to co-edit (together with Sam, Anu, and Kat) the Out on Our Own section.

When Elise passed the torch to Phil in 2012, he also inherited me as an associate editor and together we travelled the "man(ey)ic" times of the journal. Phil prevailed.

Like Elise, Phil was always open to new ideas. When I presented him the Getting Your Foot in the Door section in 2016, he told me to run with it and I did. Since then I have (co) guest edited two issues of the journal, *Careers in Medical*

Writing in March 2019 and *The Data Economy* in June 2020.

In the last 8 years, Phil has transformed *Medical Writing* into the world-class journal that it is now. So when he popped the question, it was easy for me to say "yes". Not least because of the amazing editorial board and production team who will be supporting me.

Yes, I humbly and gladly accept the torch and the responsibility of keeping the flame of the journal burning. I am no Olympian, but I will run with it while my knees can still hold me up and take it to the next level, whatever that may be. And Elise and Phil will always be my inspiration, the pacesetters and the tailwind that will push me forward.

And take note – this a relay. Someday, I will be passing the torch to someone else. When that day comes, remember – I have small feet.

References

1. Billiones R. From academia to medical writing – and staying there. *The Write Stuff*. 2007;16:177.

President's Message

As I write this, 2020 is drawing to a close. Although it has been an enormously challenging year, I want to take a moment to recognise a high point – the successful completion of EMWA's first virtual conference. What a milestone and major achievement for a membership-driven organisation! Thank you to all volunteers who made this happen!

We had more than 300 registrants from 27 countries, spread over five continents, celebrating the diversity of EMWA. We had top-notch speakers with great presentations, but what thrilled me most was the interaction amongst the attendees. What made EMWA's face-to-face conferences unique was the kind and welcoming atmosphere. Never would I have thought that we could transport this to a virtual environment. But indeed, at the networking reception we had so much fun together, chatting about which country has the best wine and food, running over time for one hour, that we basically forgot that we were not able to see each other in person. During the first session the next day, Getting into Medical Writing, there was such a friendly atmosphere in the chat that people felt comfortable asking questions and giving recommendations based on their experiences. With this, attendees not only benefitted from the experience of the speakers, but from the collective brain power of nearly 100 attendees. The same friendly and collaborative atmosphere was also present throughout the other presentations, and seeing some faces and some names in the chat several times over the day surprisingly made you feel connected, even if we did not have the chance to meet in person.

Thank you to all participants who made this happen – thank you for your kindness, it was great seeing you at least virtually. Thank you to all workshop leaders, the Head Office, and everybody else involved in organising the conference! Thank you also to Martin Delahunty and Chris Winchester, along with our conference director Slávka Baróniková, for the excellent organisation of the symposium. I hope that the conference has left you inspired, motivated, and energised.

In addition to preparing the conference, we have worked on establishing new connections in the field of medical writing / communications. Our conference director Slávka has engaged Publication Plan and Retraction Watch as media partners, which will increase EMWA's visibility. Furthermore, new connections have been developed through our AMWA-EMWA-ISMP Joint

What made EMWA's face-to-face conferences unique was the kind and welcoming atmosphere. Never would I have thought that we could transport this to a virtual environment.



Position Statement on medical publications, preprints and peer review that is currently under external review by different stakeholders and organisations. And Cemile Jakupoglu, co-chair of our Veterinary Medical Writing Special Interest Group, has established first contacts with the Federation of Veterinarians of Europe (FVE) – one of their members likely speaking at the first Veterinary Expert Seminar in Spring 2021.

This leads me to our last expert seminar on safety reporting for medical devices. Albeit this is a new area for EMWA, we had more than 50 registrants. This shows the interest in this emerging field and all presenters were in agreement that this field will benefit from the skills of medical writers/ communicators. We will continue to provide you with training options in this area.

More good news: in terms of training, I am very happy to inform you that through the huge efforts made by one of our EMWA members, Stéphane Romet, his colleagues at work, and with the help of our Honorary Secretary Claire Harmer, EMWA is now Datadock-registered. This is a major milestone, as it means that EMWA members based in France will be able to apply for a subsidy to attend EMWA conferences and participate in training activities as part of their allocated continuous professional development costs. For further information, contact the Head Office at info@emwa.org.

Have a good start to the New Year, and stay safe and healthy!

Beatrix Doerr



Professional Development Committee news

We are sad to report that Carolina Rojido has had to step down from the EMWA Professional Development Committee (EPDC). Carolina has made a fantastic contribution, not only to the webinar programme but also to other EPDC activities. We are very sorry to see her go.

We are delighted, though, to welcome Jules Kovacevic who is going to take over from Carolina as EPDC co-lead for the webinar programme, working with Laura Collada Ali. As Head of Medical Writing at Ergomed, Jules has experience using online training to develop a global team of medical writers and is keen to support the webinar programme and the EPDC.

Ambassador Programme news

As part of the EMWA Ambassador Programme's continuing efforts to reach out to new audiences to promote medical writing and EMWA, Abe Shevack gave a presentation on medical writing and the benefits of joining EMWA at the PAREXEL Academy in Berlin on August 18.

If you are an experienced medical writer and EMWA volunteer and are interested in becoming an EMWA Ambassador or if you know of any upcoming career events in your locality, please email Abe Shevack (aspscientist@gmail.com).

Armenian and Arabic translations of the Joint Position Statement on Predatory Journals

We are proud to announce the posting of the first Joint Position Statement on Predatory Journals translation into Armenian by Jack Aslanian and Mary A. Merark, and into Arabic by Chahira Katamesh and Nawal Benabbas.

- Armenian translation: <https://www.emwa.org/>

[about-us/position-statements/joint-position-statement-on-predatory-publishing/armenian/](https://www.emwa.org/about-us/position-statements/joint-position-statement-on-predatory-publishing/armenian/)

- Arabic translation: <https://www.emwa.org/about-us/position-statements/joint-position-statement-on-predatory-publishing/arabic/>

We are currently looking for translators. If you want to volunteer, please contact Abe Shevack (aspscientist@gmail.com) or the EMWA Head Office (info@emwa.org).

EMWA webinars

EMWA webinars help members to develop skills and keep up to date with new or rapidly developing areas. Most of our webinars are live, online seminars with the opportunity for participants to ask questions. For live webinars, you only need to register – you will need your EMWA membership details.

Check out the EMWA Webinars Programme page, where you can find the previews for the planned 2021 webinars: <https://www.emwa.org/training/emwa-webinars-programme-2020/>



EMWA future conferences

The EMWA spring and autumn conferences provide a medium for networking, active discussions and extensive, cost-effective professional training. It is also an opportunity to benefit from the experiences of other medical writers.

Mark your calendars for the future EMWA conferences:

- **Riga** (May 4–8, 2021), venue: Radisson Blu Latvia Hotel
- **Cascais** (November 4–6, 2021), venue: Hotel Cascais Miragem

Cascais



Scam email alert

We have been made aware of a scam email requesting payment for unpaid membership. EMWA members have received more than one version of this email.

Please do not respond with any sensitive personal information, such as banking details, as the email is not from EMWA.

If you have any related questions, please contact EMWA's Head Office at info@emwa.org.

As a tip, always check the email address, as shown in the accompanying screenshot of a scam email.

From: EUROPEAN MEDICAL WRITERS ASSOCIATION <info2@staycentered.org>

Sent: 06 January 2020 13:28

Subject: PAYMENT REMINDER

Dear Member,

This is to notify you to make payment as soon as possible for unpaid dues to the new association account which will be provided on request. Do reply back and notify us of which payment method best suits you. Payments can be made via the following: *Online Bank Transfer *Online Credit Card Payment (E-Invoice) If payments are not made on time, your membership will be temporarily suspended. If payment have already been made, do send payment confirmation for your account status to be updated.

Thanks,

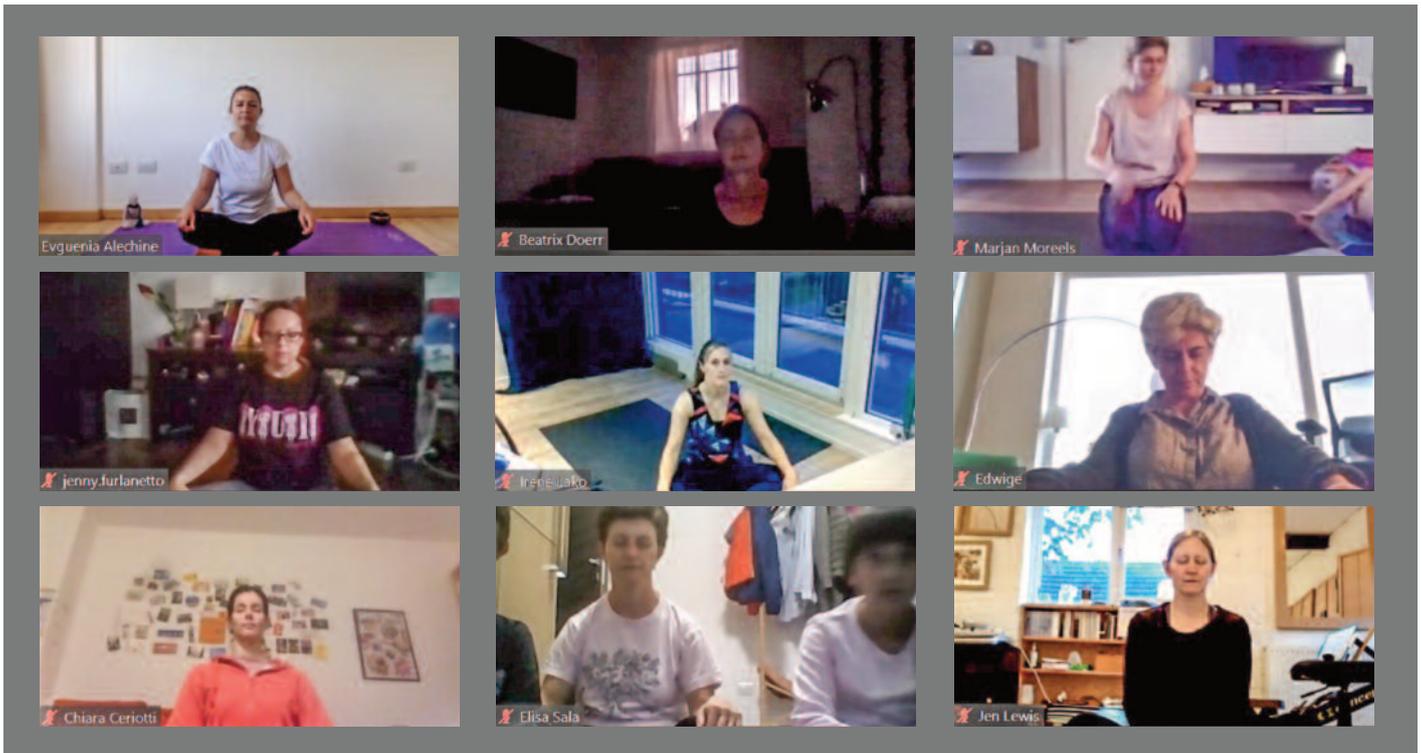
SYVIENGCHANH CALVIN GUY

European Medical Writers Association

EMWA Head Office

Registered Office:

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Virtual Conference

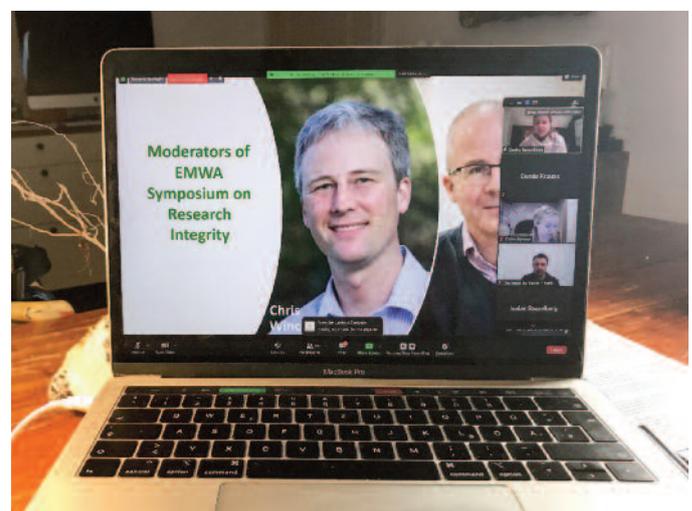


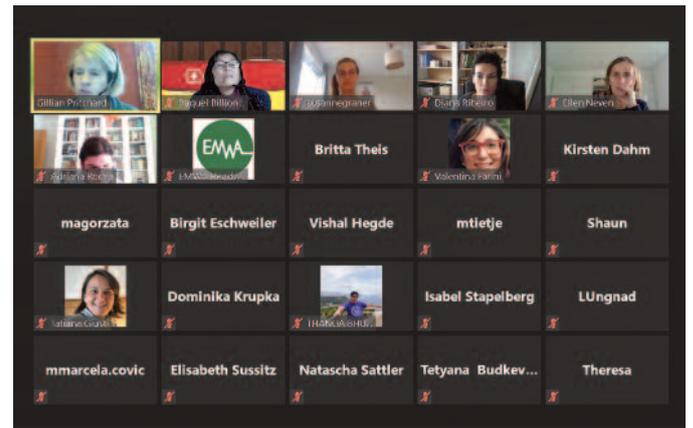
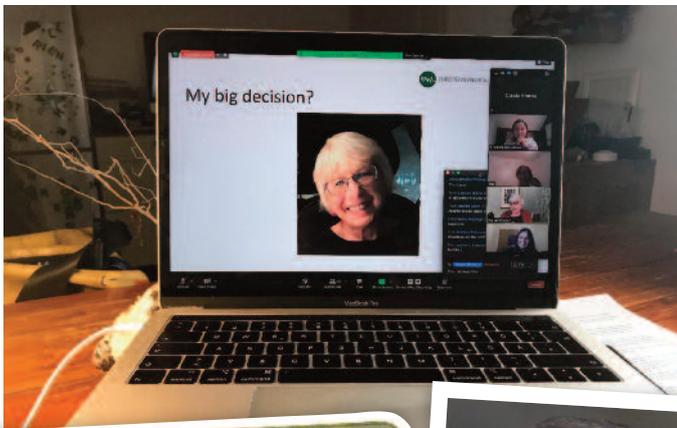
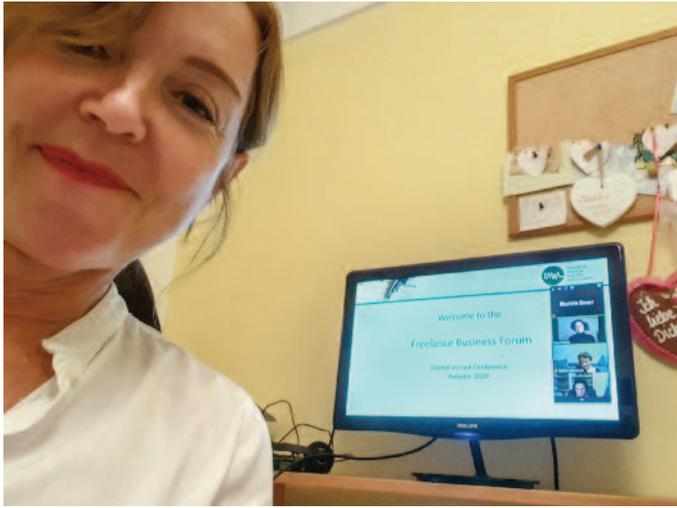
We did it! The first EMWA virtual conference is done and dusted. Symposium, workshops, seminars, yoga class, networking – we did it all – virtually.

If you missed all the educational opportunities and the fun, you might want to check out the summaries of the 8th EMWA Symposium:

- <https://www.emwa.org/news/summary-of-session-1-of-the-8th-emwa-symposium/>
- <https://www.emwa.org/news/summary-of-session-2-of-the-8th-emwa-symposium/>
- <https://www.emwa.org/news/summary-of-session-3-of-the-8th-emwa-symposium-available/>

2021, here we come!





Promoting equity in understanding: A cross-organisational plain language glossary for clinical research

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Abstract

Clear communication with the public and with potential clinical trial participants and their caregivers is foundational to the ethical tenets of respect, justice, and beneficence. However, health literacy, even of highly educated individuals, often declines when presented with complex content in unfamiliar contexts and in times of stress, all of which are characteristic of the types of situations people find themselves in when considering and participating in a research study. Here we describe an initiative to pilot the development of a cross-organisational plain language clinical research glossary to promote clarity, consistency, and transparency. The goal is to develop a common resource that can be used across clinical research stakeholder groups to increase understanding of clinical research and empower sound individual decision making.



Background

Clinical research is essential for the discovery of new treatments and medical interventions that advance public health and medicine. In order to participate in clinical trials, individuals voluntarily provide consent that is concordant with their personal values and intended to demonstrate that they understand and agree to be exposed to the potential risks and benefits of the proposed research. However, general understanding of medical and clinical research information is inadequate which is explained at least in part by the complexity of the information, coupled with low health literacy levels. Achieving adequate levels of health literacy is a global challenge, even in well-resourced communities: the European Health Literacy Survey found that about half (47.6%) of the respondents from eight countries have poor or inadequate health literacy.¹ In England, 42% of adults aged 16 to 65 years are unable to understand or make use of

everyday health information² and in the USA, 36% of the population has a basic or below basic level of literacy.³

When health literacy is discussed and defined, it is typically presented as a problem of the recipient of the information, as opposed to a responsibility of the communicator to make themselves understood. In 2015, the World Health Organization, however, defined health literacy as “the personal characteristics *and social resources* needed for individuals and communities to access, understand, appraise, and use information and services to make decisions about health”.⁴ (emphasis added). This definition acknowledges that external circumstances impact understanding. Beyond an individual's health literacy level, comprehension can be impacted by the complexity of clinical research information, and the often unfamiliar and stressful contexts within which it is presented. Thus, those who are in a position to share information must ensure

they are communicating in ways that empower the recipient to make sound research decisions and take action. One resource that could support clear communication in the life sciences is a common plain language clinical research glossary that promotes clear, consistent communication with the public, potential and enrolled study participants, and their caregivers.

A number of entities, including government agencies, life sciences companies, health systems, academic institutions, non-profit organisations, insurers, and foundations, have developed health-related and disease-specific glossaries. These resources are generally designed for a more technical audience of scientific stakeholders, and even glossaries developed for the general public are focused on medicine and health, not research. While the US FDA has made an effort to use common language in providing regulatory guidance,⁵ there is as yet, no common source of clinical research terminology designed for a non-research, non-scientific audience that can be used by stakeholders across the clinical development spectrum. In its absence, the public – including current and prospective research participants – may grapple with trying to comprehend similar terms that are used differently in different contexts by different research stakeholder groups leading to confusion due to the lack of consistency and clarity. For example, the terms *side effect*, *adverse event*, and *serious adverse event*, all have very specific regulatory definitions and significance; to a research participant, however, these terms all fall under the category of risks or “bad things that could happen to me” when participating in a research study. The clinical research enterprise should strive to decrease or eliminate the need for patients and participants to parse through the nuances of terminology and regulatory guidance in order to determine the personal significance of the presented information.

Health literacy is a broad concept that includes the use of plain language and the clear presentation of numeric information (e.g., probabilities, statistics), design elements (e.g., layout, font, colours),

and the use of audio-visuals (e.g., imagery, figures) to enhance clarity and re-enforce the message. These dimensions are a critical part of putting the Belmont Report’s⁶ ethical tenets of respect, justice, and beneficence into action and should all be considered in the development of clinical research materials for patients and participants.

Having recognised the need for a glossary, we are piloting the generation of a comprehensive, publicly available, plain language clinical research lexicon that is co-developed with patients and representative clinical research stakeholders. Envisaged to include explanations of terms and procedures frequently encountered in research – with accompanying graphical representations and descriptions, when applicable – such a resource would support the general public, including participants, to better understand clinical research.

There are a number of potential benefits of a common glossary for clinical research (See Table 1). First, as previously mentioned, the resource would be valuable to patients and the public because it would support understanding via consistent explanations that can support decision making. Second, it would improve accuracy and precision when generating public-facing research communications within and across organisations. Third, a reference plain-language lexicon would minimise barriers and increase the efficiency of creating understandable research communications that, in turn, would increase the likelihood of these documents fulfilling their intended purpose by reducing the waste associated with such issues as extended recruitment periods and participant attrition. Fourth, having common terms and usage can simplify the translation process and results in more consistent and understandable presentation of complex clinical research information in other languages. Fifth, the use of common terms would render natural

language processing easier and support electronic interoperability. Lastly, demonstrably prioritising

participant comprehension would increase transparency of research and contribute to building the trustworthiness of the entire clinical research enterprise, hopefully leading to increased access and, ultimately, better health outcomes.

We turn now to a summary of the work that preceded the proposal for the creation of a clinical research glossary pilot and a description of the pilot project itself.

The clinical research enterprise should strive to decrease or eliminate the need for patients and participants to parse through the nuances of terminology and regulatory guidance.

The proposed pilot

In 2017, the Multi-Regional Clinical Trials (MRCT) Center, a research and policy centre in Boston, released a guidance and a toolkit on the individual^{7,8} and summary^{9,10} research results. These projects identified the need for understandable communications, especially in the dissemination of study findings. Further, patient and participant feedback on prototype plain language summary examples demonstrated that written materials – even those created by individuals attentive to health literacy principles – required specific skills and experience. Subsequently, in 2018, a multi-stakeholder workgroup developed a comprehensive web-based resource on the integration of health literacy principles into the clinical development process that expanded clear communication best practices, beyond results communications, to include participant-facing materials used throughout the continuum of the clinical research life cycle. The resulting website, Health Literacy in Clinical Research,¹¹ was launched in the autumn of 2019. This work highlighted the need to create a common clinical research glossary of terms, described in plain language, that could be adopted by stakeholders across the research spectrum. While the website included a sample translation of several terms used in clinical research, the table was acknowledged to be incomplete. In the process of further developing a more robust set of terms, explanations, examples, and images, we learned of other groups within the life sciences industry, non-profit organisations, and data standards organisations that were either initiating, or interested in leading the creation of a comprehensive lexicon.

Those who are in a position to share information must ensure they are communicating in ways that empower the recipient to make sound research decisions and take action. One resource that could support clear communication in the life sciences is a common plain language clinical research glossary.

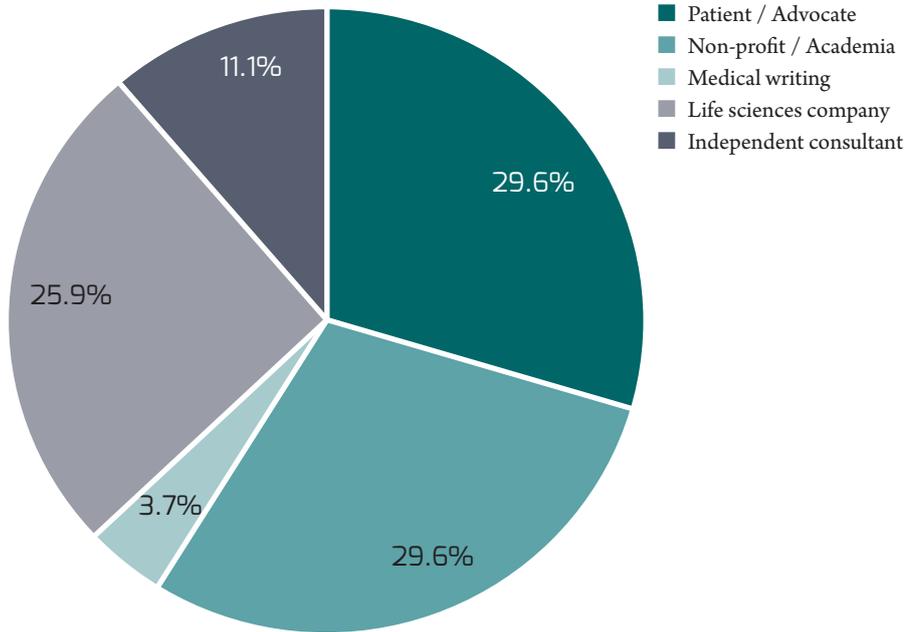


Figure 1. Distribution of clinical research representation (N=27)

Collectively, we realised the value of collaboration and that a common resource used within and across organisations would be most beneficial for the public.

With a team of committed cross-organisational stakeholders, the MRCT Center volunteered to lead a pilot initiative to determine the feasibility of co-creating a common, plain language clinical research glossary and research procedure resource. The pilot was thought to be a necessary first step to determine the feasibility of establishing a replicable process for the development of definitions and contextual explanations as a proof-of-concept before dedicating effort to a larger initiative. Further, a pilot would allow the team to determine the effort required, and assess the resulting resource’s potential utility, before expanding the scope of the project.

To date, the preliminary work has consisted of an early landscape analysis of existing initiatives and glossary resources, refinement of the pilot scope, estimation of the necessary

resources to accomplish the pilot, and, importantly, creation of partnerships with other individuals and organisations committed to the vision. The current pilot team includes representatives of the broader clinical research community, including patients and advocates, non-profit and academic organisations, life sciences companies, medical writers, and independent consultants (See Figure 1). Certain members of the group plan to develop the model terms while others will then serve as critical reviewers. The plan is to engage in iterative, rapid-cycle development until consensus is reached. The following stages are planned (see Figure 2):

Demonstrably prioritising participant comprehension would increase transparency of research and contribute to building the trustworthiness of the entire clinical research enterprise, hopefully leading to increased access and, ultimately, better health outcomes.

1. Build consensus

The pilot team will determine the feasibility of developing a process for defining terms (e.g., randomisation, blinding, placebo) and drafting research procedure descriptions (e.g., magnetic resonance imaging; pharmacokinetic study), considering that stakeholders may use different

terms and explanations, and often have their own reasons for doing so.

This stage will include determining a process for reaching consensus and finalising the choice of terms and their definitions. The analysis will include an assessment of the challenges (including when consensus cannot be achieved) and methods that will contribute to successful completion of the pilot phase. In addition, the pilot team will determine how best to consolidate and harmonise terms that may have unique and/or technical regulatory definitions, but not necessarily a practical difference to study participants. The group will also discuss whether certain technical differences are important for or irrelevant to the participant (e.g., are there important, salient differences between an “event” and a “reaction”?). In addition, technical aspects, such as the format of the glossary, nomenclature, a research procedures guide, style of definitions, as well as inclusion of icons, imagery, and audio-video content (as applicable) will be discussed.

2. Establish governance processes

The pilot team will develop an initial draft of governance principles and a model for the glossary and research procedure resource, with respect to distribution, comment, approval, updates, and use of terms and explanations. Such a governance document will consider:

- Project management resources needed;
- Review of terms and existing definitions, descriptions, and graphics, if available;
- Allowance for adaptations or modifications of existing terms and their associated definitions and media;
- Creation and evaluation of plain language definitions;
- Timely curatorial oversight to coordinate and control future changes, including ongoing maintenance and updates;
- Attribution for use, if any;
- Copyright and other legal/licensing issues (e.g., how access will be provided, links to other websites, independent website, Creative Commons <https://creativecommons.org/licenses/by-sa/4.0/>).

The governance draft will then be reviewed and finalised by additional external stakeholders who will convene to oversee transition from and possible expansion of the project to a larger initiative.

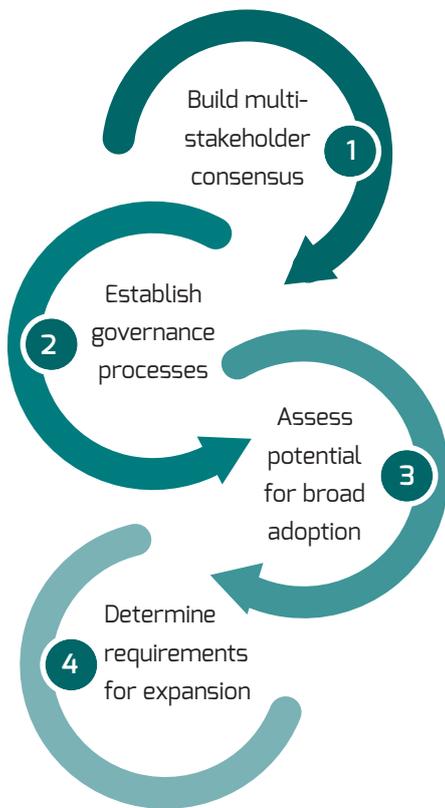


Figure 2. The four planned stages of the clinical research glossary pilot

3. Investigate the potential for broad adoption

The pilot team will explore receptivity for adoption of the proposed clinical research glossary within their organisations, as well as develop use cases for its integration into existing and newly-created policies and procedures. They will prepare recommendations for the need for, or benefit of, endorsement from advocacy organisations, foundations, regulatory, and professional groups in order to increase the likelihood of cross-organisation uptake of the glossary and research procedure guide. A plan for outreach will be developed if indicated. In addition, the pilot team will determine the anticipated format(s) and method(s) for communication and dissemination.

4. Determine the possibility for expansion

Finally, taking into account the lessons and conclusions from the preceding steps, the pilot

Table 1. Benefits realised through the availability of a harmonised plain language clinical research glossary

Benefit	Rationale
Consistency	A common lexicon will improve intra- and extra-organisational consistency throughout the communication process. It will also increase understanding/comprehension for patients and study participants who are comparing multiple trials from different sponsors.
Accuracy	Identical words are used in different ways at different times, and the explanations are not always correct, succinct, or understandable, leading to confusion or misconception. Information being presented to potential research participants and their families must be accurate and precise. This is best achieved through the adoption of definitions that have been co-created, reviewed, and user-tested by multiple different stakeholder groups including patients, resulting in a common understanding of the information presented.
Efficiency	Stakeholders currently define terms independently and differently, leading to inefficiencies and confusion. A common resource will improve efficiency in developing health-literate communications. These range from pre-study communications and those received at consent and enrolment, to those received at the end of a study and after commercialisation.
Ease of Translation	Having multiple terms for the same concept can negatively impact how well a term or concept can be translated into another language, and limit the development of accurate translation via artificial intelligence (e.g., Google Translate, Microsoft Translator) that must account for context. This is relevant not only to global clinical research studies, but also to diverse populations within countries, and to individuals for whom English is not their primary language.
Electronic Interoperability	A curated and coded glossary allows retention of the technical aspects and context of the explanation, will promote machine readable technologies, and expands the utility and interoperability of data.
Transparency	A common clinical research glossary supports clear communications, allowing potential and enrolled study participants to access information and to trust that information is complete and truthful.
Trustworthiness	Clear communications and working towards understanding and comprehension by the public, patients, and participants help support the trustworthiness of the research enterprise. Co-creation of a lexicon with patients and participants will assist in that regard.



team will determine the feasibility and resource needs of expanding the pilot to a comprehensive glossary that would include additional terms, research procedures, related images, and audio-visual formats. Again additional external stakeholders will review the summary recommendations and suggestions for refining the process and deliverables, and advise on scaling the project, including any necessary adaptations, and eventual dissemination.

Conclusion

Clear communication and understanding can potentially improve health outcomes. The development of a clinical research glossary and procedure guide using health literacy principles is needed to optimise public and participant understanding of complex terms in the context of low health literacy. We describe the planned pilot effort to test the development of such a resource. Collaborating as a clinical research community, we can communicate more

effectively with patients and participants using shared terminology and visuals to describe common research concepts and procedures. Cross-organisational cooperation can promote transparency and, thus, increase the perceived trustworthiness of the clinical research enterprise. The results of the pilot will inform whether and how to expand the work beyond the initial scope of the pilot project to a larger, more comprehensive set of terms and procedures. The clinical research community must champion the creation of resources that provide the public – and research participants – with the opportunity to better understand the information they need to support values-concordant decision making.

Conflicts of interest

The authors declare no conflicts of interest relevant to this publication.

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Medical abbreviations with multiple meanings: A prescription for disaster

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Abstract

A partial list of medical abbreviations that have dangerous contradictory or ambiguous meanings is presented. The purpose of presenting this list is to sensitise health-related practitioners and medical editors to this problem. Suggestions are made on how to prevent the introduction of dangerous contradictory or ambiguous meanings for abbreviations.

Background

My first published book in 1983 contained the meanings of 1700 abbreviations. To expand this book, I contacted US hospitals and requested lists of abbreviations that were used at their facility, searched the medical literature, and asked readers to send me abbreviations that I had not listed. I now have published 16 editions of the book, the latest one being *Medical Abbreviations: 55,000 Conveniences at the Expense of Communication and Safety* (ISBN 978-0-931431-00-5), 2020.¹ A web-version of this book (medabbrev.com) is updated each week with over 50 new entries.

Contradictory or ambiguous meanings

Over the years, I noticed how one abbreviation could have two or more contradictory or ambiguous meanings, which can create dangerous miscommunications. I collected these meanings and they represent a growing list on the website, medabbrev.com.¹ Examples from the most recent list are shown in these pages. It is obvious from

an examination of this list that the use of these abbreviations does not communicate with any certainty and presents possible dangers to the health of patients.

The US Joint Commission has required accredited health care organisations in the US to develop a *Do Not Use List* identifying dangerous abbreviations to avoid. That is a step in the right direction, but it does not completely solve the systemic problem of the numerous abbreviations with dangerous contradictory or ambiguous meanings.

Possible solutions to solving the problem

Create an International Recognised Approved (Standardised) List of Abbreviations

A simplistic approach is to create an internationally recognised list of approved abbreviations with each abbreviation having only one meaning. The problem with this approach is to get all of the medical specialties, allied health professionals, health-related organisations, and government agencies to agree on one meaning for each abbreviation.

An internationally recognised health-related organisation would have to take responsibility for creating and maintaining such a list. They would have to reach out to all of the health-related organisations to suggest abbreviations that should be on this list. There would have to be arbitration between organisations when there is conflict if a suggested abbreviation has more than one submitted meaning, such as PT for physical therapy, prothrombin time, preterm, parathyroid, patellar tendon, patient, phototoxicity, etc. It would be unrealistic to believe that health professionals would honour the distinction between the meanings of PT, pt., and Pt. Such an endeavour will take hundreds of thousands of hours. When and if such an approved list is created it will have to be maintained, as new abbreviations will be presented to be added; this would involve review and approval by all of the interested parties.

If such an endeavour were extended to be used worldwide, it would encounter the difference in how the Romance languages are structured. As an example, HIV (human

immunodeficiency virus) is expressed as VIH (*virus de la inmunodeficiencia humana*).

A European edition may have to be published showing differences such as are found in spelling.

Disallow the use of abbreviations

Not allowing the use of abbreviations would be very difficult to introduce and enforce because:

- Health-related personnel have used abbreviations as part of their daily routine throughout their entire career and it would be very difficult to break this habit.
- Some abbreviations are in such common usage that they have become word-like, such as: rehab, exam, info, demo, pro, DNA, AIDS, MRI, CAT, DNR, ASAP, ICU, WBC, RBC, CPAP, EU, US, EMA, FDA, days of the week, months of the year, AM, PM, mL, kg, lb, Na, K, MD, RN, °C, °F, H₂O, and hundreds more.
- The use of abbreviations saves time for the writer and reader, saves space, decreases the possibility of misspellings, and makes it easier to fit information into a restricted space provided on a form or table.

Practitioners and agencies, authors, and editors can attack the problem

Before a new abbreviation is invented by researchers and authors, they must question whether it is necessary to do so. Do not create an abbreviation that is already in common use or has a contradictory or ambiguous meaning. To accomplish this, use common sense or consult comprehensive and up-to-date resources such as the US National Library of Medicine's PubMed, medical abbreviation books, and websites.

As you may see in the examples included with this article, there are certain circumstances in which a proposed abbreviation may be dangerous because it can easily be misinterpreted. These similarities should lead one to consider the following:

1. Where possible, avoid abbreviating drug names.
2. Abbreviate syndromes with great care.
3. Be sensitive to the problems caused by:
 - the abbreviation B for breast, brain, blood, or bladder
 - the abbreviation L for liver or lung

- the abbreviation P for pancreas or prostate
- the abbreviation H for hand or hip
- the abbreviation R for renal or respiratory
- the abbreviation C for cerebral, coronary, or carotid
- the abbreviation N for no or normal
- the abbreviation S for special or standard
- the abbreviation O for open or obstructed

Medical editors must be diligent in following these principles when reviewing and editing proposed manuscripts to make sure they do not introduce contradictory, ambiguous, and dangerous abbreviations into the health-related vocabulary. Those abbreviations that are used must be defined. No abbreviation should be used in titles and abstracts unless it is defined, as the body of the text will not appear in an abstracting service.

There is hope that artificial intelligence, voice recognition, and future products can be used to devise additional workable solutions to the stated problems.

Conflicts of interest

The author receives proceeds from the *Medical Abbreviations* book and website.

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Anatomy-Related

APC

- advanced pancreatic cancer
- advanced prostate cancer

BCa

- bladder cancer
- breast cancer

BO

- bowel obstruction
- bowel open

CAS

- carotid artery stenosis
- cerebral arteriosclerosis
- coronary artery stenosis

CLD

- chronic liver disease
- chronic lung disease

ESLD

- end-stage liver disease
- end-stage lung disease

HAO

- hand osteoarthritis
- hip osteoarthritis

HO

- hand orthosis
- hip orthosis

IAI

- Intra-abdominal infection
- Intra-abdominal injury

IBC

- invasive bladder cancer
- invasive breast cancer

ICA

- internal carotid artery
- intracranial abscess
- intracranial aneurysm

LAPC

- locally-advanced pancreatic cancer
- locally-advanced prostatic cancer

LF

- left foot
- little finger
- long finger

LKT

- laparoscopic kidney transplantation
- liver-kidney transplantation

LL

- left leg
- left lung
- lower lid
- lower limb
- lower lip

LNE

- lymph node enlargement
- lymph node excision

LT

- liver transplantation
- lung transplantation

Ltx

- liver transplant
- lung transplant

LVO

- left ventricular opacification
- left ventricular output
- left ventricular over activity

MBC

- male breast cancer
- metastatic breast cancer

MPM

- malignant peritoneal mesothelioma
- malignant pleural mesothelioma

NBM

- no bowel movement
- normal bowel movement
- nothing by mouth

OLB

- open-liver biopsy
- open-lung biopsy

OPC

- operable pancreatic carcinoma
- oropharyngeal cancer
- oropharyngeal candidiasis

PAA

- popliteal artery aneurysm
- pulmonary artery aneurysm

PBL

- primary brain lymphoma
- primary breast lymphoma

SCCP

- small cell carcinoma of the prostate
- squamous cell carcinoma of the penis

TSCC

- thymic squamous cell carcinoma
- tongue squamous cell carcinoma
- tonsillar squamous cell carcinoma

WBRT

- whole-brain radiotherapy
- whole-breast radiotherapy



Drug names

<p>AMI</p> <ul style="list-style-type: none"> ● amifostine ● amitriptyline <p>ATR</p> <ul style="list-style-type: none"> ● Atracurium ● atropine <p>AZT</p> <ul style="list-style-type: none"> ● azathioprine ● azidothymidine (zidovudine) <p>CLOF</p> <ul style="list-style-type: none"> ● clofarabine ● clofazimine <p>CPM</p> <ul style="list-style-type: none"> ● chlorpheniramine maleate ● cyclophosphamide <p>CPZ</p> <ul style="list-style-type: none"> ● chlorpromazine ● Compazine 	<p>DNR</p> <ul style="list-style-type: none"> ● daunorubicin ● did not respond ● do not report ● do not resuscitate <p>DW</p> <ul style="list-style-type: none"> ● deionised water ● dextrose in water ● distilled water <p>DX</p> <ul style="list-style-type: none"> ● dexamethasone ● dexmedetomidine ● dextromethorphan <p>FEC</p> <ul style="list-style-type: none"> ● fluorouracil, epirubicin, and cyclophosphamide ● fluorouracil, etoposide, and cisplatin 	<p>GEM</p> <ul style="list-style-type: none"> ● gemcitabine ● gemfibrozil <p>KET</p> <ul style="list-style-type: none"> ● ketamine ● ketoconazole <p>MP</p> <ul style="list-style-type: none"> ● melphalan ● prednisone ● mitoxantrone ● prednisone <p>MTZ</p> <ul style="list-style-type: none"> ● mirtazapine ● mitoxantrone <p>NITRO</p> <ul style="list-style-type: none"> ● nitroglycerin ● sodium nitroprusside 	<p>PBZ</p> <ul style="list-style-type: none"> ● phenoxybenzamine ● phenylbutazone ● pyribenzamine <p>Pit</p> <ul style="list-style-type: none"> ● Pitocin ● Pitressin <p>TAC</p> <ul style="list-style-type: none"> ● tetracaine, adrenaline, and cocaine solution ● triamcinolone cream 	<p>TMZ</p> <ul style="list-style-type: none"> ● temazepam ● temozolomide <p>VAC</p> <ul style="list-style-type: none"> ● etoposide (VePesid), cytarabine (ara-C), and carboplatin ● vincristine, dactinomycin (actinomycin D), cyclophosphamide ● vincristine, doxorubicin (Adriamycin) and cyclophosphamide 	<p>VAD</p> <ul style="list-style-type: none"> ● vincristine, doxorubicin (Adriamycin) and dactinomycin ● vincristine, doxorubicin, (Adriamycin) and dexamethasone <p>VAP</p> <ul style="list-style-type: none"> ● vincristine, actinomycin D, and Platinol AQ ● vincristine, Adriamycin, and prednisone ● vincristine, Adriamycin, and procarbazine ● vincristine, asparaginase, and prednisone
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Diseases, symptoms, and conditions

<p>ADVT</p> <ul style="list-style-type: none"> ● acute deep venous thrombosis ● asymptomatic deep venous thrombosis <p>ED</p> <ul style="list-style-type: none"> ● eating disorder ● elbow disarticulation ● emotional disorder ● erectile dysfunction <p>EIH</p> <ul style="list-style-type: none"> ● environmentally induced hyperthermia ● exercise-induced hypertension ● exercise-induced hyperthermia ● exercise-induced hypoxaemia 	<p>EOP</p> <ul style="list-style-type: none"> ● early-onset Parkinsonism ● early-onset pneumonia ● early-onset preeclampsia ● early-onset psychosis <p>GD</p> <ul style="list-style-type: none"> ● Gaucher disease ● Graves' disease <p>HCC</p> <ul style="list-style-type: none"> ● hepatocellular carcinoma ● Hurthle cell carcinoma <p>HD</p> <ul style="list-style-type: none"> ● Hansen disease ● Hodgkin disease ● Huntington disease <p>IAD</p> <ul style="list-style-type: none"> ● incontinent associated dermatitis ● intractable atopic dermatitis 	<p>IRDM</p> <ul style="list-style-type: none"> ● insulin-required diabetes mellitus ● Insulin-resistant diabetes mellitus <p>IRF</p> <ul style="list-style-type: none"> ● impaired renal function ● improvement in renal function <p>MS</p> <ul style="list-style-type: none"> ● mitral stenosis ● multiple sclerosis <p>PD</p> <ul style="list-style-type: none"> ● Paget disease ● panic disorder ● Parkinson disease ● personality disorder ● Peyronie disease 	<p>PHTN</p> <ul style="list-style-type: none"> ● portal hypertension ● prehypertension ● pulmonary hypertension <p>PVO</p> <ul style="list-style-type: none"> ● peripheral vascular occlusion ● portal vein occlusion ● pulmonary venous occlusion 	<p>RM</p> <ul style="list-style-type: none"> ● radical mastectomy ● reduction mammoplasty <p>RTI</p> <ul style="list-style-type: none"> ● reproductive tract infection ● respiratory tract infection <p>SAD</p> <ul style="list-style-type: none"> ● seasonal affective disorder ● social anxiety disorder
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Miscellaneous

ABP

- ambulatory blood pressure
- arterial blood pressure

AQoL

- Acne Quality of Life
- Assessment of Quality of Life
- Asthma-related Quality of Life
- Australian Quality of Life

BR

- bright red
- brown

ERT

- enzyme replacement therapy
- estrogen replacement therapy

FSW

- female sex worker
- field service worker

I & D

- incision and drainage
- irrigation and debridement

IT

- intrathecal
- intratracheal
- intratumoural
- intratympanic

LAM

- laminectomy
- laparoscopic-assisted myomectomy
- laser-assisted myringotomy

LFD

- lactose-free diet
- low fat diet
- low fibre diet

LHSH

- long-handled shoehorn
- long-handled shower head

Mon

- Monday
- month

MV

- manual ventilation
- mechanical ventilation



NABS

- no active bowel sounds
- normoactive bowel sounds

NE

- no effect
- no enlargement
- not evaluated

PORT

- postoperative radiotherapy
- postoperative respiratory therapy
- prostate-only radiotherapy

S & S

- swish and spit
- swish and swallow

SA

- suicide alert
- suicide attempt

SDBP

- seated diastolic blood pressure
- standing diastolic blood pressure
- supine diastolic blood pressure

SGAs

- second-generation antihistamines
- second-generation antipsychotics

SSE

- saline solution enema
- soapsuds enema

STF

- special tube feeding
- standard tube feeding

TBA

- to be absorbed
- to be added
- to be administered
- to be admitted
- to be announced
- to be arranged
- to be assessed

T/E

- testosterone to epitestosterone (ratio)
- testosterone to estrogen (ratio)
- trunk-to-extremity skinfold thickness (index)

Tx

- therapist
- therapy
- traction
- transcription
- transfer
- transfuse
- transplant
- transplantation
- treatment

Patient care units

ACU

- acute receiving unit
- ambulatory care unit

IPCU

- inpatient palliative care unit
- intensive paediatric care unit
- intensive psychiatric care unit

PCU

- palliative care unit
- primary care unit
- progressive care unit
- protective care unit

TICU

- thoracic intensive care unit
- transplant intensive care unit
- trauma intensive care unit

Syndromes

RS

- Raynaud syndrome
- Reiter syndrome
- Rett syndrome
- Reye syndrome
- Richter syndrome

SJS

- Schwartz-Jampel syndrome
- Stevens-Johnson syndrome
- Swyer-James syndrome



TS

- Tay-Sachs (disease)
- Tourette syndrome
- Turner syndrome

WS

- Waardenburg Syndrome
- Warner Syndrome
- West Syndrome
- Williams Syndrome

Writing for patients: When and how?

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Abstract

The move towards patient engagement and patient involvement in healthcare decisions (“shared care”) has triggered a raft of new guidances from regulatory authorities, accompanied by new regulations mandating that pharmaceutical companies engage with patients and the general public in a way that has been improbable up to now. While this has generally been supported and welcomed by both industry and patients, the initiative has brought with it considerable challenges. Producing complex scientific and medical information in health-literate language that is appropriate and helpful for the general public (“plain language”) requires skills beyond those usually required for communicating with healthcare professionals and regulatory authorities. Medical writers are highly trained in a specific technical writing style and tone that is aimed at readers with a very high level of literacy, and often considerable scientific and medical knowledge. Translating this information into plain language for readers who may have low health literacy, and perhaps little or no scientific or medical knowledge, is a significant challenge – as reflected in the level of information currently available.

What do patients want and what are they getting?

The clamour for more and better information for patients has been growing over the last 5 years. In a survey of adult internet users, 83% looked online for health information and 60% admitted that it affected their actions.¹ This indicates that the quality of information for patients and the general public is of vital importance. This is echoed in the latest survey from the Patient Information Forum, which showed that two-thirds of those working within the UK National Health Service believe that patient information is rising in importance. Access to patient information is now firmly embedded in health policy across the UK, including in the National Health Service Constitution and England’s Health and Social Care Act 2012, the Patient Rights (Scotland) Act 2011, Together for Health (Wales), and Quality 2020 (Northern Ireland), as well as in professional codes of conduct, and it is at the forefront of consideration in the EU.² In this way, the EU leads the US, which operates with a more diffused regulatory framework. Global interests are following suit, making it imperative for all drug and device sponsors to develop understandable and usable information for patients.

However, the quality and amount of appropriate information available to patients is far from ideal. Twenty percent of patients say they were not given enough information about their condition or treatment while in hospital, and while doctors are the preferred source of health information for most people, 17% do not feel that their general practitioner is good at explaining tests and treatments.² Even when recommended by regulatory guidelines, information for patients is often lacking. The latest regulation involving plain-language information (EU Clinical Trial Results Regulation EU CTR 536/2014) mandates that a plain language summary of the clinical trial results should be made available to all trial participants no more than 1 year after the last patient’s, last visit. Although the portal for uploading these summaries is not yet open, companies are expected to prepare this information and make it available, following a list of 10 required items. However, less than 2% of all clinical trials completed or terminated within the past 3 years have returned results to study

volunteers in plain language.³ More worryingly, the information that is available to patients is of variable quality and is often not fit for purpose.⁴

Why is good quality information important to patients?

When people are diagnosed with a medical condition, disease, or life-threatening illness, they often feel that they have been thrown onto a foreign planet without a roadmap or dictionary, and without any type of survival training. Useful information is critical to help make some of the most important decisions in their lives, yet most current medical information is designed to “talk down to”, rather than assist, patients.

The medical system typically focuses on the medical treatment a patient may take. A person who has just become a patient, however, has a much broader spectrum to consider and has to figure out how each medical option may impact all of the facets of their life. Context is most often missing for patients. If the pharma industry can help healthcare providers accurately show how a treatment option fits into a bigger plan, patients can understand what to expect and choose those that fit their lifestyles, personal needs, and beliefs. It is important to communicate these effectively to patients, yet this is often not included in medical training or is only considered within the realm of advertising in life sciences. Companies that learn how to produce accurate, objective information for patients without it being promotional (deliberate or otherwise) will find receptive audiences with patients, those who support them, and with health authorities.

What should be available for patients and when?

In response to the previously mentioned EU regulations, much of the focus on health materials for patients is currently on clinical trials, specifically, the return of clinical trial results in plain language to patients were enrolled in a specific trial. Providing clinical trial results to those who were enrolled is certainly an important ethical, and now regulatory, obligation. However, it is only a small step toward fully meeting patients’ needs.

To more fully meet patients’ needs in clinical

Plain language is not just a translation of difficult or long scientific words – it should include sufficient explanation of the context and concepts to allow the reader to understand the importance of the information.



trials, materials understandable to all patients must be made available throughout the process, from the early stages of drug development, through recruitment and the informed consent process, to participation, maintenance, and completion of clinical trials. The same holds true in clinical care. Patients and caregivers require clear and understandable information through every step of the process, from diagnosis to selecting appropriate treatments and adopting those treatments into a workable, practical plan that works for their lives. Transitions in care settings, specifically, are particularly problematic as the risk of complications to patients is increased due to the shifting of responsibility between professionals or caregivers and the resulting potential for miscommunication.⁵

In all contexts, health materials must be understandable, contextual, and accessible. Accessibility considerations must focus on all aspects of health information, including the text, audio, images, video, and delivery formats.⁶ While there are active conversations about the use of alternate, supporting formats, such as video and illustrated versions of summary reports, particularly for paediatric trials, the

templates most commonly used for plain language clinical trial summaries are text-based with charts and figures to support the quantitative information. Delivery of plain language, accessible materials to clinical trial populations diverse in age, literacy, language access, and vision requires materials in formats other than text alone.

The challenges in writing for patients

If patient information is to be fit for purpose, it should be understandable and relevant for the patients it is aimed at. It should explain not only the scientific or medical details, but also make clear what all of this means for the patient. Plain language is not just a translation of difficult or long scientific words – it should include sufficient explanation of the context and concepts to allow the reader to understand the importance of the information.

To write appropriately and for the right audience means understanding what the reader (either patients or the general public) wants to know, what they need to know, and what they might know already. Patients prioritise four key

points of information when they read about medicines: what the medicine does, what to do and what not to do when taking the medicine, the side effects they might experience, and what the medicine means for them in their day-to-day lives.

The medical writer's job is to provide this information in a format the patient can understand as easily as possible. This is often far from simple, particularly considering that the reader's first language might not be English, they might be affected by cognitive or visual impairment, or they might not be able to read at all (necessitating the careful use of visuals). It takes experience and skill to identify potential hurdles to understanding, let alone to overcome them. Different types of context (scientific, medical, and social) may be needed to allow the reader to fully understand the messages being given.

Tips to create health-literate information

To be effective, information should be given with short words and short sentences in the active voice, and only essential information should be included. Long or unfamiliar words are often



difficult to understand, and they slow down reading speed. Content should be limited to one or two key objectives and should be appropriate for the age and culture of the target audience. If medical terms will be used with the patients on a regular basis, they should be clearly defined so that patients can comprehend their meaning and context.

Humans have a cognitive preference for picture-based information, and research has shown that using pictures, including appropriate infographics or pictographs with verbal explanations and use of models, can greatly increase patient understanding and retention of information. In one study, mean correct recall of information was 85% with pictographs and 14% without.⁷ Another study found that patients receiving wound care instructions with pictures were able to answer questions correctly 46% of the time 3 days later, compared to only 6% of patients who received only written instructions.⁸ However, graphics should be used carefully, and all images should be age- and culture-appropriate.

Using graphical information can lead to more effective communication with patients and thus higher rates of recruitment and retention in clinical trials, as well as more effective use of medicines. Producing effective material requires

additional knowledge, skills, and expertise in health literacy to refine the document for its intended audience.

Medical writers mindful of best evidence practices will often check their work for “readability”. Although automated readability scores are available, they have their drawbacks. The score is based primarily on word and sentence length without considering content or vocabulary. Therefore, it is useful to take an additional step and have patient materials reviewed by people as close to the target audience as possible to ensure that the materials can be understood and interpreted correctly. Several approaches ensure that medical information serves its purpose. One method of testing patient-facing materials is engaging with patient advocacy groups or individuals who represent the intended audience to determine whether they can find and understand key pieces of information.⁹ Individual interviews can be especially appropriate when materials are focused on sensitive health topics or involve patients who may have challenges participating in a group as a result of their health condition, geographic location, or other personal factors. There are obvious ethical, logistical, and budget implications that must be factored in to developing an audience testing plan and process

that is feasible and appropriate for a particular material or therapeutic area.

What is the future?

Plain language materials are finally being recognised and understood as essential tools to provide patients with effective treatment options. How to produce them so that they are fit for purpose and not part of a regulatory “box ticking” exercise is both an opportunity and a challenge faced by the whole pharma industry. Initiatives to discuss and standardise the content will undoubtedly help improve the quality of the information and will also help address some of the challenges, but given the variety of studies undertaken in clinical development, this is more of a mountain than a molehill.

Once the materials are produced, they must also be easily accessible to their target audience – an audience that the pharma industry has not previously been able to engage with in this way. Partnering with patients and patient advocacy groups can certainly help industry address some of the current and future challenges. As always, it will also be crucial to provide tips and tools for healthcare providers to ensure smooth communication directly with patients and their caregivers, so that they receive clear information that they can use to improve their health.

The demand for better information for patients and the general public is increasing, and this is being reflected and responded to by regulatory authorities. The expected tightening of the clinical trial results regulation and its enforcement in the EU and North America could result in global adoption, which has the potential to increase patient engagement and trust in clinical development.³ Despite the challenges this brings, it will be a positive move for everyone involved. The pharma industry now has the opportunity to engage directly with the general public in a way forbidden up to now; and if used correctly, patients and the general public will have access to unbiased, trustworthy information that is evidence-based and easily digestible. To do this well, we must listen to and understand patients, either through user testing or engagement with patient advocacy groups.

Medical writers are uniquely placed to carry these initiatives through and to make sure that the information produced is really what patients want and need.

Conflicts of interest

The authors declare no conflicts of interest.

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Deborah Collyar has been a leader in patient engagement and advocacy since her first cancer diagnosis. She founded the Patient Advocates in Research (PAIR) international network in 1996, has infused hundreds of patient advocates into research programmes while creating many trainings and her work encompasses many

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Allen Todd is the Director of Partnership and Initiatives for Health Literacy Media. He has nearly two decades of experience in relationship development and clear communication through his work at various non-profit, governmental, and political organisations. His policy career is diverse and includes work on issues such as healthcare, education, poverty, homeland security, and national defence. Allen holds a bachelor's degree in communication from University of Missouri-Columbia. He is a member of numerous boards and committees, including serving on the Webster Groves School District Board of Education, where his children attend school. Allen is also the Secretary /

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As President and CEO, **Catina O'Leary**, PhD, LMSW oversees Health Literacy Media's core activities and the strategic vision for the organisation. Catina has steered HLM onto becoming a true partner to a broad spectrum of health care organisations globally. A primary goal is to empower people with health information they can use. Catina believes in changing health behaviours to improve quality of life. For more than a decade, she led research at Washington University School of Medicine on connecting people at-risk for health conditions with medical and social resources aimed at improving health behaviours, preventing illness, and improving health and well-being. Catina is an active member of many boards and committees, including the International Health Literacy Association's Standing Committee on Strategic Planning and Implementation and the National Academies of Sciences, Engineering, and Medicine's Roundtable on Health Literacy.

Lay summaries for Phase I trials in healthy volunteers

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Abstract

Lay summaries of Phase I trials in healthy volunteers pose a challenge because their endpoints are complex, the targeted indication may not be known when they are conducted, their results are often reported years after the trial ended, and the majority of substances tested in Phase I never reach the market. Nevertheless, the European Union Clinical Trials Regulation (EU CTR) mandates that lay summaries are to be provided for all clinical trials regardless of clinical phase. As lay summaries are intended to inform the public about the results of clinical studies, they need to be understandable to people without specific knowledge of the disease or the clinical research process. It is challenging to write lay summaries for Phase I trials that are both meaningful for the public and in line with the requirements of the EU CTR. We have developed a template to facilitate writing of lay summaries of Phase I trials in healthy volunteers. Using a template ensures that study designs and endpoints are described in a consistent lay-friendly manner across different types of Phase I trials.

Introduction

A lay summary is a short document that provides important information about a clinical trial in language that the public can easily understand. Providing lay summaries enables transparency and ensures that the clinical trial results are accessible to participants and the public. The European Union Clinical Trials Regulation 536/2014 (EU CTR) mandates that lay summaries are to be provided for all clinical trials regardless of clinical phase, therapeutic area, and trial outcome. Thus, the provision includes Phase I trials in healthy volunteers (in the text we will use “Phase I trials” as a shorthand for Phase I trials in healthy volunteers; this article does not address lay summaries for Phase I trials in patients such as those in oncology). The content of lay summaries is specified by Annex V of the EU CTR in the form of a list comprising 10 items.¹ Lay summaries are to be posted on a web-portal that will serve as a database for information on clinical trials, together with other trial documents such as the scientific summary, the protocol, and the clinical study report (§67 of the EU CTR).

Following the publication of the EU CTR in 2014, an expert group of stakeholders developed guidance on the structure and content of lay summaries (referred to as “expert recommendations” in the text).² The expert recommendations state that the primary audience for lay summaries is the general public, who should not be assumed to have any prior knowledge of medical terminology, clinical research, or the specific context of the study. Lay summaries need to be written in a way that they are understandable to people with low literacy skills. Literacy levels within the general population are typically at level 2 to 3 on the International Adult Literacy Survey (a scale from 1 to 5), with level 3 roughly corresponding to a level attained after completing secondary school.^{3–5}

It is a considerable challenge to transfer complex information about a clinical trial into a short summary that is both accessible and relevant to a lay audience. Lay summaries of later phase trials (Phase II and above) may provide results that are relevant to patients because they include data on a new therapeutic

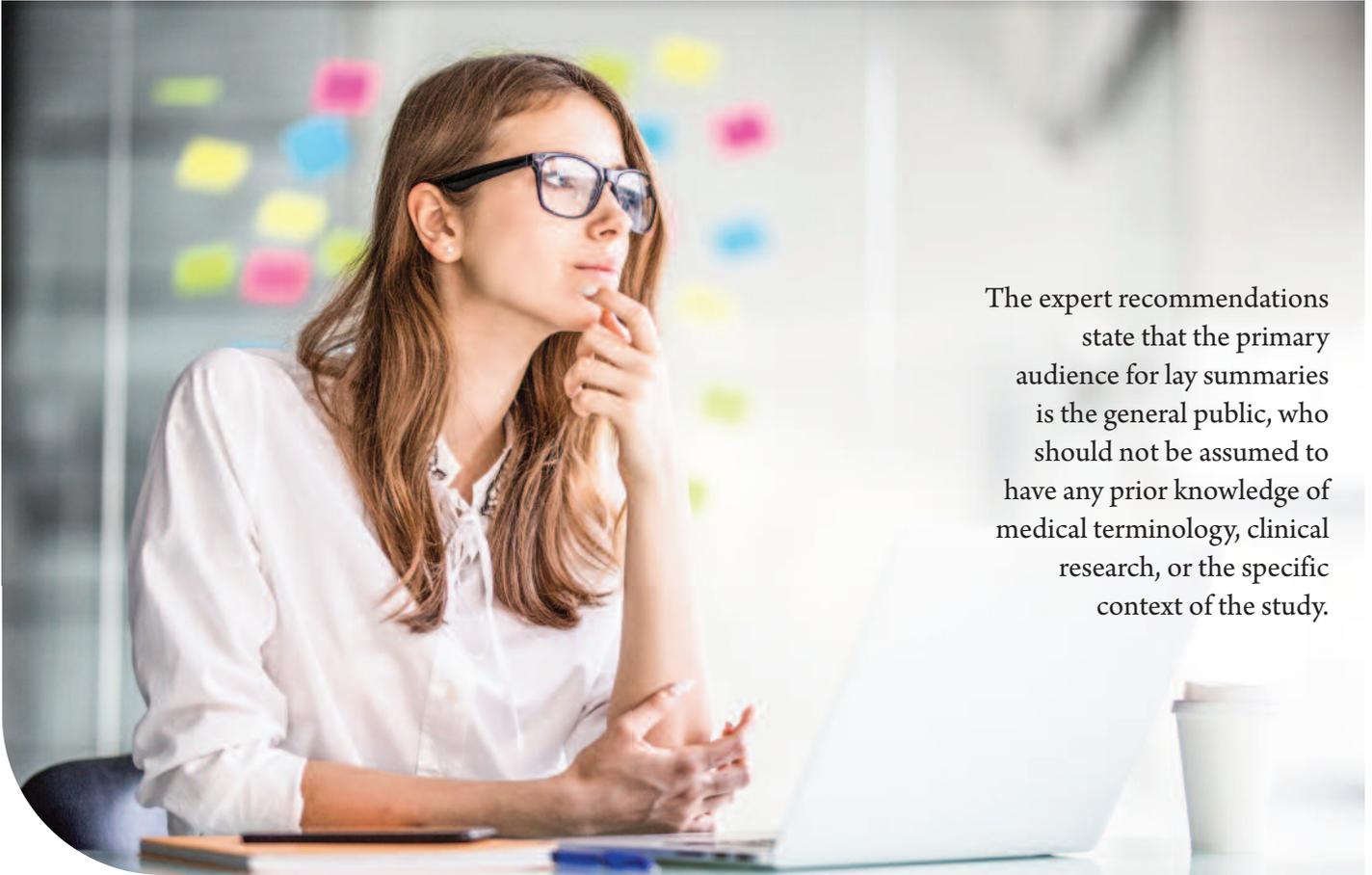
principle or confirm the efficacy of a new substance in a large group of patients. Phase I trials, on the other hand, address clinical questions that are only of indirect relevance to patients. Phase I trials are generally conducted in early stages of clinical development and usually evaluate the pharmacokinetic and pharmacodynamic properties of a new compound and assess initial tolerability but do not evaluate clinical endpoints. In this article, we outline some of the challenges associated with writing lay summaries of Phase I trials and provide recommendations.

Challenges in writing lay summaries of Phase I studies

To help readers understand a Phase I trial, a lay summary needs to describe it in a way that shows its contribution to the overall clinical development process. The evaluation of a new substance in humans usually starts with single and multiple rising dose trials, progressing through drug-drug interaction trials, food-effect trials, and bio-availability and bioequivalence trials until the pharmacokinetic and pharmacodynamics properties are established. Occasionally, Phase I trials are conducted in the later stages of clinical development (for example, bioequivalence trials for fixed-dose combinations).

Endpoints assessed in Phase I trials have limited meaning for readers

A characteristic feature of Phase I trials is that the endpoints are usually not as meaningful to lay readers as the clinical endpoints in higher phase trials. Endpoints assessed in Phase I trials pertain to uptake, metabolism, and excretion of a new substance and essentially consist of a series of measurements of blood concentrations of the new substance and its metabolites at various time points. Such endpoints include, among others, the maximal concentration (C_{max}) and exposure (area under the curve, AUC), half-life, and concentration at steady state. These endpoints are complex and often require mathematical derivation. Generally, individual pharmacokinetic endpoints cannot be interpreted in isolation but need to be evaluated in conjunction with each other. Both the individual endpoints and their



The expert recommendations state that the primary audience for lay summaries is the general public, who should not be assumed to have any prior knowledge of medical terminology, clinical research, or the specific context of the study.

overall interpretation are difficult to explain in lay language. In addition, usually none of these endpoints corresponds to a physical or psychological experience of the study participants. Lay summaries of Phase I trials therefore need to summarise and aggregate pharmacokinetic and pharmacodynamic endpoints at the appropriate level to facilitate understanding. Providing details may impede, rather than enable, comprehension of the results. Therefore, it is more informative to summarise the trial results in a qualitative statement.

Another key objective of Phase I trials is the initial evaluation of the tolerability of new substances. However, the assessment of tolerability in Phase I trials is always preliminary because the participants do not have the target disease and because the small number of participants does not allow infrequent adverse events to be detected. The safety signals seen in Phase I trials need to be confirmed in later phase studies. Therefore, the safety results of a single Phase I trial may be of limited value to a reader who is interested in the possible side effects of a finally marketed medicine.

The indication for substances tested in a Phase I trial may not be known when the trial is conducted

Unlike in later phase clinical trials, the intended indication of a new substance may not have been determined at this early stage. In most instances, new molecules that are tested in humans will be designed to modify a certain biochemical entity that characterises a particular disease. However, some substances that act on the immune system, such as antibodies to interleukins, affect many pathways that are relevant for different diseases. Hence, the target disease may not have been established when the substance is tested in Phase I. If the disease area is not known when the lay summary is written, or the one provided in the lay summary changes during the course of further clinical development, its usefulness for the public is limited.

Many substances evaluated in Phase I trials do not reach market authorisation

It is very hard to obtain reliable estimates of the number of Phase I trials conducted in Europe or in the US. This is mainly because registration

obligations for trials in healthy volunteers differ from those in patients. Either no registration is required (ClinicalTrials.gov) or registered trials are available to authorities only but are not made public (EudraCT). However, the overall number of clinical studies in healthy volunteers is likely to be very high, outnumbering the trials in other clinical phases by far. The high number of new substances in early phase trials is in great contrast to the number of molecules that reach market approval after full clinical development. Recent calculations show that across all therapeutic areas only 13.8% of all drug development programmes lead to approval.⁶ Most substances that are evaluated in Phase I trials never become available to patients. Therefore, lay summaries of such trials are likely to be of limited or no value to the public. However, the workload and cost associated with their generation is considerable for both commercial and academic sponsors.

Results of Phase I trials in healthy volunteers are not made available immediately

At the time of the first testing in humans, the details of an investigational substance are kept

Table 1. Key issues and proposals for writing lay summaries of Phase I trials in healthy volunteers

Issue	Solutions
To avoid misleading conclusions, readers must understand that the purpose of the trial was not curative and that it was not conducted in patients with a disease.	<ul style="list-style-type: none"> Specify in the lay title that trial participants were healthy people. Add a statement to emphasise that the trial was done in healthy people who volunteered to participate. Visually distinguish lay summaries of Phase I trials from those of higher phases.
Readers may not have the knowledge to understand the purpose of the trial.	<ul style="list-style-type: none"> Explain why the trial is conducted in healthy volunteers, e.g.: <i>“When we develop a new medicine, we need to understand how the body processes it. Studies in healthy people help us answer this question”</i>.
Pharmacokinetic endpoints are the focus of Phase I trials in healthy volunteers but are unlikely to be of immediate relevance to a lay reader.	<ul style="list-style-type: none"> Describe the underlying trial design in lay language, e.g.: <i>“This study tested whether there is a difference in how the body processes <<medicine A>> and <<medicine B>> when they are taken as 1 single tablet or as 2 separate tablets”</i>. Avoid technical terms like <i>bioequivalence</i>.
Intended indication(s) of the investigational product may not be known at the time of writing.	<ul style="list-style-type: none"> Include a broader statement about the target organ or group of diseases instead of a specific indication, e.g., “diseases of the brain” instead of “Alzheimer’s disease”.
Phase I trials may have complicated designs, details of which may confuse readers.	<ul style="list-style-type: none"> Provide details of the trial design and procedures sparingly. Do not use technical terms (e.g., <i>two-sequence crossover study</i>). Example: <i>“We measured the amount of <<medicine A>> and <<medicine B>> in the blood when the participants took them as separate tablets and combined in a single tablet. The doctors took blood samples at different times during the study. The doctors also collected information about the participants’ health.”</i>
Numerical data for endpoints typically evaluated in Phase I trials in healthy volunteers may be not meaningful to readers.	<ul style="list-style-type: none"> Describe the results qualitatively, e.g., <i>“This study showed that the amount of <<medicine>> in the blood was about the same, no matter whether it was taken as <<formulation 1>> or <<formulation 2>>.”</i>

confidential to protect the sponsors’ intellectual property. Unlike later phase trials, the results of Phase I trials are usually not made available within 1 year after study completion. In major clinical trial registries, Phase I trial results only need to be made publicly available once a drug receives marketing approval and this is usually many years after the Phase I trial is conducted.

Even after the EU CTR comes into effect, it will be possible to defer Phase I study results from publication for 30 months, and sponsors are likely to make use of this option.⁷ Hence, when a Phase I trial is completed, the participants will not be informed about the results in a timely manner.

A standardised approach to writing lay summaries of Phase I trials

As outlined above, writing a lay summary for a Phase I trial presents specific challenges, particularly making it relevant for the public. On the other hand, there is considerable scope for harmonising lay summaries of Phase I trials in terms of wording, structure, and overall appearance. This is because Phase I trials tend to have similar types of designs and endpoints, independent of the therapeutic area or intended indication. Therefore, for each Phase I trial design, standardised lay-friendly wording could be used to describe the background, methodology, and results for any investigational substance.

A template for writing lay summaries of Phase I trials

To establish an efficient, lean, and cost-saving process for writing lay summaries of Phase I trials, we designed a template. We based the template on the proposals in the expert recommendations and on our standard for lay summaries of higher phase trials. Our template not only provides the structure of the lay summary and annotated guidance for the writer, but also includes standard text that the writer can select depending on the trial design. The template aids the writing and ensures that lay summaries are harmonised with regard to the overall structure, the level of detail given, and the lay language used. Table 1 shows our approach according to this template and Figure 1 provides an example lay summary.

Title and statement that the trial was conducted in healthy volunteers

We routinely develop lay titles for all clinical studies based on the full scientific title. A good lay title allows the reader to judge quickly whether the trial is relevant for them. For Phase I trials, readers should understand that the trial was not conducted in patients with a certain disease. Therefore, our lay titles always specify that trial participants were healthy. To highlight this fact, we add a statement immediately below the title (see Figure 1). The lay titles are also used for other trial-related documents such as informed consent forms and for the posting on ClinicalTrials.gov.⁸

This was a study in healthy volunteers 

This study in healthy people tested whether taking a low strength of empagliflozin, linagliptin, and metformin together in 1 pill is the same as taking them in separate pills

This is a summary of results from one clinical study.

We thank all volunteers who took part in this study. You helped to answer important questions about the combination of empagliflozin, linagliptin, and metformin.

 What was this study about?

The purpose of this study was to find out about the amount of 3 different medicines (empagliflozin, linagliptin, and metformin) in the blood. We wanted to know if the amount is different if they are taken as separate tablets or as combination tablets.

 Why was this study needed?

Before testing a new medicine in patients, we need to know how the body processes the medicine. Studies in healthy people can help us answer this question.

Empagliflozin, linagliptin, and metformin might be taken together. A new combination tablet contains all 3 of these medicines. We wanted to know about the new combination tablets. Are they taken up by the body in the same way as when each medicine is taken as separate tablets?

 Which medicines were studied?

We studied the medicines called empagliflozin, linagliptin, and metformin. These are all medicines that can help to lower blood sugar in patients with type 2 diabetes.

All 3 medicines are taken as tablets that patients swallow. The combination of all 3 medicines is also taken as a tablet that patients swallow. The metformin was extended release in both types of tablets.

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This was a study in healthy volunteers 

During this study, 7 out of 29 participants (24%) had unwanted effects while taking the medicines as combination tablets. 6 out of 30 participants (20%) had unwanted effects while taking the medicines as separate tablets.

The table below shows the unwanted effects.

Unwanted effect	Empagliflozin, linagliptin, metformin - combination (29 people)	Empagliflozin, linagliptin, metformin - separate (30 people)
Nausea	4 people (14%)	3 people (10%)
Headache	4 people (14%)	2 people (7%)
Decreased appetite	1 person (3%)	2 people (7%)
Vomiting	1 person (3%)	1 person (3%)
Diarrhoea	1 person (3%)	1 person (3%)

None of the unwanted effects were serious.

 Where can I find more information about this study?

You can find further information about the study at these websites:

- Go to <http://www.trials.boehringer-ingelheim.com/> and search for the study number 1361.11.
- Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number 2018-001266-42.
- Go to www.clinicaltrials.gov and search for the NCT number NCT03629054.

Boehringer Ingelheim sponsored this study.

The full title of the study is: "Bioequivalence of a low strength fixed dose combination tablet of empagliflozin/linagliptin/metformin extended release compared to the free combination of empagliflozin, linagliptin, and metformin extended release tablets following oral administration in healthy male and female subjects (an open-label, randomised, single-dose, two-period, two-sequence crossover study)".

This was a Phase I study. This study started in September 2018 and finished in November 2018.

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This was a study in healthy volunteers 

 Who took part in this study?

A total of 30 healthy people took part in the study. This included 19 men and 11 women. The youngest participant was 24 years old and the oldest participant was 55 years old. This study was done in Germany.

 How was this study done?

All participants were to receive the empagliflozin, linagliptin, and metformin as separate tablets and also as combination tablets. The participants were divided into 2 groups.

One group started by taking separate tablets of 10 mg empagliflozin, 5 mg linagliptin, and 500 mg metformin as a single dose. Then they switched to take combination tablets of the same amounts of each medicine, again as a single dose. The other group started by taking the combination tablets, and then switched to take the separate tablets. The participants had to wait at least 35 days between taking the separate tablets and taking the combination tablets.

The participants and doctors knew which tablets of medicine the participants were taking.

We wanted to find out how much of each of the medicines (empagliflozin, linagliptin, and metformin) was in the blood. We also wanted to know the highest amount of each medicine in the blood. To find out, the doctors took blood at different times before and after participants took the medicines. The blood samples were collected after they took the separate tablets and after the combination tablets.

 What were the results of this study?

This study showed that the amount of each medicine (empagliflozin, linagliptin, and metformin) in the blood was about the same if taken as separate tablets or as combination tablets.

 Did the participants have any unwanted effects?

Yes, participants had unwanted effects while taking the medicines as separate tablets and as combination tablets. Unwanted effects are any health problems that the doctors think were caused by empagliflozin, linagliptin, or metformin.

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This was a study in healthy volunteers 

 Are there additional studies?

If we do more clinical studies with empagliflozin, linagliptin, and metformin you will find them on the websites listed above. To search for these studies, use the words empagliflozin, linagliptin, and metformin.

Important notice

This summary shows only the results from one study and may not represent all of the knowledge about the medicine studied. Usually, more than one study is carried out in order to find out how well a medicine works and the side effects of the medicine. Other studies may have different results.

You should not change your therapy based on the results of this study without first talking to your treating physician. Always consult your treating physician about your specific therapy.

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Figure 1. A lay summary for a phase I trial in healthy volunteers, also available at the [Boehringer Ingelheim Trial Results page:](http://trials.boehringer-ingelheim.com/public/trial_results_documents/1361/1361-0011_english_136111laysummaryenglishpdf.pdf#page=1)

https://trials.boehringer-ingelheim.com/public/trial_results_documents/1361/1361-0011_english_136111laysummaryenglishpdf.pdf#page=1 or search for Trijardy



Background to the trial

This section should provide the reader with sufficient information to understand what the trial was about and why it was needed. It should start with a purpose statement followed by an explanation as to why the trial was conducted in healthy volunteers. We keep the text about the trial rationale at a high level and omit scientific details that are not relevant for lay readers. For the trial rationale, we developed standardised text covering different trial types (e.g., dose escalation, drug-drug interaction, or bioavailability/bioequivalence trials). As the name of the investigational product (usually a code number or International Nonproprietary Name, INN) is linked with the trial rationale, we provide it in this section. With regard to the intended indication, we only include a general statement (e.g., “diseases of the brain” rather than “Alzheimer’s disease”).

Trial participants

We include the total number of participants and their breakdown by age and sex. We list key inclusion or exclusion criteria if relevant, e.g., if participants had to be within a certain BMI range. We also provide the country in which the trial was conducted. We use the term *participant* instead of *subject* because we feel that this term is the most appropriate factual description.

How the trial was done

To help the readers understand the trial and in the interest of transparency, we provide some detail on procedures performed during the trial. This includes dose groups and dosing intervals, whether some participants received placebo (and a definition of placebo), the mode of administration of the investigational medicine(s), and information about blood sampling (or other sampling) and any special procedures (e.g., imaging). This section also includes a statement that the overall health of the participants was regularly monitored during the trial.

The results of the trial

In line with the expert recommendations, the results of the primary endpoint are given. Pharmacokinetic endpoints are difficult to translate into lay language. Furthermore, in consideration of the low- to medium numeracy of the general population,⁵ we try to limit the amount of numerical information. We therefore recommend providing the results of the primary endpoint in a qualitative statement addressing the purpose of the trial. An example from the results section of a drug-drug interaction trial is shown below:

This study showed that taking medicine A did not affect the removal of medicine B from the blood. When the participants took medicine B with medicine A, the amount of medicine B in the

blood was about the same as when they took medicine B alone.

In some Phase I trials, the primary endpoint is a safety endpoint, e.g., the frequency of drug-related adverse events. In this case, the results section and adverse reactions section (described below) may be combined.

Description of adverse reactions and their frequency

We usually list the most frequent adverse reactions by treatment group in a table. We use the term *unwanted effects* because this is more lay-friendly than *adverse reactions*. If very few adverse reactions are reported, it may be sufficient to provide them in a sentence or bulleted list rather than a table. The Medical Dictionary for Regulatory Activities (MedDRA) preferred terms are often not lay-friendly, therefore we additionally provide a lay term. Retaining the MedDRA term provides consistency with other sources such as postings in registries, publications, and clinical study report synopses. We add the number of serious adverse reactions in each treatment group if any have occurred.

Discussion and conclusion

Results of a Phase I trial are not as relevant to patients as the results of Phase III trials that investigate efficacy and safety in specific indications. Indeed, even the Multi-Regional Clinical Trial guideline on returning results to participants suggests that lay summaries of certain types of studies may not be warranted because the results may not be informative, or because the benefit may not justify the administrative burden and expense.⁹ Also, in a comment on the EU CTR, the European Federation of Exploratory Medicine (EUFEMED), an association of organisations involved in early clinical development, proposed publishing lay summaries of Phase I trials only once trial information has ceased to be commercially confidential.¹⁰ Nonetheless, lay summaries for Phase I trials remain mandated by the EU CTR and serve the overarching objective of making the entire clinical research process transparent, which was one of the driving principles of the EU CTR. Therefore, sponsors need to find efficient ways for providing these lay summaries.

The challenge for writing lay summaries of Phase I trials is to achieve a balance between providing meaningful information about trial

design and results, making the information accessible without over-simplification, preventing the release of commercially sensitive information, and finding an efficient way of writing these documents. Our template for lay summaries of Phase I trials provides standards for structure, content, and wording for the different types of Phase I trials. It provides information that is informative for lay readers with the aim of maximising the value of these documents for the public.

Disclaimers

The opinions expressed in this article are the authors' own and not necessarily shared by their employer or EMWA.

Conflicts of interest

The authors declare no conflicts of interest.

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Participant information – an ethics committee view

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Abstract

The participant information sheet (PIS) is one of the documents that promote most discussion and concern for research ethics committees (REC). This article looks at ways to ensure the PIS meets their requirements based on the specific experience of a REC member. General problems include the fact that the PIS is too long, too complex, and written from the researcher's perspective rather than the participant's perspective. In addition, certain details are often lacking or unclear, the wording needs to be appropriate for the specific country and the benefit/risk balance should not be skewed in any way. Finally, every PIS should be proofread and tested on someone unconnected with the study. Following the advice given in this article will minimise requests for changes to the submitted PIS.

The UK Health Research Authority (HRA) is part of the National Health System (NHS) and was created to protect and promote the interests of patients and the public in health and social care research and to enable and support ethical research in the NHS. The Research Ethics Service is one of the core functions of the HRA. There are more than 80 research ethics committees (REC) across the UK. These RECs consist of between seven and 18 members who are a mix of experts (someone who is a registered healthcare or social work professional, or retired doctor) and lay members, and are entirely independent of research sponsors, funders, and the researchers themselves. This allows them to put the needs of

research participants at the centre of their review. Their role is twofold:

- to protect the rights, safety, dignity, and well-being of research participants
- to facilitate and promote ethical research that is of potential benefit to participants, science, and society.

As a member of our local REC, I review a lot of research study applications and the documents that promote most discussion and concern are almost always those aimed at the study participants: the participant information sheet (PIS), consent form, and any direct recruitment documents. The information provided to study participants is crucial for a number of reasons. It explains to individuals everything that will happen to them, should they consent to participate, and it allows them to weigh up the risks and benefits of taking part so that they can give true "informed" consent. The aim of this article is to provide an insight into the issues that are seen by our REC in relation to the PIS, and to help applicants minimise possible problems in obtaining a favourable opinion from their REC.

Guidance from the HRA

The HRA provides very comprehensive and detailed guidance for researchers and ethics committees on the PIS and consent documentation.¹ This includes recommended content, design, and style for preparing an effective PIS and consent form and some very useful example documents, as well as a template with suggested subheadings. I strongly recommend readers consult this guidance before preparing these documents. I do not intend to repeat the guidance here but to concentrate on a few issues that are repeatedly seen by our REC. The HRA makes it very clear that this guidance should be considered as a framework, not a rigid template, and that one size will not fit all. Information requirements can vary greatly between different studies. For example, you do not need to produce the same detailed PIS and consent form to support a

straightforward questionnaire study as you would to recruit into a complex drug trial.

Experience from the REC

Keep it simple

When patients are anxious or worried about their condition, treatment, or procedure, it is often difficult to retain information and therefore the documents need to be easy to understand and to the point. The HRA recommends a reading age of no more than 11-12 years. Those seen by the REC often use language that is far too complicated. Short, simple vocabulary and sentence structure should be used wherever possible. The REC will often request changes to ensure the document is understandable by prospective participants and written from their perspective rather than taken directly from the study protocol. We also recommend using simple pictures, charts, or diagrams showing what will be done and when. These are a very useful way of explaining what will happen in the study and are generally underused, however, the practice of direct transfer of the study schedule from the protocol into the PIS is not appropriate.

The view that the PIS is generally written at a level above the average literacy level of participants is supported by a study of 128 PISs carried out in 2019, which showed a mean Flesch Reading Ease score of 56.2 (SD 8.67), equivalent to a reading age of 16-17.² The study concluded that "patient information sheets are generally too complex for all patients to easily comprehend and researchers would benefit from clear national guidance from ethics' committees on writing patient information at a more appropriate level; participants would benefit from being provided with an easy-to-read research summary sheet". This is a consistent ongoing problem and, despite attempts to provide advice and guidance, it does not appear to have improved.

Keep it short

The PIS submitted for review by the REC is often far too long – sometimes approaching 35-40

When patients are anxious or worried about their condition, treatment, or procedure, it is often difficult to retain information and therefore the documents need to be easy to understand and to the point.

pages. In particular, parts of some sheets appear to have been taken over by company lawyers and include long complex sections relating to “liability” and “compensation”. Whilst this information needs to be there, it should always be included as supporting information at the end of the document and kept to the minimum possible. For example, the PIS should not go into details of how a claim process will be carried out, only how it should be initiated.

Although the HRA suggests splitting lengthy sheets into three sections (introduction, what’s involved, and supporting/further information), this advice is rarely followed. The REC will often request that researchers reduce the length by removing duplicate and unnecessary information and, if the length is still considered too high and cannot be reduced further, will suggest that supporting information be separated out for inclusion in a separate section at the end and that a half-page summary of the important points is included at the beginning of the PIS.

Involve the participants

The best way to write appropriate information for participants is to involve them in the creation of the information. It is often difficult for researchers to know what information is important to study for participants. For example: Can they eat and drink before their visit? How long is their visit likely to last? Involving them in the review of the documentation will help greatly. Currently, this is very rarely done and means that the documents provided to the REC are often written from the researcher’s perspective rather than the patient’s perspective.

Ensure appropriate content

Whilst every study is unique, there are certain things that the REC will always want to see fully explained:

- What is the study about?
- What will happen to the participant if they consent to take part?
- What side effects might develop?
- What limitations to their lifestyle will taking part impose?
- What payments (including for expenses) will be made?
- What will happen at the end of the participant’s involvement in the research?

Some specific issues are regularly raised during REC review of participant information. In



particular, certain details are often lacking or need to be made clearer to the participants. These include which procedures are optional and which are a standard part of the study, as well as which procedures are part of standard treatment and which are additional procedures completed only as part of the study. This is particularly important when patients receive a lot of general testing or monitoring as part of their standard treatment for example in studies of patients with long-term chronic conditions. It must be clear what happens to blood and tissue samples at the end of the study. Will they be retained and if so where and what will be done with them? It must be clear what will happen to the data, is it personal data or anonymised data? Where will it go and who will have access to it? Information regarding how participants will be informed of the results of the study should also be included where appropriate.

The wording must be appropriate for the specific country. This is often a problem where a multi-national study has submitted a single, standard PIS to all countries. In the UK, for example, sections relating to the “cost of treatment” will normally not be appropriate as treatment will be provided under the NHS. Some specific words should be avoided, for example, patients are “invited” to take part rather than “chosen”, studies are “reviewed” by the REC (and a favourable opinion given) not “approved”.

The benefit/risk balance should not be skewed in any way. The benefits of taking part are often overstated and may unrealistically raise hope of successfully treating the disease, which could be seen as coercive. The discomfort, disadvantages, and risks of all study procedures and treatments must be clearly stated. The number of patients who have previously received the treatment and the number of adverse events reported by those patients should be given, in preference to the use of general terms such as “uncommon”. Where the researchers are requesting potentially distressing information such as details of incontinence or previous miscarriage, the PIS should mention the potential for distress as an adverse outcome and

how it will be dealt with. Sign-posting to relevant support and resources should be added to the PIS.

Studies that include different types of participants, e.g., patients and their care providers, or adolescent participants and their guardian, present a challenge when preparing a PIS. A single PIS for all participants often becomes confusing as their involvement in the study will be different in each case. For this reason, the use of a separate PIS for each type of participant is recommended.

Finally

Having followed the guidance from the HRA and taken into account the issues detailed above make sure you proofread the PIS for typographical errors and test it out on someone unconnected with the study. This way, you will minimise problems in obtaining a favourable opinion from your REC and will ensure participants fully understand what is being asked of them and can give true “informed” consent.

Disclaimers

The opinions expressed here are those of the author and not necessarily those of the Research Ethics Committee or the Health Research Agency.

Conflicts of interest

The authors declare that they have no conflicts of interest to report.

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Establishing a patient publication steering committee: A case study with insights for medical writers

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Abstract

Development of a patient publication steering committee (PPSC) is an innovation in industry publication practices. In this brief article, we summarise how UCB Pharma, a global biopharmaceutical company, plans to partner with patients to establish a PPSC and share insights on how medical writers could support PPSCs. The purpose of a PPSC is to plan and oversee the timely and ethical development of high-quality publications on disease burden and the patient journey, as identified by patients. In this case study, we collaborated with key internal and external stakeholders, including medical writers, to identify the key roles, governance, and documentation required for a PPSC. We have demonstrated that it is feasible to develop a PPSC framework that will guide the ethical and effective development of a patient-led publication plan. Medical writers would work within this framework to help develop and implement the plan.

About the word *patient*

In this article, we use the word *patient* in a broad sense to encompass people living with or affected by disease (this includes caregivers and family members).

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Patient involvement in the publication life cycle is an innovation in industry publication practices. The most recent version of the Good Publication Practice guidelines (GPP3)¹ did not cover patient involvement in publications, but this gap should be addressed in the next version. This evolution reflects the increasing interest from patient leaders, industry sponsors, medical writers, publishers, journal editors, researchers, and other stakeholders in HOW to involve patients ethically, compliantly, and effectively in publications. Medical writers will need evidence-based guidance and practical insights to provide professional support in this

A patient publication steering committee can plan and oversee the timely and ethical development of high-quality publications on disease burden and the patient journey, as identified by patients.

new patient-partnered publication era.

We have proposed that patients can be involved, as partners, at multiple points during the publication life cycle (Figure 1).

We have conducted and published research on how to involve patients as co-creators of plain language summaries of publications and as authors of publications.²⁻⁵ However, to the best of our knowledge, there have been no published studies on how to involve patients as members of a patient publication steering committee (PPSC), nor any guidance offered to medical writers about how to support PPSCs. The

purpose of a PPSC would be to plan and oversee the timely and ethical development of high-quality publications on disease burden and the patient journey, as identified by patients. Our objectives for this real-world feasibility study were to identify the key roles, governance, and documentation required to establish a PPSC for a global biopharmaceutical company.

Through this article, we hope to share our early insights about establishing a PPSC and how medical writers could provide valuable support to PPSCs.





Figure 1. Patient involvement in the publication life cycle

Method

To establish a framework for UCB Pharma’s first PPSC, we followed a stepwise process from October 2019 through to May 2020 (Figure 2). After conducting a literature search to confirm that the PPSC would be an innovation in industry publication practices, we consulted with stakeholders who would be required to support, approve, and implement a PPSC. These stakeholders included key internal (patient engagement and advocacy, publications, compliance, medical) and external (expert patients, patient advocates, medical writers) partners. These early and critical discussions confirmed the need for a PPSC, a compliant process to implement the PPSC, and plain language documents to guide PPSC governance

and operations. We subsequently collaborated with internal and external stakeholders, including medical writers to develop a PPSC framework that would be needed for the ethical, compliant, and effective initiation of UCB Pharma’s first PPSC.

Results

Our PPSC initiative is ongoing, with a pilot planned for 2021. However, the critical stages to prepare for the first PPSC meeting have been completed successfully (Figure 3).^{6,7}

Our PPSC framework is based on UCB Pharma’s existing publications standard operating procedure, which aligns with GPP3, and addresses important compliance considerations including:

Methods

- **October 2019**
Review literature to confirm PPSC would be an innovation in industry publication practices
- **November 2019-February 2020**
Collaborate with internal (patient engagement and advocacy, publications, compliance, medical) and external (expert patient partners, publication professionals) stakeholders
- **November 2019-April 2020**
Co-create PPSC governance documents and measure document metrics (readability, reading speed, speaking speed)
- **May 2020**
Endorsed by key internal stakeholders



Figure 2. Timeline and key steps for developing the patient publication steering committee framework

- Pre-specified, fair, and robust selection criteria for patient representatives to join the PPSC
- A written PPSC charter that clearly defines roles and responsibilities for PPSC members
- Transparent and justifiable inclusion of clearly identified, non-product specific, publications in a strategic publication plan.

Draft PPSC documents (N=7) for the first meeting were co-created by patient experts and medical writers who had expertise in plain language and patient involvement in publications. For legal reasons, we did not alter UCB Pharma’s Confidentiality Agreement and Author Agreement forms but did co-create a plain language guide to each. These guides were more suitable for patients (Figure 4). The other documents (PPSC Charter; PPSC Invitation; Publication Process Overview; Patient Author Candidate Matrix; Plain Language Summary of GPP3 guideline) followed plain language principles, met readability targets, and were deemed suitable for patients.

In terms of next steps, we plan to pilot the PPSC in one therapeutic area and follow UCB Pharma’s existing patient engagement principles.

COMPLETED STEPS



NEXT STEPS

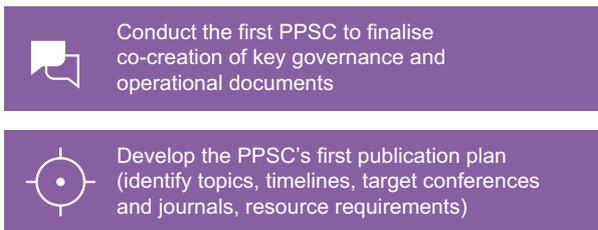


Figure 3. Completed and planned steps for the patient publication steering committee pilot

We will invite qualifying members of one of UCB Pharma’s existing patient councils to become PPSC members. The council members will select PPSC members based on pre-specified PPSC

selection criteria (e.g., recognised patient expertise in the disease area knowledge of the relevant patient community, fluent in oral and written English, interest, availability, and willingness to participate). The first PPSC meeting will focus on PPSC roles and responsibilities and will include a formal review of the draft PPSC documents. The PPSC documents will be finalised based on the input from the PPSC members.

Discussion

To the best of our knowledge, we have conducted the first feasibility study to establish a PPSC for a global biopharmaceutical company.^{6,7} Our results indicate that it is feasible for industry sponsors to partner with patients to establish PPSCs.^{6,7} This has the potential to change industry publication practices to enable early, compliant, and important partnerships with patients in the publication life cycle. Medical writers could play a key role in supporting PPSC members to plan, develop, and share patient-led publications.

Within the broad field of medical communications, patient engagement in publications is novel. Patient engagement in publications of industry-sponsored research is certainly a recent innovation, even in comparison with patient engagement in other relatively new areas (e.g., patient engagement in protocol development, clinical trial conduct, and involvement in regulatory and reimbursement reviews). In order to remain at the forefront of innovations in medical communications, medical writers should have training in patient engagement. The training could include The Patient Focused Medicines Development (PFMD) Patient Engagement



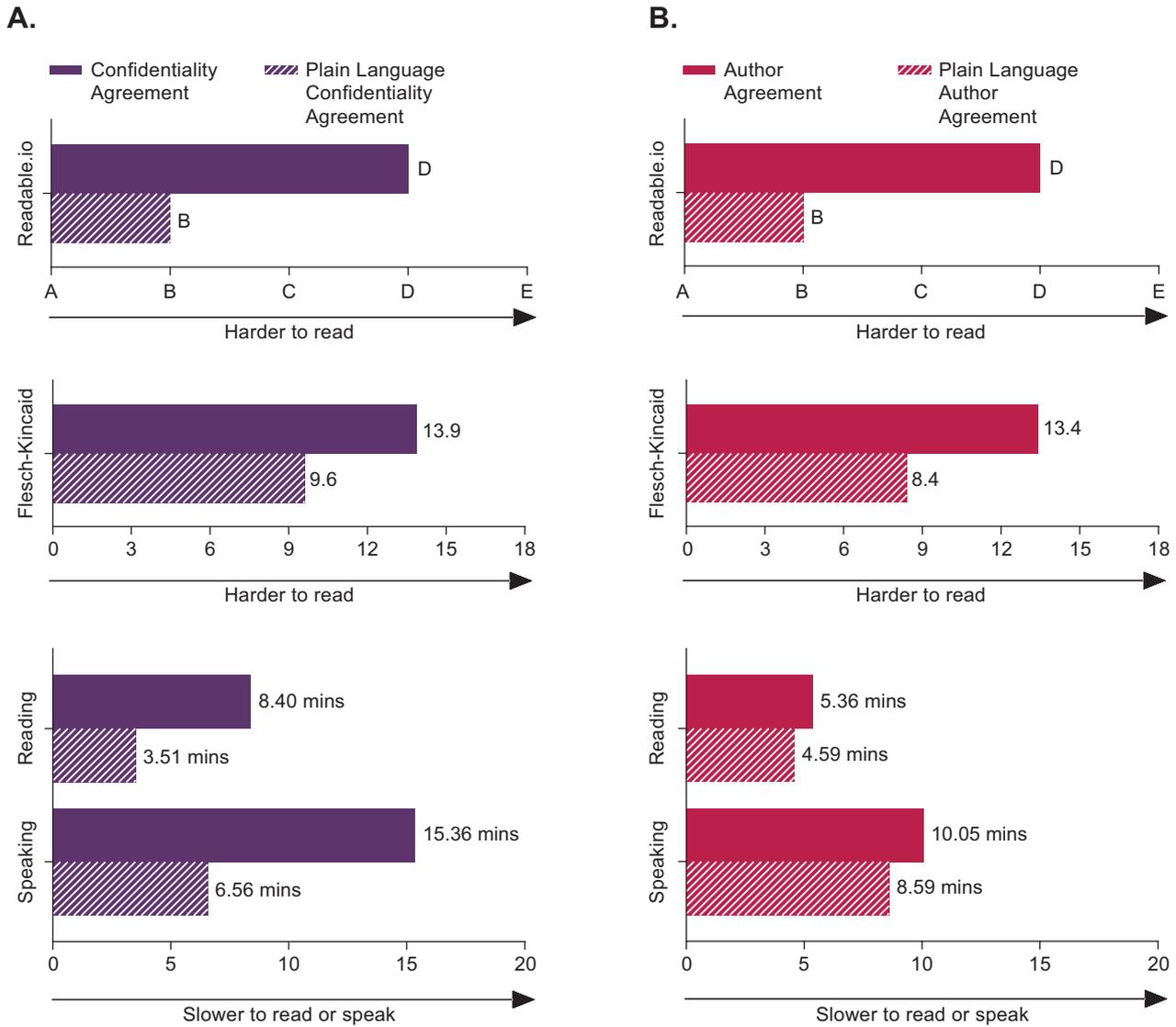


Figure 4. Readability metrics for the original document and the accompanying plain language guide for the (A) confidentiality agreement and (B) author agreement

Metrics were generated by the Readable.io software program.



Quality Guidance,⁸ which was co-created with patients and provides a useful framework for planning, developing, and assessing the quality of patient engagement activities throughout the development and lifecycle of medicines. The guidance contains seven quality criteria based on an agreed set of principles to improve consistency in patient engagement practices that could be applied by medical writers or other stakeholders to plan and assess a PPSC (Figure 5).

Although pharmaceutical companies have recognised the value of plain language summaries of publications,⁹ and have started to involve patient experts later in the publication life cycle

(e.g., as co-creators of plain language summaries of publications and as authors of publications), we are unaware of published reports of patient involvement early in the publication life cycle (e.g., in publication steering committees). Our interest in establishing a PPSC was driven by several factors, including:

- Belief in the unique and important value that the patient perspective can provide to presentations and publications^{6,7}
- Recognition that publication steering committees are recommended in GPP3 for industry-sponsored research¹
- Increasing advocacy by patient experts and



Figure 5. Seven patient engagement quality criteria⁸

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patient advocates for involvement in publication planning

- Evidence from our recent systematic review on patient authorship that reinforced the importance of involving patients before publication writing begins³
- Recognition of the benefits of early and non-tokenistic involvement of patients in other advisory groups (e.g., trial steering committees)¹⁰⁻¹²

As experts in GPP3 and publication planning, medical writers can play an important role in supporting the PPSC and patient authors throughout the publication life cycle, providing guidance and practical assistance as needed. As part of the current initiative, medical writers were involved in generating the documents needed for industry compliance purposes, as well as preparing plain language guides and documents for use in the first PPSC meeting. Although we are still in the early stages of this PPSC initiative, we anticipate that medical writers will continue

to play a key role in the development and execution of the strategic publication plan. We have identified a number of ways in which medical writers could contribute to success of a PPSC. These insights reflect the diversity of perspectives from our PPSC initiation team (Table 1).

As medical writers may appreciate, “upstream” involvement of patients at the publication steering committee stage of the publication life cycle should differentiate patient-led publication plans from traditional publication plans. Both plans should complement each other, but a patient-led publication plan may differ in terms of:

- **Publication topics.** Patients are in the best position to identify topics that are important to their care in the real world. As topic prioritisation may differ between patients and healthcare

professionals, a PPSC would ensure that the publication plan addresses patient priorities. Ultimately, these publications should help inform shared decision-making and, thus, help both patients and clinicians.

- **Publication author candidates.** Patient leaders have access to networks that could include people with the most relevant skills and expertise to author or contribute to publications. Training courses for patient authors are being developed,¹³ and a PPSC could help ensure that the pool of potential authors expands to include patients. Healthcare professionals do not have to be the surrogate voice for patients in the peer-reviewed literature.
- **Publication dissemination plans.** Patients have started to present at conferences and author publications in peer-reviewed medical journals.³⁻⁵ These experiences could help patients nominate target conferences and journals that may be most interested in patient-led publications. Patients may also be less tied to traditional considerations regarding dissemination (e.g., a strong focus on journal impact factors). This “freedom” from historical and academic constraints could help drive innovation. For example, patients and the public have advocated for plain language summaries of publications and have been shown to drive awareness of publications and accompanying plain language summaries within their patient advocacy communities and via social media.¹⁴

We recognise that our study has limitations. We are only able to share one industry sponsor’s experience and we are conducting a pilot PPSC

study in only one therapeutic area. However, we believe that this highly focused approach is prudent for a feasibility study. We intend to update and share our PPSC insights as we continue this PPSC initiative. We welcome the uptake of PPSCs by other sponsors and encourage them to share their findings with the broader publication community, including patients.

To conclude, this novel, real-world, “how to” case study indicates it is feasible for a global

This novel, real-world, “how to” case study indicates it is feasible for a global biopharmaceutical company to partner with patients to establish a patient publication steering committee.

biopharmaceutical company to partner with patients to establish a PPSC.^{6,7} By working collaboratively with internal and external stake-

Table 1. Perspectives from different stakeholders on how medical writers could support a patient publication steering committee

Stakeholder	How medical writers could support a PPSC
Industry sponsor	<ul style="list-style-type: none"> ● Help prepare documents for internal colleagues (e.g., compliance) to gain their support and approval for a PPSC ● Contribute to the PPSC framework document that will guide the development of the PPSCs and ensure consistency across the company ● Contribute to the first PPSC meeting (e.g., to provide an overview of GPP3 and outline the stepwise approach used for publication planning and development) ● Assist with the development and execution of the strategic publication plan
Patient advocate	<ul style="list-style-type: none"> ● Work with patient leaders to gather and summarise feedback from patient communities that could help inform the development and implementation of a PPSC ● Identify PPSC documents that should have a plain language version ● Help co-create PPSC documentation ● Work with patient leaders to identify suitable candidates for the PPSC based on the skills and knowledge that could optimise effective involvement ● Identify novel and suitable dissemination methods for publications to wider and targeted audiences ● Identify and address training requirements and knowledge gaps for PPSC members to fully engage successfully with the publications process
Medical writer	<ul style="list-style-type: none"> ● In general, be the “go to” person for PPSC members and patient authors for questions about GPP3 (consider setting up recurring check-in meetings) ● Work in an ethical, compliant, and effective manner with PPSC members to help them develop and execute the publication plan ● Provide a summary of scientific publishing practices ● Provide a practical overview of the key steps and timelines involved in preparing a publication plan, as well as presentations and publications ● Explain common terminology and abbreviations used in scientific publishing (e.g., abstract, encore, congress, manuscript, journal, disclosure of COI, GPP3, ICMJE, IF, open access, peer review) ● Explain key considerations in selecting a target journal or congress ● Provide guidance to the PPSC on how to nominate and select patient authors in a compliant manner ● Help explain authorship roles and responsibilities to the patient author candidates identified by PPSC members (e.g., share the Plain Language Guide to GPP3¹⁵) including issues that might affect their decision to accept authorship (e.g., inclusion of their name on the publication, potential time required) ● Explain who co-authors are and their roles in the research (if necessary) ● Establish patient author’s preferred publication feedback method (in writing, via phone/email) and be aware they may need more time or flexibility to provide feedback ● Provide medical writing support to translate author feedback into publications ● Suggest metrics for evaluating the success of the PPSC ● Volunteer to help adapt tools and processes that will contribute to the success of future PPSCs

Abbreviations: COI, conflict of interest; GPP3, Good Publication Practice 3 guideline; ICMJE, International Committee of Medical Journal Editors; IF, impact factor; PPSC, Patient Publication Steering Committee

holders, we developed a compliant PPSC process and plain language documents.^{6,7} By sharing our insights, we hope other industry sponsors will consider how to partner with patients to establish PPSCs and that medical writers will recognise how they could play an important role in supporting PPSCs.

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Non-financial: All authors support patient involvement in medicines development. Financial: LF and AM are employees of UCB Pharma and hold stock and/or stock options in UCB Pharma. TB is a patient engagement consultant to Envision Pharma Group, receiving fees for plain language document review. NM, HC, and KW are employees of Envision Pharma Group.

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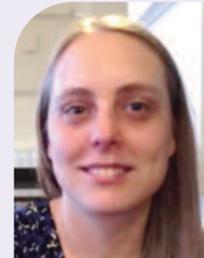


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Translation: A transcultural activity

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Abstract

Effective communication is the goal of any professional medical and communication writer. Transferring the correct messages from one language to another is a task that is increasingly covered by software, but translation machines cannot confer the feeling of people with a different background. Any medical translation is not just a transformation of the text from the source language to the output one: a translated text must communicate the exact meaning in the source language and, thus, has to fit with the reader's culture.

Introduction

The word translation derives from the Latin *translatio*, which itself comes from *trans-* and *fero*, together meaning “to carry across” or “to bring across”. The modern Romance languages use words for translation derived from that and the alternative Latin *traduco* (“to lead across”). The Germanic (except Dutch) and Slavic languages likewise use calques of these Latin sources.¹ The Ancient Greek term for translation, *μετάφρασις* (*metaphrasis*, “a speaking across”), has supplied English with the term “metaphrase” (a “literal”, or “word-for-word”, translation) – as opposed to “paraphrase” (“a saying in other words”, from *παράφρασις*, *paraphrasis*).¹ Metaphrase corresponds, in one of the more recent terminologies, to “formal equivalence”; and paraphrase, to “dynamic equivalence”.¹

The traditional Oxford definition of translation as “the process of translating words or text from one language into another”² has been extended to “translation is the communication of

the meaning of a source-language text through an equivalent target-language text”.³ The Cambridge definition is “something that is translated, or the process of translating something, from one language to another”.⁴ Others define the same activity as “an act through which the content of a text is transferred from the source language into the target language”, “a mental activity in which the meaning of given linguistic discourse is rendered from one language to another”, or “the act of transferring the linguistic entities from one language into their equivalents into another language”.⁵

In contrast to other languages, English distinguishes between translating (a written text) and interpreting (oral or signed communication between users of different languages). According to this distinction, translation can begin only after the appearance of writing within a language community;⁶ it does not apply to texts that are expected to be used without the use of non-written signs.

Is translating enough to effectively communicate?

Communication is derived from the Latin *cum* (with) and *munire* (link), and the Latin word *communico* means to “share, let participate”. The term “communication” has the common meaning “to impart or exchange information, ideas, or feelings”. Thus, communication is a process that involves what a receiver understands or thinks of something⁷ and is successful when all parties have the same understanding of what has been communicated (Figure 1).

This is one of the most difficult tasks a scientific communicator must face.

Effectively communicating when using different languages is paramount. If you feel communicating in another language is difficult, you are a candid communicator: each language developed in different human populations and continuously evolves with the culture of its speakers. Any effective communication must be targeted to the reader's culture to be effective. This means that you have to know your readers' culture.

The word “culture” derives from the Latin

“*colere*”, which means to tend to the earth and grow, or to cultivate and nurture.⁸ Culture encompasses the social behaviour and norms found in human societies, as well as the knowledge, beliefs, arts, laws, customs, capabilities, and habits of the individuals in these groups.⁹ The intangible cultural heritage of each society includes science, together with practices of political organisation and social institutions, mythology, philosophy, and literature.¹⁰ Humans acquire culture through the processes of enculturation and socialisation, resulting in the diversity of cultures across societies.

When writing about health, translation of scientific texts plays a special role aimed at public education and prevention of diseases as well as saving mental and physical health. For instance, when the readers are specialised healthcare providers, the language to be used is usually well coded to assure the reader of the expertise of the author in the specific field. Some medical texts, especially when published in peer-reviewed journals, regulatory documents, or specialised books, are exceedingly difficult to read by non-specialised readers, meaning they can even be difficult for a physician with a different area of specialisation.

This scientific style provides information, presents exact and relatively complete scientific knowledge, and addresses a relatively small group of professionals well acquainted with the subject. It is characterised by the matter of fact, being clear, explicit, unambiguous, precise, and concise; it must have stereotypical lexicology and syntax and

In contrast to other languages, English distinguishes between translating (a written text) and interpreting (oral or signed communication between users of different languages).

Figure 1. The fundamentals of successful communication

- Communication is a two-way process
- Success is attained when ALL parties involved have the SAME understanding of what has been communicated



must remain impersonal and objective. Known concepts are referenced to other texts, whereas new findings are presented as diagrams, charts, sketches, or illustrations expressing numerical data. Ideally, the personality of the author does not need to emerge to emphasise the results, as the results are far more important than their implications in clinical practice.

We all know this is not the most attractive style for the general reader. Some writing practices suggest “telling a story” when describing a study and its results to make it most attractive for the reader.¹¹ But when technical wording is maintained, the general reader is generally not attracted by this text. Improving the reader’s health literacy to let them appreciate the text is a long and not always successful option:^{12,13} when translating a text for the general reader, the translator needs to adapt to their thinking and language level.

The legal and regulatory requests

The European Medicines Agency requests that

for any centrally authorised product, Annex II, Annex A, SmPC, labelling, or package leaflet, as well as Annex IV and Annex 127a, if applicable, be translated from the original English to all other European language. Each translation undergoes a linguistic review by the member state, and the European Medicines Agency ensures that all comments have been implemented for each translated document before their final approval.¹⁴ These reviews are performed by selected reference centres (so-called “contact points for translations review”), which provide a qualitative opinion on the quality of the translated version of each document (very good, good, acceptable, unacceptable) and the nature of comments (missing words or sentences; scientific incorrect translations [e.g., terminology]; inaccuracies [incorrect translations – including spelling, punctuation, grammatical mistakes]; and editorial, stylistic changes [e.g., rephrasing]). Although the timelines and roles are well established, no guidance is provided on how to ensure that the translated documents correctly

communicate their contents in the different target languages.

When translations are needed for clinical trial documents (e.g., patient informed consent), the ethics committee or institutional review board can request a back-translation.¹⁵ In this case, a comparison of the back-translation with the original text is used to check the accuracy of the original translation, with the same rationale that a mathematical operation is checked by reversing the operation, although such back-translations are not always fully reliable¹⁶ because, unlike mathematical symbols, some words can be ambiguous. Thus, subjective evaluations seem the preferred way to check the quality of translated clinical trial and health product-related documents.

Cultural translations

Why are literal translations dangerous?

It is impossible to provide effective communication in a target language using word-for-word translation. This is one of the reasons why

machine translation, where a computer program analyses a source text and produces a target text without human intervention, is not yet a reliable and professional option. A growing number of software options are available on the internet such as Babel Fish, Babylon, FoxTranslate, Google Translate, Lingo, TransPerfect, StarDict, U.S. Translation Company, and Yahoo! Also, companies like Ectaco, TimeKeffle, and eFlyTek produce pocket translation devices.

Communication in human language is context-dependent, and it takes a person to comprehend the context of the original text. Thus, even if artificial intelligence has greatly enhanced the ability of translations systems to interpret natural language, translations performed by a machine must be substantially revised by a human, although the work can be reduced when the translation system is integrated with a translation-memory or globalisation-management system.^{17,18}

Even human-generated translations, however, are prone to error. Therefore, to ensure that a machine-generated translation will be useful and that the translation is of publishable quality, they must be reviewed and edited by a human with the appropriate cultural background to appreciate the tone and the deep meaning of the text in both the source and output languages.

A crazy example of cultural mistranslation.

A few years ago – about 15 (sigh, I am old) – my professional responsibilities included the preparation and approval of promotional materials to be used by the Italian affiliate of my company. As you probably know, Italian is spoken by about 60 million Italians and by about 720,000 people in the Italian-speaking cantons of Switzerland.¹⁹ Thus, when a new drug for the treatment of erectile dysfunction was close to being approved in Italy, we asked Swiss colleagues to review the material they were to use for the product in Switzerland. Upon opening the document, my colleague was unable to stop laughing, even though she is a deeply serious and professional person, so we all were surprised. She pointed her finger at the computer screen, unable to say anything because of the unstoppable laughter. We read “Quando il tuo piccolo amico ti pianta in asso...” (literally “When your little friend leaves you alone...”) and all of us started laughing uncontrollably. Although it is

perfect Italian, it is unacceptable for any Italian because Italians do not have a “little friend”. Italian men are Latin lovers, so even if a virgin, 95 years old, or a chaste Catholic priest, our “friends” are not “little”. Even Italian women would not accept this. And your “friend” never “leaves you alone” – it might be ill, but he is always with you! For any Italian, this is hilarious.

When we finally stopped laughing, we called our Swiss colleague to ask him what he had been thinking. We asked about the “little friend”, and he could not understand what we were talking about: he was shocked by our reaction to his translation. He finally explained they had translated from the original German version, which might have been “Wenn dein kleiner Freund dich alleine lässt...” (German speakers please stop laughing, I was unable to find the original version and it is what Google Translate said!) Probably, it is a good way for communicating the concept of erectile dysfunction to the Swiss Italian-speaking general public.

How to assess the quality of translations

A translation must consider cultural aspects. Knowing a culture allows for a better manipulation of the language: being familiar with customs and traditions makes it easier to find distinctions, double meanings, and embarrassing phrasing. Consequently, cultural translation involves a deeper comprehension of both the target and source languages. We could even say that it is a more advanced

version of translation because it provides more than simple word-to-word conversion.

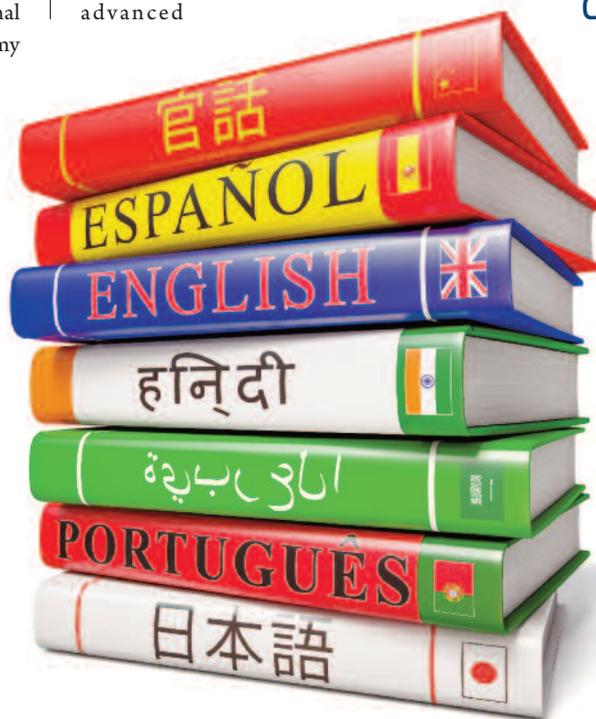
Cultural translation also adds a consultancy dimension to translation. It is a deeper version of translation, so the translator is an important actor in a company’s expansion abroad. Translators are entrusted with a cultural mission; they are not only experts in the target medical area but are also asked to effectively communicate to healthcare providers and the general public. In addition to translating and adapting graphics, currencies, date formats, addresses, phone numbers, colour choices, punctuation, and so on, they must ensure that communication in the target language is professional. This implies rethinking the structure of the text. Thus, a key aspect of cultural translation in health management is that the final communication must be understood, avoid conflict, and align with the targeted needs.

Who is the right translator?

Medical translators are essential for preventing misunderstanding or miscommunication of healthcare information. International organisations, researchers, and companies are increasingly becoming aware of the importance of translation professionals in considering the different cultural approaches. A cultural translator must know the cultural background of the source text and must live in the culture of the targeted health care professionals.

Conclusion

In my experience in collaborating with people in North and South America, I have found that many people living there do not consider the importance of different cultural backgrounds. I have seen that some well-known and respected top managers are hardly able to distinguish one European country from another, and they barely know that we speak different languages. Luckily, the vast majority of North and South Americans know and appreciate the “Old World” cultures and languages. On the other hand, as Europeans have become exposed to New World cultural models, differences between countries have decreased. And although a growing number of healthcare providers worldwide speak English, non-native English speakers often do not recognise the





difference between British, American, Australian, and Canadian English, each of which has its own cultural background.

We all need to understand our limits. Cultural translation is not an option for health communication professionals; it is the only way to achieve an effective translation.

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The opinions expressed in this article are the author's own and not necessarily shared by his employers or EMWA.

Conflicts of interest

The author has no conflicts of interest related to this article.

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Writing for the internet

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Abstract

Writing for online sources requires a slightly different skillset than writing for print publications. Authors need to be aware of their potential audience's interests. This article explains how avoiding typical online mistakes, and both knowing and making use of the advantages that the web presents, can help to equip authors to write for the internet.

Writing for the Internet

Writing for the internet *is different* to the printed word. In this article, I will outline some of the quirks of writing online which you should keep in mind if you are setting out in that direction. I will also try to turn these differences into tips to improve your online writing.

Why do people read online?

I must admit that I am the kind of person who likes to have a physical copy of what I am reading. I find myself a cosy nook and take my time to read. This is how I tend to read *Medical Writing*. That is, unless I am at work and think of an article I previously saw in the journal which could help me with a particular task. Then I jump on the net, search the archives, and quickly download the relevant text.

Sometimes as I read, I realise it's actually not the article I was thinking of, but it's interesting, so I keep on reading it. Sometimes the articles found this way are even better! If I need to dig deeper, I often click on likely-looking papers listed as a reference. Then these papers might also yield some other interesting references... and on it goes... until I look up at the clock and realise I

have spent an hour this way.

This scenario is perhaps more typical of online readers like medical writers and researchers. It is different for the general public. They don't browse like you do in a library; they are looking for something specific, and they want it quickly or they will soon lose interest in the website. Such readers will jump past lots of content in order to find the section of interest by quickly scanning or using the "find button" to search for the word in question.

People read online for different reasons than reading in print. They usually have something specific in mind to help them complete a task. Readers will scan text quickly to find what they want.

Who is reading online text?

I have probably already burst your bubble. The harsh truth is that while anyone in the world with an internet connection can access and read your work, the reality is that most people will not. Those who do will most likely merely scan over your hard work before clicking away to something else.

The internet is where a lot of people go for medical information – and very soon they wish they hadn't due to the scary things they read there! Keep in mind who your audience potentially is. The European health literacy survey (HLS-EU) is a questionnaire designed to measure health literacy. It was used in a comparative survey conducted in eight European countries in 2011, which found that almost half (47%) of the approximately 8,000 respondents had limited levels of health literacy.¹ Keep this in mind when you are writing online, knowing that patients may access your work. Create something of value by making your piece understandable for everyone who seeks it out.

How is online text read?

When we read books or newspapers, our eyes follow the text from left to right. Studies have shown that when people read online, their eyes start in the middle of the page and move to the right before dropping down to the next line or

section. You can actually see this "F-shaped" style of reading at work if you secretly observe someone reading from their screen. Online content has to therefore look different to the printed page. Paragraphs should be shorter, and lists of bullet points should be more widely used. It has been reported that readers will only read about 20% of the content of an online article about 600 words in length.² Therefore you need to make it easy for your readers to scan the text.

Why do readers abandon pages so quickly? Especially given all the hard work that authors such as ourselves put into each text? We should perhaps be a little more forgiving, because research has shown that reading from a computer screen instead of a page slows down readers by as much as 30%.³ Online readers also experience reading fatigue quicker than "traditional" readers do. Don't forget, online readers are sadly usually not there to enjoy the writing but to get a kick. This kick could be information or diversion.

Think of it like this, offline readers tend to be more conscientious; online readers are scavengers.

Bearing all this in mind, we can improve our online text for potential readers in several ways.

1. Make it shorter

You would not attempt to read *War and Peace* online, (you probably wouldn't offline either, to be honest!) People generally do not like reading long online articles. When someone does, it is usually because it has come from a source well known for long-form reporting such as *The New Yorker*. Otherwise, 1000 words for an online piece is the word limit you often find referenced in articles on the internet. While this might seem like a restriction – an article that is around two pages long – it also works to writers' advantage. Like Quentin Tarantino splitting up *Kill Bill* into two separate films, you too can split up topics or even split one topic into a series of articles – and hopefully get

paid for each one!

Just as the speed of consumption is different for online articles, so too is the speed of production. When I write for print publications, I tend to take my time drafting the article. It is

People read online for different reasons than reading in print. They usually have something specific in mind to help them complete a task. Readers will scan text quickly to find what they want.



often a self-imposed torture that increases as the deadline approaches. I then very reluctantly take a scalpel to my draft article and try to skilfully remove any excess fat without having to do any major reconstruction. When I write for the internet, I tend to write quicker. And then I wield an axe to my work and chop out everything I can. I remove flowery language. I kill any word or phrase that is redundant. I attack prepositions and move sentences around so that clauses or phrases are simply no longer needed. Yes, it hurts any writer to so mercilessly take a knife to their own work (and word count), but I know that it makes for better online text. You might have heard people say that the length of online writing should be 50% of what it would be in print media. That's a tall order for a lot of people! And it gets worse! "Get rid of half the words on each page, then get rid of half of what's left", writes Steve

Krug, a guru on this subject.⁴

Don't make lines too long for the reader to scan. One simple tip I have used is to consider replacing the word "and" anytime you have used it to link sentences with a full stop. If you know that you tend to meander as you write sentences, then check out Stanford University's Writing in the Sciences free online course.⁵ It has certainly helped me to keep my worst excesses in check – obviously not in this article though!

Don't forget, there are advantages to online writing, particularly when we talk about article length. Laborious footnotes are replaced by hyperlinks. Any reader unfamiliar with the subject can choose to follow the links or conduct their own search of unexplained terms. It usually means less "beating about the bush" for the

author as you can assume the reader will fill any important gaps in their knowledge themselves.

Links, of course, can be the rabbit hole of Alice in Wonderland, down which many a reader has lost their way. You can't help what your reader does, but give yourself a fighting chance by making sure each link opens in a new tab. Readers will then not be completely lost if they want to navigate back to your article.

Think of it like this, offline readers tend to be more conscientious; online readers are scavengers.

2. Give clear signposts

Remember that many people will quickly leave your online writing if they don't see what they want straight away. Give yourself a chance of keeping them on the page by making it very clear what the topic is! Luckily, the structure of online writing is very conducive to this.

You should write in short paragraphs. Adding more headers than you would in print not only breaks up the “wall of words” but also broadens the chances of your article being found by a search machine. It also allows you to use different words for the same topic within the piece to help people to find what they are looking for. This is particularly useful when you think about people using the search function and the fact there are different terms for the same thing. Take “mandible”, “lower jaw”, and “jawbone” for example. A reader might miss what they are looking for if they only search for “jaw” when you have used the term “mandible” throughout instead. Before you know it, they have already jumped back to their list of search results.

Something else to keep in mind is that readers can come from anywhere. By that I don’t just mean from anywhere in the world, but how they get to the page containing your writing. Maybe they have followed a link from your previous piece, maybe they used a crazy combination of words on Google, maybe they are already experts in the topic, maybe they are schoolchildren researching for a project. You simply have no way of knowing. Once again, this is another rationale for clearly signposting what the piece is about each time it appears on a new webpage. Repetition or duplication of information isn’t as big a problem online as it is in print. Modern web design will often take care of this for you by having a “fixed” headline above the text, but not always! Research in advance how articles appear on the website you are targeting. (It’s not that dissimilar to when you research the layout of print journals in advance of submitting pieces to them).

You can use boldface or add hyperlinks (which often appear in a different colour and underlined) to make certain words or phrases stand out. Hyperlinks are also useful because they help your page to be more easily found by search engines. Be careful not to overdo it though; it looks amateurish if huge quantities of text are highlighted this way.

Consider credibility too. Make sure your

hyperlinks are to reputable sources. If possible, make sure that relevant information about you, your company, etc. is also available. Online readers are (rightly) suspicious of the *bona fides* of many websites these days.

3. Be mindful of tone

The tone of writing is different online. It is usually more direct and more informal. This article has been written somewhere between the normal tone of a printed article and an online one. Online writing has the advantage of allowing you to express your voice more. You will know this is true when you consider that any one of a number of writers could write a similar sounding scientific report while a popular science blog, for example, will have a very discernible style. Don’t be afraid to embrace the “room to manoeuvre”

that online writing gives you. There is a bit of cyberspace reserved for you!

A quick word on graphics and pictures. They must be appropriate to the piece and of high quality. Unfortunately, this is often not the case. Medical journals still publish graphs that are unreadable. I have seen photos still containing copyright watermarks used by companies that should know better. Don’t let the images around your words have a negative overall effect!

Where to start writing online?

Luckily, because the internet is endless, there are myriad possibilities for where you can start. Maybe you want to begin writing a blog? This could be for your own website, be it

personal or professional. Or why not pitch the idea to your boss (with you taking the writing lead of course)? Many “traditional” companies also have online blogs.

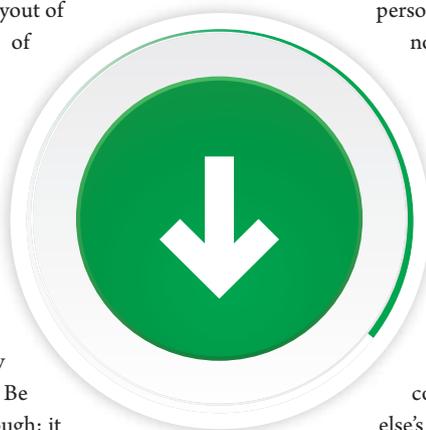
LinkedIn is an excellent option if you just want to dip your toe into online writing. You don’t even have to write a full article. A short commentary on someone else’s work might well be enough to generate some online attention to your words. Some people have lots of followers due to the high-quality posts and articles they

share. Take some time to analyse why certain pieces are gaining traction in your industry and try to incorporate these learnings into your own online writing for LinkedIn. You could post a short piece on something very contemporary, or a longer piece that is more philosophical or analytical.

Of course, there is one place where a medical writer’s work intended for the web is very likely to find a good home. If you are an EMWA member and would like to put what you have just read into action, please remember that we are always looking for content for the EMWA website. Just drop me a line (webmanager@emwa.org) with your article or an idea for an article and your work could soon be available to the whole online world!

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Social media: A tool that can benefit public health?

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Abstract

The global use of social media has changed access to health information, and the internet has become its primary source for the general public. However, judging health information on social networks remains difficult for non-medical readers since most available information is unregulated and of questionable quality, possibly leading to poor health behaviours and decisions. COVID-19 is the greatest public health emergency of this generation that led to a widespread increase of misinformation. Health communicators can play a role in fighting this infodemic by writing about complex issues in accessible language and providing reliable sources. Filtering and translating the information published online is an essential process that will positively influence public health.

The internet has drastically changed the way people access information about almost anything. Health is no exception to this trend and the internet has become the main source of information for many patients wanting to know more about specific health issues.¹

The internet gave rise to social media, enabling individuals or communities to share information and ideas in real-time using internet-based tools: e.g., Facebook, Twitter, Instagram, and blogs. Social media quickly spread from a purely social function for young people to having a wider use across all ages and professions, enhancing education or professional networking and community interaction.²

In recent years, the importance social media has had in influencing societal trends has been amazing. Although influencer marketing is an established marketing strategy, social media has



made it extremely powerful. Influential people become well-known online, they build a reputation within their area of expertise and gather a large number of followers, who pay close attention to their views and are guided by their choices and lifestyle.

Social media and the COVID-19 infodemic

Social media also became an essential part of public health communication and influence, enabling patients to become more active consumers of health information. However, unlike sponsored medical communication and health journalism, blog posts and personal commentary channels have been completely unregulated. With increased social media and internet participation, it has become obvious that there is a need for quality assurance of such information and its sources.¹ This need was brought into sharp focus this year as the world

went through the enormous COVID-19 challenge that created both a huge demand for information as well as a breeding ground for fake news and ludicrous myths. This health crisis was

associated with a new concept: an infodemic, which refers to the large volume of misinformation generated about the disease, its spread, and its treatments. The WHO defined an infodemic as an excessive amount of misinformation that creates confusion and distrust among people, hampering an effective public health response.³

One of the challenges was dealing with the increasing amount of false health content circulating on social media platforms.⁴ Most social media companies (e.g., Facebook and

Twitter) worked alongside the WHO to filter out unfounded medical advice to counter the spread of non-founded ideas that could risk public health.³ Examples of this are taking drugs

The internet has drastically changed the way people access information about almost anything. Health is no exception to this trend and the internet has become the main source of information for many patients wanting to know more about specific health issues.

without a prescription or a bath in bovine faecal matter, drinking toxic detergents, or otherwise partaking in risky behaviours that could have a social negative impact, such as panic shopping or spreading “conspiracy theories”.⁵ Nevertheless, social media was responsible for much unfiltered information online, due to its accessibility and the infinite possibility to spread data throughout the general public.

With the obvious growth of social networking and the public’s hunger for accurate COVID-19 related information, science organisations, policy-makers, healthcare professionals, and organisations also began to communicate via social media. This was helpful in mitigating the infodemic phenomenon and was effective in raising awareness about misinformation and how it can be minimised.

Ways to improve health communication on social media

Judging health information on social networks remains difficult for nonmedical readers as much of this freely available information is unregulated and of questionable quality. Accurate methodology and reporting is important as it adds to the belief construct and reassures the scientific community that the data the authors set out to obtain is correct and accurate. For example, scientific communication is usually regulated by the peer-review and publishing process, which ensures that each published study is appropriately designed, performed, and reported.⁶ However, for the general public, this peer-review process is non-existent. Sometimes a press release, blog, or a simple statement citing data can be confusing and raise unfulfillable expectations. To avoid this, health writers should highlight whether or not a given study was peer-reviewed and explain that this means the validity and quality of reporting has been checked by other experts in the field. Also, it is important to place the study data in the long evidence-building process, e.g., “this is the first study in humans and the results will now need to be confirmed in larger, controlled studies”, so the public knows what to expect and how to act accordingly.

When writing for patients and lay audiences, word choice is imperative. Each word must accurately reflect the data in a language the reader understands. One single word can alter the meaning of a simple sentence, for example: “This study *shows* treatment X is effective” vs. “This study *suggests* treatment X is effective”. The

general public may perceive the word “shows” as the same as “suggests”, thus raising false certainties about a subject that can be wrongly relayed across social media platforms. Another example is the word “significantly” that is often used when reporting quantitative data but has a specific meaning in science. Undoubtedly, the word “significantly” should only be used if there is a p-value associated with the datapoint. However, if a study result has a non-significant result, it does not mean there is no clinical difference. Other factors such as the sample size must be taken into account for the practical significance to be determined, so it is also important that the medical writer places the study results in context when communicating to the lay audience.

Furthermore, the language and vocabulary used should be appropriate for the lay audience, and it has to be engaging and appealing on social media. Using short sentences with a straightforward message in a relaxed tone with everyday language is preferable, and bullet points make complicated concepts easier for the reader to capture, understand, and remember.

Lastly, reconceptualising the data by using imagery, visualisation, or numeracy are useful ways of explaining health data. For example, in the context of the COVID-19 pandemic, several health organisations like WHO adopted this strategy and used engaging imagery on social media to make the public aware of important health issues to be taken into account during the pandemic (Figure 1).



Figure 1. WHO’s infographics available on Facebook, designed to educate about ways to reduce the risk of becoming infected with COVID-19

(<https://www.facebook.com/WHO/photos/a.167668209945237/3538127066232651>)

Thus, filtering information published online and, sometimes, translating it so that it targets a specific audience is a necessary process that can have positive implications on public health. It is clear that governments and institutions must create guidelines and mechanisms to control the information flow on the internet.⁷ Health writers should also be encouraged to critically analyse information before communicating it on social media and be a part of the filtering and “translating” process, as this is their field of expertise.

The COVID-19 infodemic brought to light the urgent need to teach the public about the clinical trial process and the role that scientists, regulators, and manufacturers have in creating and developing a drug and, to what lengths they go to ensure that medicines are safe and effective. This information, brought by the science communicators, must be reliable and accessible, as the general public should be able to understand the basics of science in order to make correct and informed decisions. Since patients increasingly use social media to educate themselves about their health problems, used responsibly, it could be a useful tool to educate patients and promote public health messages.^{8,9}

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Conflicts of interest

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Since patients increasingly use social media to educate themselves about their health problems, used responsibly, it could be a useful tool to educate patients and promote public health messages.

Partnering with patient associations: Engaging medical writers to support health literacy for patients

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Abstract

As patients are increasingly involved in healthcare decisions, there is a growing need for them to have access to appropriate health information. Medical writers, being a link between medical research and published data, are well placed to make medical research accessible for patients. Presented here is a discussion with Otto Spranger, patient advocate of the Global Allergy and Airways Patient Platform, Vienna, Austria, about access to clinical research data and the role of medical writers in improving health literacy.

What challenges do patients face in getting healthcare information today?

In recent years, the healthcare industry in Europe has faced growing challenges and pressure to effectively manage human health. The current population demographics are putting pressure on the sustainability of our health systems. New epidemics, such as coronaviruses, put peaks of pressure on hospital and community care, and new technologies such as artificial intelligence and e-health are revolutionising the way health is managed.¹

In this context, patients are taking on increasing responsibility for their health in a situation where they have less time with their traditional information source, their doctors. This lack of health information support is driving patient hunger for health news and information. However, for a patient to be empowered to make

sound health decisions, they need to be sufficiently informed and health literate. Yet, many patients lack sufficient health literacy to understand the information to make these health decisions. Although the level of health literacy worldwide is improving, many patients still have difficulty obtaining and understanding health information. One such problem is access to clinical research data. Many patients find themselves lost in a plethora of information that is difficult for them to understand and relate to their health issues.

What challenges do patients face in accessing clinical research data and how does it impact treatment?

In recent years, access to clinical research data has improved remarkably. Researchers in both academia and industry have been making clinical documents and datasets available through various independent portals such as clinicalstudydatarequest.com, yoda.yale.edu, clinicaltrials.gov, EudraCT, ICTRP, and other publicly available, sponsored websites.

More recently, the (EU) Clinical Trials Regulation No 536/2014

formalised clinical research data access by requiring sponsors to make layperson summaries available on a European Medicines Agency portal and database. These layperson summaries describe the designs and results of individual clinical studies using plain language, figures, and pictograms.

They are written for interested readers with limited health literacy or scientific expertise to help them understand clinical study results.³ Although this will provide easier access to clinical research data, it will also create a problem for interested readers who will then need to deal with the vast volume of mostly industry-sponsored data. The public will also have to learn how to place individual trial results into the overall research context, which raises another issue: the lack of independent academic research.

Currently, a large proportion of clinical research studies are run by industry. Although the EU actively supports basic research, more independent clinical research is needed. A particular example is in the field of allergies. In recent years, few innovations have appeared in this field and most interventions only treat symptoms. This lack of basic and clinical research means that information about the treatment of asthma or other respiratory diseases is limited. This lack of balanced information is particularly problematic for both patients and general practitioners, who need to understand the underlying disease process and appropriate treatment.

A clear example of this is the current overuse of short-acting beta 2 adrenergics (SABAs). Inhaled SABAs have been a part of first line and emergency treatment for 50 years and both doctors and patients appreciate this treatment it provides rapid symptom relief. But then, patients begin to rely on symptom relief and often

discontinue the background inhaled corticosteroid therapy that prevents the underlying inflammation. One reason for this is some patients are anxious about taking cortisone. Hence, this results in situations today where patients do not always take their asthma medication correctly and this is leading to unnecessary deaths. The Global Initiative for Asthma (GINA), a joint programme involving international stakeholders, is determined to improve asthma treatment.⁴ The GINA reports provide physicians with an up-to-date review of the literature and evidence-based strategies that can be easily implemented in clinical practice to help improve asthma treatment.

What are the current patient needs?

There is a current need to educate patients after diagnosis about medication. Patients need to take their medication, have good lifestyle habits, and



avoid behaviours that may worsen their disease, even if they are feeling well. In asthma, learning to use the inhaler correctly to fully benefit from the medication is important. Yet in the UK alone, almost two-thirds (65%) of people with asthma do not receive primary care from a healthcare professional, which includes an annual review and a check to ensure they are using their inhaler correctly. There is a need to ensure that clinicians follow treatment guidelines, and that patient preferences be included into practice guidelines.⁵ Also, more patients need to become better informed about their condition and how to manage it best. The improvements made in patient management in the diabetes field could be a benchmark for other disease areas.

What advice do you have for medical writers?

Medical writers as communicators of medical research play a key role in making medical

research data accessible for patients and help them to sift through misinformation. They can become involved with industry-sponsored websites or web-based services destined for patients, families, and carers. When publishing protocols or research data, medical writers can keep the patient in mind since patients also have access to public databases and may need assistance to understand the impact of these data on them. Also, medical writers can

The improvements made in patient management in the diabetes field could be a benchmark for other disease areas.

help to place the research data in context of the overall clinical research process.

Medical writers have close contact with researchers. This means that they are well-placed to encourage authors of both academic and industry studies to publish research. This may be particularly important for trials where the endpoint is not met or for subpopulation analyses that show a strong activity of interest to patient association members, even though they may have less priority for industrial partners who

may be more focused on registration and reimbursement.

Medical writers understand the clinical research process and as storytellers are well placed to educate patients. Working with patient associations, medical writers can help educate patients to disseminate truthful information. This may involve explaining a disease process, treatment, or where a study may fit and what the results of a given trial may mean to them. They can also ensure that trial reporting is balanced and that ethical standards are maintained.

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Pharmaceutical clinical trials transparency and privacy

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Abstract

With the introduction of new clinical trial transparency regulations around the world, transparency functions have had to adapt to a range of reporting requirements. In 2007, the FDA Amendments Act (FDAAA) established requirements for trial sponsors to reveal trial results to participants and patients, physicians, and independent researchers. Since then, more requirements have emerged, including anonymisation and publication policies introduced by the EMA and Health Canada. Going beyond regulatory compliance, transparency leaders have launched voluntary data-sharing initiatives to enable researchers' access to structured individual patient data. With this move toward greater transparency and the drive for more data, transparency functions working with the clinical trials environment need a broader toolkit of capabilities, including anonymisation, to protect participants' privacy. The authors explored these emerging trends in a webinar for FDANews on July 23, 2020 (<https://www.fdanews.com>). FDANews has an 80,000-person database, mainly from the clinical trial space. This article summarises the webinar.

Clinical trial transparency goals

The clinical trial transparency landscape has evolved over the last decade, with rising expectations for openness and disclosure. The goals of greater clinical trial transparency are multiple, with benefits to trial participants,

clinical trial sponsors, regulators, the scientific community, and, ultimately, patients. Examples of these benefits include:

- **Avoiding duplication.** Transparency can help ensure the right trials are conducted by informing funders and researchers on which trials are needed and avoiding research duplication.
- **Patient access.** Transparency can help potential clinical trial participants better understand their options to enrol in new trials.
- **Better decisions.** With more complete information available from trials, better decisions can be made by those using evidence from clinical trials.
- **Higher quality.** By enabling the scientific community to examine clinical research, engage in quality improvement, and identify gaps in data, a more robust quality-predicated system can be attained.
- **Trust.** Transparency can build trust between the public, sponsors, and regulators through greater openness and collaboration.

Transparency involves multiple points of disclosure prior to, during, and after the clinical trial:¹

1. Registration on a publicly accessible registry, such as ClinicalTrials.gov
2. Posting of summary results in a timely fashion, using plain language
3. Making trial reports publicly accessible and publishing trial outcomes
4. Sharing individual participant data in a privacy-preserving manner

Several new regulations have emerged to enforce greater transparency, from trial registration to publication of the clinical study reports (CSRs).^{2,3} In addition to regulatory shifts toward greater transparency, many sponsors are adopting discretionary measures, such as voluntarily sharing anonymised participant data with researchers.^{4,5}

FDA requirements

The Food and Drug Administration Amendments Act of 2007⁶ (known as FDAAA) established a requirement for certain (applicable) clinical trials to be registered at trial initiation and

to report summary results after trial completion in the public registry and results database (ClinicalTrials.gov). This law was intended to facilitate enrolment in clinical trials, allow for tracking of the progress of such trials, and address problems with the lack of timely dissemination of research findings.

What is an applicable clinical trial (ACT)? ClinicalTrials.gov has a checklist for evaluating whether a clinical trial or study is an ACT.⁷ In general, ACTs are trials of drugs and biologics: controlled clinical investigations, other than Phase 1 clinical investigations, of a drug, biological product, or medical device subject to FDA regulation, where a controlled clinical investigation generally includes interventional studies (with one or more arms) that meet one of the following conditions:

- have one or more sites in the US
- are conducted under an FDA investigational new drug application (IND) [or, in case of a device trial, investigational device exemption]
- involves a drug, biologic, or device that is manufactured in the US and is exported for research.

Since September 2007, it has been a requirement to submit registration information to ClinicalTrials.gov for all ACTs that were either initiated after September 27, 2007, or initiated on or before that date and were still ongoing as of December 26, 2007. This registration submission must be made no later than 21 days after enrolment of the first participant. Subsequent updates have included:⁸

- September 2008: the requirement to submit summary results for clinical trials of approved products within 12 months of the completion date (primary completion date [PCD]), where the PCD is the date of final data collection for the primary outcome measure(s) (OMs).
- September 2009: the requirement to include certain adverse event information in the summary results.
- September 2016: the Final Rule extended the requirement for results information submission to ACTs of a drug, biological product, or medical device that is *not* approved, licenced, or cleared by the FDA, thus alleviating concerns regarding bias in the

Since September 2007, it has been a requirement to submit registration information to ClinicalTrials.gov for all ACTs that were either initiated after September 27, 2007, or initiated on or before that date and were still ongoing as of December 26, 2007.



literature and possible selective publication of only those approved products.⁹ The Final Rule, which took effect on January 18, 2017, also introduced the requirement to submit the full protocol and statistical analysis plan along with the final results posting.

- January 2019: the requirement to indicate whether there is a plan to make individual participant data collected in the study, including data dictionaries, available to other researchers (typically after the end of the study).
- January 2020: all results postings (trials with a start date on or after January 18, 2017, with first submitted results information on or after January 01, 2020) will be publicly posted within 30 days of submission, regardless of a completed review process by ClinicalTrials.gov (Protocol Registration and Results System [PRS] review), including any brief Quality Control (QC) comments that identify at least one major issue (major issues identified in the comments must be corrected or addressed),

along with a note that the QC has not concluded. All versions of the QC reviewed record will then be posted until the review process concludes.

ClinicalTrials.gov common pain points

Within the results database, examples of common pain points include, but are not limited to:

- Changes made to the text in the treatment arm descriptions are not carried throughout the tabulated database, so any changes made to the descriptive text must be manually repeated throughout the database each time the treatment arm is presented.
- A similar issue exists if there is a need to repeat a statistical analysis: no option to copy.
- Unable to have multiple units of measure within an OM, e.g., for a table presenting pharmacokinetic results. The only option is to split the OM over multiple OMs, i.e., by unit.
- When a study has two or more periods: ClinicalTrials.gov dictates that all treatment arms are repeated for all periods, utility would

be improved if there was the option to select different treatment arms for multiple periods.

With regard to the PRS review/QC, examples of common pain points include, but are not limited to:

- Contributors may use a “lesson learned” approach from a previous posting to guide addressing a similar scenario in a different posting; however, that does not necessarily mitigate for conflicting PRS comments. This lack of consistency is also apparent when results are resubmitted following updates due to PRS comments. It would be advantageous to have the same PRS reviewer for resubmitted results to avoid the scenario where a different reviewer raises a separate issue with the resubmitted results that was not raised at the initial submission.
- Despite the clarity of the definition between “major” and “advisory” issues, there is inconsistency across studies in the ranking of the identified issues. Each major issue must

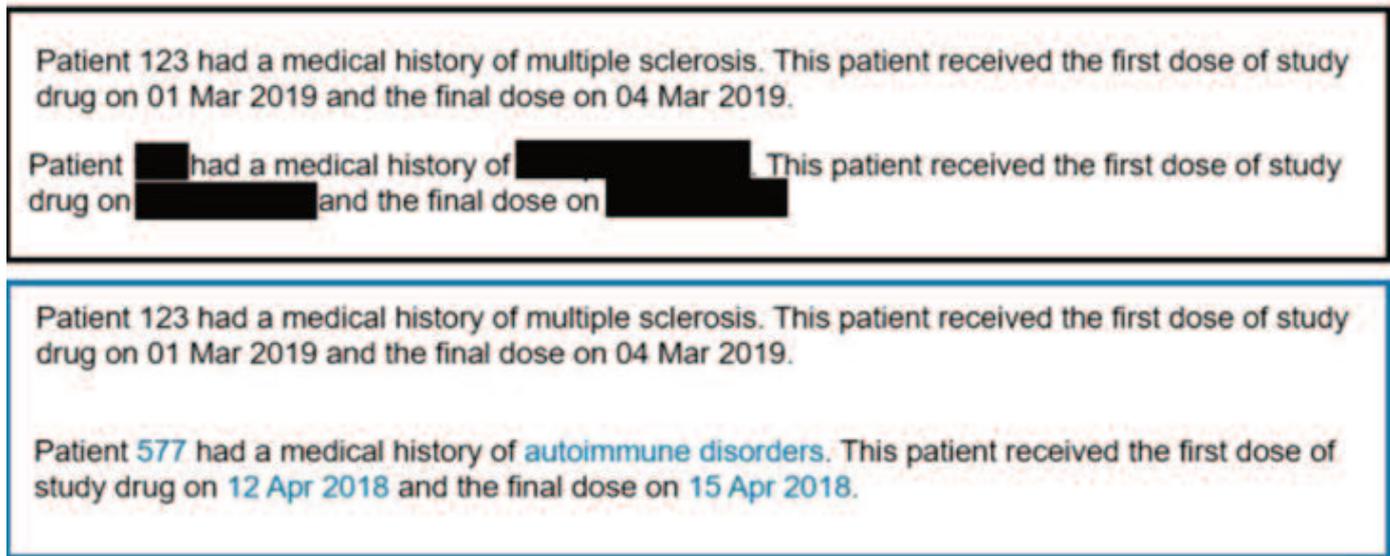


Figure 1. Visual comparison of redaction and anonymisation

Redaction of text shown above, where an opaque box obscures the information. Anonymisation of the same text shown below. A combination of pseudonymisation, generalisation, and date shifting are used to transform the text. The transformations are highlighted in blue in the figure for illustrative purposes only, whereas actual anonymisation benefits from the privacy concept of ‘hiding in plain sight’ whereby the information altered is not discernible.

be corrected or addressed, while advisory issues are suggestions only for improving the clarity of the record.

ClinicalTrials.gov best practices

In terms of clinical trial registration, submitting registration information to the PRS is relatively straightforward since there is typically limited interpretation required if the protocol is complete. The required content includes descriptive information, recruitment information, location and contact information, and administrative data elements.

The results section, on the other hand, while straightforward when it comes to entering appropriately compiled data, is often more complex, so it is important to assign the appropriate personnel. The preparation of clinical trial results posting is more than just an administrative task and is more suited to someone familiar with study protocols and CSRs and has experience in summarising clinical trial data. Lessons learned have suggested basic results entries have fewer errors and quality review comments from ClinicalTrials.gov when the appropriate person (e.g., medical writer) is tasked with preparing results information for submission.

Future considerations of clinical trial registration and results information submission

In 2019, the National Library of Medicine launched the ClinicalTrials.gov modernisation effort, which included a request for information from the public to guide efforts to enhance and better support the users of ClinicalTrials.gov.

All responses from the public were to be received by March 14, 2020, and were both published and shared via a public meeting in April 2020.¹⁰ At the time this article went to press, the outcome of the modernisation effort was still awaited.

Other requirements around the globe

Other regulators around the world have introduced similar measures to promote transparency. Two have recently gone further by mandating the anonymisation and publication of CSRs: the EMA and Health Canada.

EMA Policy 0070

In 2016, the EMA implemented Policy 0070, which requires publication of the regulatory documents used in a successful marketing authorisation application.

These documents include the CSR and selected appendices, as well as clinical overviews and clinical summaries. The CSR provides extensive details on the clinical trial, including the study objective, the investigational plan, and study design, the evaluation and analysis performed, as well as specific information about the trial subjects. This last item – detailed information about the participants’ experience in the trial – creates potential privacy concerns and necessitates effective anonymisation of the CSR prior to publication.

The EMA’s external guidance on the implementation of Policy 0070 encourages applicants to use quantitative methods to measure the risk of re-identification, recommending a risk threshold of 0.09.¹¹ The re-identification risk will depend upon indirectly identifying information in the documents, such as demographics and medical history information. The CSRs must be anonymised to mitigate the re-identification risk and reduce it to an acceptably low level (below 0.09). Applicants are asked by the EMA to justify alterations to the data and their choice of anonymisation techniques.

This updated guidance from the EMA in 2018 further reinforced a preference for

quantitative measures of risk over qualitative assessments and from redaction to anonymisation. Redaction, in this case, means complete concealment of patient data with an opaque box, such that all the inherent usefulness of the information is effectively removed. Anonymisation refers to the replacement of the original text with re-synthesised values selected to bring the re-identification of a given trial participant below the threshold. A visual comparison is presented in Figure 1.

While the EMA paused its Policy 0070 efforts due to a temporary closure following Brexit, it plans to resume efforts from its new headquarters in Amsterdam. During its June 2020 board meeting, the EMA affirmed its plan to resume publication for COVID-19 trial information, citing assurance needed by the public over the quality of evidence behind regulatory decisions.¹²

EMA's Policy 0070 contemplates a second phase in which the disclosure of participant-level data will be mandated, though timelines have not yet been announced.

Health Canada Public Release of Clinical Information

In 2019, Health Canada introduced its Public Release of Clinical Information (PRCI) requirements. PRCI mirrors EMA requirements, with the disclosure of CSRs now required for market authorisation. However, unlike EMA Policy 0070, PRCI also applies to historical submissions upon request.

Health Canada's guidance asks manufacturers to anonymise the clinical information using a risk-based statistical anonymisation process that is closely aligned to EMA guidance. Like EMA, Health Canada recommends a threshold of 0.09.¹³

While Health Canada has been explicit in their preference for a quantitative approach to re-identification risk measurement, during the early period of adoption, they have accepted submissions where a non-analytical or qualitative approach was taken, as well as those in which redaction was applied. However, there is a strong indication that Health Canada is encouraging a movement away from reliance on these methods. As an example, certain submissions that were heavily redacted were published with a notice from Health Canada:



NOTICE:

This clinical information package includes extensive redactions to the patient information. These redactions do not conform to Health Canada guidance, which encourages manufacturers to retain the analytical value of information by using other transformation methods (e.g., generalisation or randomisation), and to apply these methods to specific information that risks re-identifying an individual rather than to redact broad sections of information.

Health Canada encourages manufacturers to anonymise personal information according to the principles outlined in Guidance Document: Public Release of Clinical Information. Health Canada will continue to explore ways to help ensure all publications include anonymized personal clinical information.

If you require access to the redacted information, you may submit inquiries to the Information Science and Openness Division (hc.clinicaldata-donneescliniques.sc@canada.ca).

Health Canada's PRCI is very similar to the EMA's Policy 0070, with a few notable differences:

1. Health Canada's PRCI applies to device trials, in addition to drug and biologic trials.
2. In addition to proactive submissions for market authorisation, Health Canada's PRCI includes the publication of historical studies in response to access-to-information requests from the public.
3. Health Canada has not announced plans to enforce disclosure of individual participant-level data, whereas EMA has indicated its intent for a Phase 2 encompassing participant-level data.

Other minor variances exist, such as abnormal laboratory value listings being "in scope" for Health Canada PRCI but not for EMA Policy 0070. However, Health Canada has indicated its intent on accepting previously approved EMA packages to avoid effort duplication.

Statistical anonymisation

With the shifts to publishing the complete CSRs, several manufacturers have also shifted from using basic redaction methods to statistical anonymisation.¹⁴ With the regulatory timelines, particularly for historical study requests in Canada, the need for scalable, efficient anonymisation capabilities has become more apparent.



By developing statistical anonymisation capabilities, organisations can safely share and reuse data for a variety of beneficial purposes, transforming data in a manner commensurate with the risk to protect privacy and achieve transparency.

With investment in anonymisation capabilities, new opportunities to reuse data for other purposes, including internal innovation, have become more evident. Organisations can use anonymisation to gain secondary benefits from trial data, such as gaining insights into the drug discovery process.

A statistical anonymisation approach and capability can be applied to a wide range of contexts and data types. The process of anonymisation evaluates the context of disclosure to understand potential threats and uses this to evaluate the identifiability of the data. The contextual evaluation should consider all means reasonably likely to be used to re-identify individual people. The data are then evaluated using generally accepted statistical techniques that measure whether individuals can be identified in the data. Finally, the data are transformed to the degree necessary to be rendered non-identifying.

When anonymising documents for transparency, a key first step in the process is detecting all the identifying variables associated with each individual data subject (i.e., trial participant) in order to measure identifiability. While directly identifying information (e.g., subject IDs, or direct identifiers like names, addresses or email addresses) is removed or pseudonymised, the

indirectly identifying information is typically preserved as much as possible without compromising privacy through re-identification. Indirectly identifying information includes demographics, medical histories, event dates, diagnoses, treatments, and other information that may be used in combination to identify an individual person. Many transformation techniques, such as generalisation, randomisation, date shifting, and targeted suppression, can be used in a flexible manner that preserves as much utility (and transparency) as possible.

A recent article in the journal *Trials* (February 2020) included results from a commissioned re-identification attack on a clinical study that had been anonymised using statistical methods according to EMA Policy 0070 guidance.¹⁴ The study results suggest that anonymisation provides adequate privacy protection for trial participants, with very low confidence match scores achieved with over 24 hours of effort per attempted match during the commissioned attack.

The same statistical anonymisation methodology can be applied to discretionary data sharing in support of transparency, transforming individual participant data to the degree necessary to safely support secondary research. Similarly, internal reuse of the data can be achieved through

functional anonymisation. Contextual factors, such as security, privacy, and contractual controls, should be considered in the anonymisation approach, with less controlled releases needing more data transformation. By developing statistical anonymisation capabilities, organisations can safely share and reuse data for a variety of beneficial purposes, transforming data in a manner commensurate with the risk to protect privacy and achieve transparency.

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Disclaimers

The opinions expressed in this article are the authors' own and not necessarily shared by their employer or EMWA.

Conflicts of interest

The authors declare no conflicts of interest.

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News from the EMA

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Making the best use of big data for public health: Publication of the Big Data Steering Group workplan for 2020–2021

September 14, 2020 – The Big Data Steering Group set up by EMA and the Heads of Medicines Agencies (HMA) has published its workplan which sets actions to be delivered in 2020–2021. With the European Medicines Regulatory Network focused on the response to the COVID-19 pandemic, the workplan aims to progress evolution to data-driven regulation through smart working, leveraging collaboration with stakeholders and the use of remote expert workshops.

In the past three years, EMA and HMA have led a thorough assessment of the challenges and opportunities posed by big data in medicines' regulation. This culminated in January 2020 with the publication of recommendations for regulators to evolve their approach to data use and evidence generation. Following this preparatory work, the Big Data Steering Group was established in February 2020 to advise the EMA

Management Board and HMA on implementing ten priority recommendations.

Its first workplan, published on September 14, 2020, aims to increase the utility of big data in regulation from the quality of data through study methods to assessment and decision-making. It foresees closely involving patients and is guided by advances in science and technology. Other stakeholders will also be involved and the workplan intends to leverage international collaboration. Stakeholders will have the opportunity to discuss the workplan and its implementation in the context of a virtual multi-stakeholder forum scheduled for late 2020.

Big data are extremely large, rapidly accumulating datasets captured across multiple settings and devices, for example through wearable devices and electronic health records. Coupled to rapidly developing technology, big data can complement the evidence from clinical

trials and fill knowledge gaps on a medicine, and help to better characterise diseases, treatments, and the performance of medicines in individual healthcare systems. The rapidly changing data landscape forces regulators to evolve and change the way they access, manage, and analyse data and to keep pace with the rapid advances in science and technology.

The work carried out by the Big Data Steering Group builds on the Regulatory Science Strategy to 2025, published in March 2020, and will support the European Medicines Agencies Network Strategy to 2025, currently under development. The European Medicines Regulatory Network has to prioritise the unprecedented public health challenge of the COVID-19 pandemic and implementation of the Big Data Steering Group workplan will need to be flexible and certain actions may need to be re-scheduled depending on the development of the pandemic.



September 18, 2020 – EMA has recommended granting an extension of indication for Velphoro (sucroferic oxyhydroxide) to include control of serum phosphorus levels in children aged 2 years or older with chronic kidney disease (CKD) stages 4–5 or with CKD on dialysis. Patients with severe kidney disease cannot eliminate phosphate from their bodies. This leads to hyperphosphataemia (high blood phosphate levels), which, in the long term, can cause complications such as heart and bone disease.

The active substance in Velphoro, sucroferic oxyhydroxide, a mixture of iron (III)-oxyhydroxide, sucrose, and starches, is a phosphate binder. When taken with meals, the iron contained in Velphoro attaches to phosphate from food within the gut, preventing it from being absorbed into the body and helping to keep down the phosphate levels in the blood. Velphoro should be used with other treatments such as calcium or vitamin-D supplements, which help to control bone disease linked to kidney failure and high phosphate levels.

Velphoro in the new therapeutic indication brings a significant clinical benefit compared to existing treatments. There are currently no

New treatment for children with chronic kidney disease



existing therapies of phosphate binders indicated for the control of serum phosphorus levels in children between 2 and 6 years old with CKD stages 4–5 who are not on dialysis. In addition, the medicine has been re-formulated into 125 mg powder for oral suspension, which is easier to be administered to small children.

EMA's human medicines committee (CHMP) based its recommendation for Velphoro on the assessment of an open-label, randomised phase 3 clinical study, which included 85 children from 2 years of age with CKD and hyperphosphatemia. The results showed normal phosphorus range after treatment in a large proportion of

patients, comparable to what was observed for adults. The adverse reactions most frequently reported with this treatment were gastrointestinal disorders, including diarrhoea, vomiting, gastritis and discoloured faeces.

The marketing authorisation (valid throughout the European Union since August 26, 2014) holder is Vifor Fresenius Medical Care Renal Pharma France. Currently, Velphoro is approved as 500 mg chewable tablets for use in adults only. Following the CHMP recommendation, the summary of product characteristics, the package leaflet, and the labelling for Velphoro will be updated accordingly.

EMA endorses use of dexamethasone in COVID-19 patients on oxygen or mechanical ventilation

September 18, 2020 – EMA's human medicines committee (CHMP) has completed its review of results from the RECOVERY study arm that involved the use of the corticosteroid medicine dexamethasone in the treatment of patients with COVID-19 admitted to hospital, and has concluded that dexamethasone can be considered a treatment option for patients who require oxygen therapy (from supplemental oxygen to mechanical ventilation).

Based on the review of available data, EMA is endorsing the use of dexamethasone in adults and adolescents (from 12 years of age and weighing at least 40 kg) who require supplemental oxygen therapy. Dexamethasone can be taken by mouth or given as an injection or infusion (drip) into a vein. In all cases, the recommended dose in adults and adolescents is 6 milligrams once a day for up to 10 days.

Published data from the RECOVERY study show that in patients on invasive mechanical ventilation, 29% of those treated with dexamethasone died within 28 days of starting dexamethasone treatment compared with 41% of

patients receiving usual care, with a relative reduction of about 35%. In patients receiving oxygen without mechanical ventilation, the figures were 23% with dexamethasone and 26% with usual care, with a relative reduction of about 20%. No reduction in the risk of death occurred in patients who were not receiving oxygen therapy or mechanical ventilation. These results were supported by additional published data, including a meta-analysis conducted by the World Health Organization, which looked at data from seven clinical studies investigating the use of corticosteroids for the treatment of patients with COVID-19.

Companies that market dexamethasone medicines can request this new use to be added to their product's licence by submitting an application to national medicines agencies or to EMA. The proposed changes to the dexametha-

some product information for patients and healthcare professionals are available.

Dexamethasone is a corticosteroid medicine that has been authorised in the EU by national medicines authorities and has been available for several decades. It can be used by mouth and by injection for treating a range of inflammatory conditions and for reducing the body's immune response in the treatment of allergies and autoimmune diseases. It is also used with cancer medicines to treat certain cancers and to prevent vomiting. Dexamethasone was first considered a potential treatment for COVID-19 because of its ability to reduce inflammation, which plays an important role in the disease process in some patients who have been admitted to hospital with COVID-19.



How incidents with medicines are managed in the EU – a 10-year analysis

September 23, 2020 – The EU medicines network is supported by a robust regulatory framework with defined processes and clear responsibilities in place to handle public health incidents, according to a 10-year analysis of the European Union incident management plan (EU-IMP) published in the journal *Pharmacoepidemiology and Drug Safety*.

EMA, in collaboration with the HMA and the European Commission, established the EU-IMP in 2009 to enable rapid and effective actions across the EU in case of an event or new information on medicines authorised in the EU with a potential serious impact on public health. Such incidents can affect the safety, quality, efficacy, or availability of a medicinal product and causes may include the product's safety profile, manufacturing compliance, or supply chain issues.

When an incident is suspected, a group of experts from EMA and its scientific committees, the European Commission, and the national

competent authorities, called the Incident Review Network (IRN), convenes within the shortest possible time to assess the potential public health impact and recommend the appropriate regulatory pathway and the most appropriate communications.

During the first ten years of operation of the EU-IMP, a total of 78 incidents were managed through the IRN. Of these, 70% were triggered by information that came to EMA from national competent authorities, followed by information from marketing authorisation holders (17%). During the observation period, more than half of the issues addressed concerned the safety of medicines, while quality and non-compliance with good manufacturing practices accounted for over one third of issues.

Regarding the final outcomes of the incidents managed through the IRN, almost half resulted in a variation to the marketing authorisation and/or risk minimisation measures of the

concerned medicine. 22% led to no change to the marketing authorisation, 10% led to the suspension and 9% to the revocation of a medicine's marketing authorisation.

The analysis also highlights that the implementation of the revised pharmacovigilance legislation in 2012 has offered robust regulatory instruments and has established clear roles and responsibilities to directly manage most safety issues without the need to go through the IRN mechanism.

The published article can be accessed free of restrictions: Santoro A, Caplanusi I, Sweeney F, Cappelli B, Nolan L, Straus S, Arlett P. Navigating stormy waters: 10 years of operation of the European Union Regulatory Network Incident Management Plan for Medicines for Human Use. *Pharmacoepidemiol Drug Saf.* 2020 Sep 21. doi: 10.1002/pds.5133. PMID: 32954565.





EMA recommends first COVID-19 vaccine for authorisation in the EU

December 21, 2020 – EMA has recommended granting a conditional marketing authorisation for the vaccine Comirnaty, developed by BioNTech and Pfizer, to prevent coronavirus disease 2019 (COVID-19) in people from 16 years of age. EMA's scientific opinion paves the way for the first marketing authorisation of a COVID-19 vaccine in the EU by the European Commission, with all the safeguards, controls, and obligations this entails.

EMA's human medicines committee (CHMP) has completed its rigorous evaluation of Comirnaty, concluding by consensus that sufficiently robust data on the quality, safety, and efficacy of the vaccine are now available to recommend a formal conditional marketing authorisation. This will provide a controlled and robust framework to underpin EU-wide vaccination campaigns and protect EU citizens.

"Today's positive news is an important step forward in our fight against this pandemic, which has caused suffering and hardship for so many", said Emer Cooke, Executive Director of EMA. "We have achieved this milestone thanks to the dedication of scientists, doctors, developers and trial volunteers as well as many experts from all EU Member States.

"Our thorough evaluation means that we can confidently assure EU citizens of the safety and efficacy of this vaccine and that it meets necessary quality standards. However, our work

does not stop here. We will continue to collect and analyse data on the safety and effectiveness of this vaccine to protect people taking the vaccine in the EU."

A very large clinical trial showed that Comirnaty was effective at preventing COVID-19 in people from 16 years of age.

The trial involved around 44,000 people in total. Half received the vaccine and half were given a dummy injection. People did not know whether they received the vaccine or the dummy injection.

Efficacy was calculated in over 36,000 people from 16 years of age (including people over 75 years of age) who had no sign of previous infection. The study showed a 95% reduction in the number of symptomatic COVID-19 cases in the people who received the vaccine (8 cases out of 18,198 got COVID-19 symptoms) compared with people who received a dummy injection (162 cases out of 18,325 got COVID-19 symptoms). This means that the vaccine demonstrated a 95% efficacy in the clinical trial.

The trial also showed around 95% efficacy in the participants at risk of severe COVID-19, including those with asthma, chronic lung disease, diabetes, high blood pressure or a body mass index ≥ 30 kg/m². The high efficacy was maintained across genders, racial and ethnic groups.

Comirnaty is given as two injections into the

arm, at least 21 days apart. The most common side effects with Comirnaty were usually mild or moderate and got better within a few days after vaccination. They included pain and swelling at the injection site, tiredness, headache, muscle and joint pain, chills and fever. The safety and effectiveness of the vaccine will continue to be monitored as it is used across the member states, through the EU pharmacovigilance system and additional studies by the company and by European authorities.

Where to find more information

The product information approved by the CHMP for Comirnaty contains prescribing information for healthcare professionals, a package leaflet for members of the public and details of conditions of the vaccine's authorisation.

An assessment report, with details of EMA's evaluation of Comirnaty, and the full risk management plan will be published within days. Clinical trial data submitted by the company in the application for marketing authorisation will be published on the agency's clinical data website in due course.

More information is available in an overview of the vaccine in lay language, including a description of the vaccine's benefits and risks and why EMA recommended its authorisation in the EU.



Editorial

Medical device writers, you, too, can now enhance your skill set by writing for patients. Access to information about medical devices is expanding for patients in Europe with the implementation of the new Medical Device Regulation (MDR). One of the new requirements of the MDR is to provide a summary of

safety and clinical performance (SSCP) that includes detailed information on a medical device for both healthcare providers and patients. In this issue, Laura C. Collada Ali and Katharina Friedrich summarise the content of the EMWA webinar they led in September to share their initial experience writing SSCPs. They describe here some of the common pitfalls they

encountered and strategies to help you avoid them. If you missed the live webinar or simply want to watch it again, you can access the recording on the EMWA Webinars Archive webpage (https://members.emwa.org/EMWA/Member_Area/Webinars.aspx).

Kelly

First experiences writing summaries of safety and clinical performance for medical devices

The Medical Devices Regulation (MDR 2017/745) has been postponed due to the coronavirus pandemic and will now take effect on May 26, 2021.¹ Some manufacturers may regard this as a slight breather, but there are still enough obstacles to overcome. The MDR enforces stricter rules on the clinical evaluation process with a focus on safety and performance of medical devices and introduced several new document requirements. The summary of safety and clinical performance (SSCP) is one such document, completely new to the medical device industry and unique in its structure and purpose. The SSCP will be available to the public, including a section for healthcare professionals and a separate section for patients, if necessary. The patient section is required for implantable devices that include an implant card and for class



III devices that are used directly by patients. To prepare this document, medical writers need strong technical writing skills, and in addition,

must transfer a lot of technical content into lay language.

In 2019, the Medical Devices Coordination Group published a guidance on the SSCP with writing instructions and recommendations for the minimal required content.² The content for the healthcare professional and the patient sections are quite similar; detailed information on the device, pre-clinical and clinical data, alternative treatment methods as well as risk management and post-market surveillance activities have to be disclosed (Table 1).

The SSCP should be completely sourced from the technical documentation. At first glance, preparing such a document does not seem to be a challenge, entailing more copying and pasting of existing text than real writing. However, as a medical writer, you will notice that there are

Table 1. Comparison of SSCP table of contents for healthcare professionals and patients

Healthcare professionals

1. Identification of the device and the manufacturer
2. Intended use of the device
3. Device description
4. Residual risks, undesirable side effects, warnings and precautions
5. Summary of the clinical evaluation, including post-market clinical follow-up
6. Diagnostic or therapeutic alternatives
7. Suggested training for users
8. Reference to harmonised standards
9. Revision history

Patients (lay audiences)

1. Identification of the device and the manufacturer
2. Intended use of the device
3. Device description
4. Risks and warnings
5. Summary of the clinical evaluation, including post-market clinical follow-up
6. General description of therapeutic alternatives
7. Suggested training for users

Table 2. Useful resources for writing for lay audiences

Grammar and style online checker	www.grammarly.com
Singh N. Writing lay summaries: What medical writers need to know. <i>Med Writ.</i> 2018;27(2):49–54	http://journal.emwa.org/public-disclosure/writing-lay-summaries-what-medical-writers-need-to-know/article/3806/singh-and-vasudha_writing-lay-summaries.pdf
Readability application online	www.readable.com
EMWA Workshop run by John Dixon at EMWA conferences: ‘Using Readability Tools to Help Edit Biomedical Research Articles.’	http://filemaker.emwa.org/workshops/EPDP%20Brochure.php
Good Lay Summary Practice, by the European Federation of Pharmaceutical Industries and Associations	https://efgcp.eu/documents/GoodLaySummaryPractice_PublicConsultation199.pdf
Recommendations for drafting non-promotional lay summaries of clinical trial results, by TransCelerate Biopharma Inc.	http://www.transceleratebiopharmainc.com/wp-content/uploads/2015/04/TransCelerate-Non-Promotional-Language-Guidelines-v10-1.pdf
Summaries of Clinical Trial Results for Laypersons. Recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, 5 February 2018	https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2017_01_26_summaries_of_ct_results_for_laypersons.pdf

several potential pitfalls related to the SSCP. Based on our first experience writing SSCPs, here we share some of the challenges we encountered during the writing process and some tips and tricks to overcome these challenges.

Expectations of manufacturers versus competent authorities

The SSCP is intended to be published on

Eudamed – the European data base for medical devices. The launch of Eudamed has been postponed to 2022, yet the SSCP continues to be a requirement for MDR submissions. Once this document is available, everybody will be able to access the SSCP: physicians might change their treatment strategies, patients might demand to be treated with a certain device or might even refuse a treatment. For manufacturers, this transparency is a chance to direct attention to

their devices and – maybe even more importantly – to gather information on competitor devices as well. While some manufacturers may also consider using this document for marketing purposes, the SSCP should be completely sourced directly from the technical documentation and it is not intended to spread marketing claims. As a medical writer, you will have to focus on the technical information and provide both favourable and unfavourable information on the device.

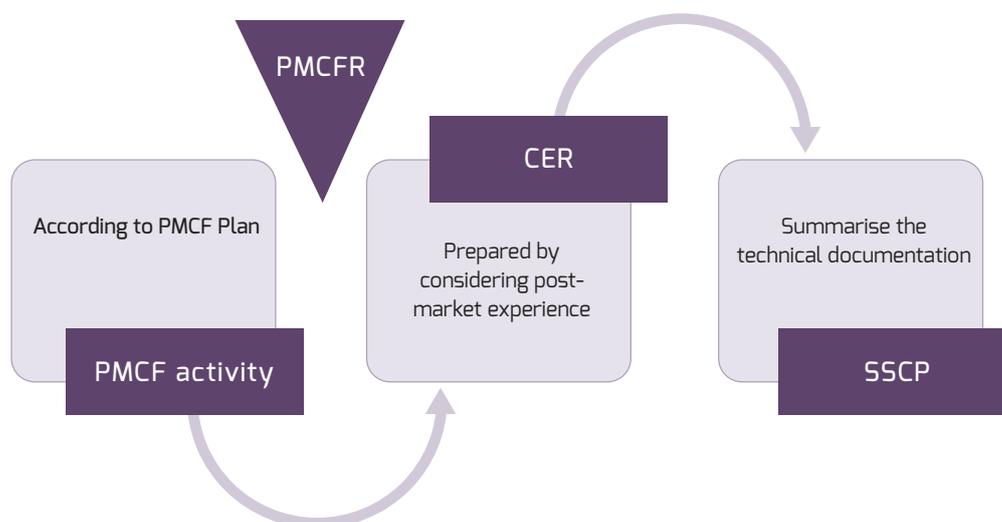


Figure 1. The SSCP in relation to other documents

Abbreviations: PMCF, post-market clinical follow-up; PMCFR, PMCF report; CER, clinical evaluation report.

Table 3. SSCP Q&A session summary

Templates/format/content

Where can one find templates or example SSCPs?	The Medical Device Coordination Group guideline presents a list of contents and template that can be used. Example SSCPs will be available once Eudamed is published.
How long should the SSCP be?	This is entirely device-dependent; from very simple to extremely complex devices, the document may change in its length to a great extent.
What is the extent of effort needed to prepare an SSCP?	It depends on the complexity of the device and on how well prepared the input technical documentation is.

Applicability of the SSCP

Do we need to prepare an SSCP for sutures used for aesthetical use? Is a lay summary necessary if the device (e.g., software for testing devices in patients) is just used by healthcare professionals?	The SSCP is a requirement for class III and class IIb implantable devices; still, there is a list of exempt implantable devices which includes the following: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors. For these devices, the SSCP for patients or lay audiences is not needed. Software is not considered as an implantable device and, as such, it is exempted from the SSCP requirement.
Can the state of the art be the same as the one in the clinical evaluation report (CER) or does it have to be specific for the SSCP?	The SSCP is a summary, and as such, the state of the art needs to be specifically summarised.

Lay audience

Is the language used in plain language summaries similar to that used in the patients' section of the SSCP?	Yes, as the audience is similar; a lay audience.
Given that the SSCP has two different audiences (technical and lay), do medical writers need to prepare two different documents?	No, it should be one single document, with two differentiated sections; one for healthcare professionals, and one for lay audiences.
Are formal readability tests required for SSCPs as they are for patient leaflets for pharmaceuticals?	SSCP should pass a readability test by lay audiences and the test should be traced within the technical documentation.
Is a lay summary necessary if the device (e.g., software for testing devices in patients) is just used by healthcare professionals?	No. A lay summary is only required for implantable devices that are delivered with an implant card and for class III devices that are directly used by patients.

Compliance

Even if MDR has been delayed until May 2021, is it already mandatory to provide an SSCP for relevant devices?	The SSCP is an MDR requirement, as such, only devices already complying with the MDR would require an SSCP. If the device in question is still certified under the Medical Device Directive, the SSCP is not needed and will only be prepared when the technical documentation is migrated into the MDR requirements.
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Surveillance/risks/complications

How do you quantify the risks coming from different types of sources (e.g., clinical studies, observational studies, complaint reporting, etc.)? Do you quantify in ranges or categories, or do you report a specific value of incidence?	These should be quantified in the CER from which the SSCP takes the appropriate information and presents it in a summarised manner. Ideally, the different sources should be quantified separately as may not be easily considered as comparable; as an example, it is well known that complaints are under reported, while in clinical studies all complications and complaints are usually traced.
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Consistency

Could you recommend some tools to keep the documents (like CEP, CER, PMCFP and SSCP) consistent?	Microsoft Teams is one of them. There are many others in the market.
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Abbreviations: SSCP, summary of safety and clinical performance; CER, clinical evaluation report; MDR, Medical Device Regulation; CEP, clinical evaluation plan; PMCFP, post-market clinical follow-up

Consistency between the SSCP and the technical documentation

Most manufacturers set up MDR project teams to meet the new requirements and their timelines. With the MDR, the documentation from different sections (quality, regulatory, clinical, etc.) have become more interdependent. Sometimes it seems impossible to establish consistency across all MDR documents, especially when the manufacturer plans to prepare the documentation in parallel. Medical writers with experience writing Clinical Evaluation Reports are likely to be familiar with this problem where you have the responsibility to compile all the information from other sections into one file at the last step of the process. And this is the same for the SSCP: no matter how manufacturers plan their timelines, you will not be able to finalise the SSCP before gathering all the information needed from other departments. Figure 1 depicts these dependencies and input documents needed for the SSCP.

Inconsistency between the SSCP and the relevant parts in the technical documentation will cause confusion for the notified body, is likely to raise questions, and will prolong the review period. So, keep your timelines in mind and plan enough time for review cycles and consistency checks. With the SSCP being publicly available, the review is likely to include several people. As if this was not enough, the SSCP also needs to be translated into the same languages as the Instructions for Use! The English version is validated by the notified body, whereas the accuracy of all other translations must be validated by the manufacturer. Annual review cycles are necessary to include new information or changes relevant to the safety and performance of the device.

So how can medical writers handle consistency, timelines, and review cycles? First, make clear that the SSCP can only be completed after all relevant input documents are ready and approved. Second, plan sufficient time for review and approval of the document. Third, think about technical solutions to ensure consistency and streamline review cycles.

The lay audience

After finalising the SSCP section for healthcare professionals, you “only” have to translate the content into lay language for the patient. Okay, the “only” is misleading here. The SSCP compiles information about the state-of-the-art and alternative treatment options to the subject device. It is also expected to provide detailed



information on the device, results from clinical trials, methods for risk mitigation, plans for post-market clinical follow-up, and finally, information on residual risks and side effects. Especially for medical writers with a regulatory focus, it is a real challenge to present all this information in a way that is understandable to a general audience. Luckily, lots of online sources and training courses can support you to further develop your lay audience writing skills, including EMWA workshops (Table 2). Here are a few simple tips that you should follow when writing for the public:

- Try to avoid abbreviations or acronyms;
- If abbreviations or acronyms are necessary, use them consistently within the text;
- Explain medical terms in simple language;
- Consider using figures, tables, or graphs for data visualisation;
- Show your text to a non-specialist and proof its readability (readability testing);
- And most importantly: train yourself!

Writing for the public is not easy, especially when you must transfer a lot of technical information into simple language. However, this is another chance for medical writers: lay summaries have gained importance in the last years. They are a strong tool to inform patients and to prevent misinformation. Being a new requirement, the SSCP triggers significant interest within the industry and questions among medical writers, as evidenced by the many questions raised during our EMWA webinar on this topic. To conclude, we have summarised the main topics from the Q&A session held at the end of the webinar (Table 3).

With the SSCP providing so much valuable information to the public, it is likely to become one of the most important documents under the MDR. There are still many uncertainties about what notified bodies expect from the SSCP, but one thing is already clear: it is another great opportunity for medical writers either to test our skills or to gain experience in combining regulatory writing with writing for patients.

Acknowledgements

The authors would like to thank Kelly Goodwin Burri for her assistance in editing this text.

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Writing clinical trial summaries in plain language: Some tips from patient education

Ever since the EMA mandate for plain-language summaries of clinical trials was codified in Clinical Trial Regulation EU No. 536/2014, medical writers have grappled with the task of making these documents accessible to the public, including to participants with low literacy.

Although the regulation is not fully applicable pending approval of the planned portal for clinical trials information,¹ a great deal of effort already goes into creating clinical trial summaries (CTS), as they will be called here. The European Union's guidance document refers to them by four different terms: "summary results", "lay-person summaries", "lay summaries", and "clinical trial results for laypersons" in its first three paragraphs.² The word "lay" is avoided here partly because of its frequent use in ecclesiastical circles, among other reasons.

The effort expended to develop CTS is partly because the EU 536/2014 implementation has been pushed back so many times, giving us ample time to prepare, practice, and prepare again to explain trial results to the public.

The challenge of writing plain-language summaries

Experts have already described the challenges of creating CTS.³⁻⁵ The EU's guidance document on creating CTS lists elements that must be included and provides a template.² However, the format, language level, and design of summaries vary across organisations that produce them. This gives sponsors, writers, and designers both freedom and room for uncertainty.

In addition, most writers who are tasked with creating CTS work in the regulatory space. They are trained and accustomed to creating complex, data-rich documents for audiences with high general literacy, high health and science literacy, and a strong interest in the data and results. These readers are nearly the opposite of most members of the public.

An outsider's perspective

I first wrote CTS in early 2015, working with the nonprofit Center for Information and Study on Clinical Research Participation (CISCRP).



My background is in writing instruction and patient-care administration – far from the laboratory bench, but closer to patients and families.

As the demand for plain-language CTS grew, more writers were needed. Specialists in patient education make up a small fraction of medical writers in the United States, and as the regulatory environment already had many writers available, it seemed logical for them to take over most CTS work.

The solution seems natural, but the differences in perspective between scientists and non-scientists, and in the perception of what makes for accessible writing, present some hurdles. In this article, I share a few of the challenges I believe regulatory writers cope with and offer some suggestions from the other side of the bench.

A glimpse through patients' eyes

A few years ago, my uncle Brian was diagnosed with double-hit lymphoma. The prognosis was poor, and a stem-cell transplant trial was his best

chance of survival.

A highly educated member of the US diplomatic corps, my uncle spoke and read several languages. He was an accomplished amateur photographer with a passion for aviation, and a world traveller with five grown children. He and my aunt were not concerned with how they could advance clinical research. They were focused on my uncle's "new birthday" – the January 1 transplant date. As his son-in-law said at the funeral, "He wanted to live."

The world of medical research was not one they chose to enter. Had my uncle lived to receive a CTS, he would likely have skimmed it, tossed it on his desk, and returned to work.

Keep our excitement, remember their perspective

Research is the lifeblood of an academic career. Original contributions and the discovery of new knowledge bring us rewards ranging from tenure to outright fame. The desire to ameliorate suffering and improve public health also figure in.

Writers who create CTS are likely excited

about the clinical research enterprise, and we know that participants want to learn the results of their trials.⁶ But it's important to remember that their main interests lie elsewhere. I once heard an interviewer ask a trial participant, "Why did you decide to join the Keytruda [pembrolizumab] trial?"

"I was 40 years old, I've got kids, and I had lung cancer. I would have tried anything," he said. "I'm just lucky it's working for me."

The curse of a specialised vocabulary

If you've worked in science, medicine, or nursing for many years, its specialised language, or jargon,⁷ is the water in which you swim. Using short, familiar words is a key tenet of writing for the public, but it's easy to forget that "lab", "exam", "follow-up", and "outcome" are more familiar to health care providers than the public.

But while readers may put up with some jargon in a medical thriller, CTS readers may simply give up. I tutor lower-literacy adult learners who typically skip unfamiliar words or read them aloud as nonsense syllables. I have learned first-hand that reading a document is not the same as understanding it.

Table 1 provides a few examples of more jargon terms to avoid, with plain-language translations. Note that plain language sometimes involves using more words to translate scientific and medical terms into everyday language. Jargon is a form of shorthand within the community, allowing us to communicate quickly with each other. Those outside the community simply need different words.

The US Centers for Disease Control offers a variety of plain-language resources,⁸ and many glossaries are available. Avoid the mistake of just translating in a way that feels right to you because you are steeped in scientific vocabulary. When writing for people outside this environment, your fluency is actually a disadvantage. You can learn more about plain language and readability in *Medical Writing*⁹ and elsewhere.

The challenge of writing simply

The following sentence is from the first page of a CTS written in "plain language."

This clinical study for the drug nusinersen, also known as ISIS 396433, helped researchers learn more about the safety of nusinersen and if it might help infants with spinal muscular atrophy, or SMA.

Health literacy expert Helen Osborne and others recommend a single main idea and a

maximum of about 15 words in each sentence.¹⁰ Other readability guidelines recommend eight to 11 words, particularly for content that is read online.¹¹ The sentence above is 33 words long and contains several ideas:

- **The study drug is called nusinersen.** Readers other than experts will probably skip the drug name, or read it as nonsense syllables.
- **The drug has another name,** likely also skipped or read as nonsense syllables. (Ask five non-scientists to read "ISIS 396433" and "nusinersen" in the sentence and observe their strategies for handling these technical terms.)
- **The study helped researchers learn something.**
- **The drug is intended for infants** [a medical term] with a certain condition [medical term, medical abbreviation].

Microsoft Word's readability checker uses the Flesch-Kincaid reading level. The validity and usefulness of readability formulas has been extensively discussed,¹² but the MS Word checker is readily available. By this measure, the sentence above reads at Grade 18.7.

Specific techniques and training are essential to write plain-language content. The syntax of the sentence above has not been modified for the general reader, and only some of the words are modified to plain language. Here is a sample plain-language translation:

Your study was about a medicine called "nusinersen" (say "NEW-suh-NER-sen"). Scientists wanted to learn more about how safe it is. They also wanted to know if it helped babies with a problem called "spinal muscular atrophy" (say "spy-null MUSS-kew-lur AT-row-fee"). You might also hear this problem called SMA (say "ess-em-AY").

Reading level? Grade 8.4, according to the MS Word readability checker. There are 12.5 words per sentence. Not perfect, but more accessible for general readers. A skilled plain-language editor can adjust the reading level further to accommodate readers at different levels, including children.

The Medical Library Association has developed MedSpeak,¹³ a resource to help patients and other members of the public understand medical and scientific terms. Many other resources are available for medical writers and editors to use in creating

clinical trial summaries. You can find MedSpeak at <https://www.mlanet.org/p/cm/ld/fid=580>.

Creating accessible content is not just about word choice, but about arranging ideas in an order that the readers can easily follow, helping them access medical terms that must be included, and making the container for ideas, the sentence, easier to open.

What to do (for now)?

Researchers, writers, and editors have long worked in teams – flexible and customised for specific projects. Our profession is also dedicated to continuing education. We can build on these strengths to do the following.

Train regulatory writers in plain language

The Plain English Campaign in the UK, Simply Put guide from the US Centers for Disease Control, and organisations such as Health Literacy Media and the Maximus Center for Health Literacy provide guidance and training in writing plainly for the public, as does the Plain Language Association International (PLAIN). Writers interested in writing CTS for participants will ideally pursue training from these sources and others.

Plain-language and health literacy training for regulatory writers, sponsored by employers including contract research organisations, would allow companies to use their current teams to produce truly accessible documents that meet the spirit of EU No. 536/2014.

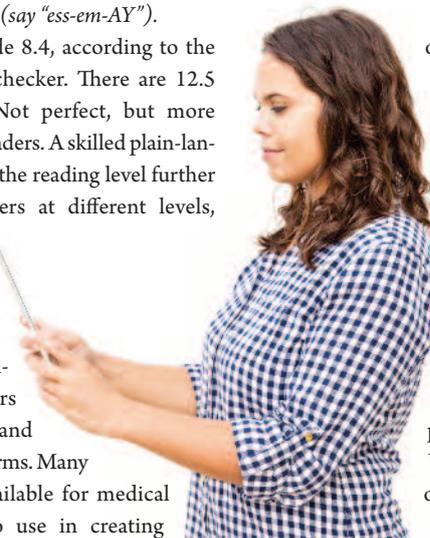
Use specialist editors as needed

Patient education (full disclosure: my specialty) is a small sub-field of medical communications. It requires a different set of techniques and aptitudes than writing regulatory documents, as well as familiarity with principles of health literacy, readability, and usability.

With a plain-language editor on the team, a regulatory writer can produce a CTS first draft and have it edited for readability, ensuring that both the science and the accessibility are top-notch. The EMWA and AMWA directories can help you find plain-language and patient education specialists.

Include truly naïve participants in reviews

Using "professional patients" is one of the major confounds in CTS user review. By profes-



sional patients, I mean dedicated patient advocates or activists who are highly familiar with a given condition and the associated terminology.

If a CTS review group includes a physician, a social worker, a participant who serves as a patient advocate, and two randomly chosen participants, this is not a review group of five, but more likely of two. The physician, social worker, and patient advocate have too much expertise to provide the general public's perspective.

Why we do it

Aside from the EU regulation, creating plain-language summaries of clinical trials is part of a much larger trend towards patients taking part in their own healthcare. Thus, adjusting our perspective to match participants', seeking training and assistance from plain-language specialists, and including naïve participants in our reviews is not simply the appropriate move for our times. In the current climate of fear around COVID-19 and the struggle for greater equity worldwide, striving to increase participants' access and comfort level with research information represents genuine scientific progress.

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Table 1. Ten to translate: Medical or science jargon with suggested plain-language translations

Here are some terms that seem easy to understand if you have a scientific background or work in healthcare, but which are not common in everyday language.

Medical or scientific jargon	Plain-language translation
Adverse event	Medical problem
Biopsy	Sample; small sample for testing
Blood sugar	Level of sugar in your blood (not “blood glucose,” because glucose is a scientific term)
Chronic	Long-lasting; keeps coming back; lasts more than 3 months
Diagnosis, diagnosed	Your condition (for “your diagnosis”); Learn if you have (for “to diagnose”); You have (for “to be diagnosed with”)
Exam	Examination
Outcome	Result
Randomised	A computer assigns you to a group; put in a group by a computer
Screening, screening test	Check-up; to look for (for “screening”); Test to learn if you have (for “screening test”)
Therapy	Treatment

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In the Bookstores

A Sonnet to Science: Scientists and Their Poetry

By Sam Illingworth
Manchester University Press

2019 (hardback);
2020 (paperback)
ISBN: 978-1-5261-52268
(paperback)
€12.99. 224 pages



Last year, I wrote my first poem – 10 lines of free verse that, after three rejections and 229 days in queue, was purchased and published. Although I have been selling short stories since 2016, poetry is something new for me, undiscovered territory, something to be explored with exhilaration, enthusiasm, and perhaps also apprehension. Why apprehension? As a scientist, the two disciplines seem polar opposites, science based in logic and rules, poetry based in beauty and creativity. They are disciplines that don't often cross paths, sharing very little common ground. Two sides of two very different coins. Why, then, have there been so many scientists that have written poetry in the past? What is it that draws these two disciplines together? Sam Illingworth attempts to answer these questions in *A Sonnet to Science*.

A Sonnet to Science is 224 pages of historical non-fiction containing six short biographies – or biographettes, if you will – of famous scientists who also wrote poetry. The author, who is himself a scientist, science communicator, and a poet, delivers his perspective on the opposing worlds of science and poetry through reliving the life of each of the six scientists. He examines each scientist's struggles and triumphs, both personal and scientific, through the lens of their poetry. And in doing this, each biographette is an examination of beauty, logic, and creativity.

The book begins with a short introduction where Illingworth states his purposes for writing *A Sonnet to Science*. He explains his hypotheses and his methods for selecting the subject of each biographette, which are scientists from the western world, where mixing poetry and science is viewed less "acceptable"; and scientists that published in English or approved translations of their work within their lifetime.

In the introduction, Illingworth also mixes this scientific approach with poetry, using poetry

from John Keats and Edgar Allen Poe (whose "Sonnet – To Science" is alluded to in the title of this book) to illustrate how the two disciplines are often viewed as oppositional to one another. However, the juxtaposition of a passage from a scientific paper and a poem shows that both media beautifully describes the lives and deaths of birds, and serves as a powerful reminder that both science and poetry share many similar characteristics, such as observation, description, and attention to detail.

The biographettes in the book are arranged to create a chronology, beginning with the birth of the "modern scientist" (late eighteenth century), passing through six overlapping generations, which stretch to the beginning of the 21st century. Each of the six is provided with their own poetic description.

The first scientist-poet that Illingworth puts under his microscope is Humphrey Davy ("the Romantic scientist"). He was a chemist whose experiments with electricity led to the isolation of potassium and sodium, and whose experimentation with nitrous oxide led to the nickname "laughing gas". Humphrey Davy, however, did not only impress in the laboratory. He was the author of many poems, was friends with the romantic poet Samuel Taylor Coleridge, and is even mentioned in a poem by Lord Byron.

The next biographette is that of Lord Byron's daughter, Ada Lovelace ("the metaphysical poet"). Illingworth writes of Lovelace's contributions to mathematics and the "Difference Engine", a precursor to the modern computer. Lovelace's creativity, sharpened through her literary guile, led her to make additions and improvements to the scientific translations on which she worked, contributions which helped to imagine the power of the modern computer, in the 1840s.

James Clerk Maxwell ("the lyrical visionary"), who is known for his discovery of the Maxwell equations, four mathematical equations that govern the laws of electromagnetism, follows Lovelace. We learn that religion, science, and poetry intertwined throughout his life and career. After Maxwell there is a biographette of Ronald Ross ("the medical metrist"), a British physician who won

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a Nobel Prize for his work on the lifecycle of the parasite that causes malaria. Spending most of his life in India, he explored his thoughts on art and science in verse in poems such as "Thought" and "Indian Fevers".

Maybe the most delightful biographettes are the final two. These are the two scientists in the book with whom I found myself identifying with most strongly. Both Miroslav Holub ("the reluctant poet"), a Czech immunologist, and Rebecca Elson ("the poetic pioneer"), a Canadian astronomer, were unknown to me before I read *A Sonnet to Science*. Holub, a survivor of the Nazi occupation of Pilsen, lived most of his life behind the Iron Curtain. Holub published papers in *Nature* describing the production of antibodies by lymphocytes and is perhaps more often recognised as a poet than a scientist. Elson wrote both short stories and poetry while researching star clusters. She was a prominent astronomer, using the Hubble telescope to make many discoveries before her life was tragically cut short at only 29 years of age. Her poetry and other writings were published posthumously.

In *A Sonnet to Science*, Illingworth tells a tale of two disciplines, winding it through lives and generations, on a path to discover what draws these two opposites together, and in doing so explains how logic, beauty, and creativity entangle in science and our hearts. I would recommend this book to anyone interested in the history of science and scientific communications or to anyone with a heart for poetry.

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Poetic medical writers

Are you a poet who is also a medical writer? Or a medical writer who is also a poet? However you define yourself, consider submitting your poems to *Medical Writing*. We are interested in receiving submissions whose themes would have special resonance with nature, science, or our audience of professional medical writers.

Please send poems or questions about submission to Nathan Susnik, MEWpoetry@posteo.net.

Good Writing Practice

Grammatical disagreement in number

Part II - Subject to non-verb constituents

Introduction

In addition to subject-verb disagreement in grammatical number, a disagreement in number is common between a subject and other sentence constituents, which appears in the experimental and contextual sections of a journal article.

Experimental sections

Part 1 – Materials and Methods section: Method

Example: Singular subject antecedent – plural referent

Before data acquisition, each individual was instructed about how to move their centre of gravity.

Revision 1

Before data acquisition, **all individuals were instructed about how to move their centre of gravity.**

Revision 2

Before data acquisition, each individual was instructed about how to move his or her centre of gravity.

Notes

Can the possessive plural pronoun *their* be used as a singular? The use of the plural *their* is a hypercorrection to avoid the sexism of *his* and the awkwardness of repeated *his* or *her*. In the example, the singular pronoun *each* as a subject determiner intensifies the disagreement with the plural referent (*their*) and sounds awkward.

Transformation of the subject into the plural (*all individuals*) avoids the two distractions (hypercorrection and awkwardness). Although the revision is focused on individuals and not on each individual, the meaning is essentially the same. However, *all individuals* would not apply to just two or three individuals. Instead, *the three individuals* would suffice.

In Revision 2, minimal repetition of **his and her** with the focus on the singular is recommended, because the singular is usually more readily comprehended than the plural.

Part 2 – Materials and Methods section: Method

Example: Coordinated modifiers – singular subject

Transporter clones 2 and 3 expression was correlated to the uptake of free neutral amino acids.

Revision

Transporter **clone 2 and 3 expression each** was correlated to the uptake of free neutral amino acids.

Notes

In the example *clones* not only primarily convey that there are two clone types, but also secondarily that there may be more than one clone of clone 2 and clone 3. Although context, convention, or science familiarity may eliminate such a distraction, in the Revision no such distraction is incurred by use of *each*.

Part 3 – Results section: Result statement/ observation

Example: Coordinated modifiers – singular subject

In patients with MHC class II deficiency, symptomatic and prophylactic treatments of infection prevented continued

Revision 1

In patients with MHC class II deficiency, symptomatic and prophylactic combined treatment of infection prevented continued organ dysfunction.

Revision 2

In patients with MHC class II deficiency, symptomatic and prophylactic sequential treatment of infection prevented continued organ dysfunction.

Notes

In this example, it is uncertain whether the symptomatic and prophylactic are combined or in sequence. In the revisions, the combined (Revision 1) and sequential (Revision 2) relation is explicit.

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Part 4 – Results section: Result statement/ observation

Example: Plural subject – singular direct object

All patients had an enlarged heart.

Revision 1

Every patient had an enlarged heart.

Revision 2

Each patient had an enlarged heart.

Notes

In the example, the image of many patients sharing one heart is distracting. Just as implausible is *all the patients had enlarged hearts* (more than one per patient).

Revision 1 is a compromise: the grammatical singularity of *every* (but the connotation of more than one patient) and the singular *heart* is less distracting.

In Revision 2, *each* is the most un-nuanced revision, supporting a principle that disagreement in number can often be achieved by focusing on the singular.

Contextual sections

Part 1 – Introduction section: Research problem pertinent background

Example: Singular subject – plural subject complement

The second indication of apoptosis is changes in morphologic features.

Revision

The second indication of apoptosis is a change in morphologic features.

Notes

The difference in grammatical number between

the subject *indication* and the subject complement *changes* creates a dissonant distraction? The inverse of the example is also a distraction: *Changes in morphologic features is the second indication of apoptosis*. The subject is connected to its complement by a linking verb, whereas to a direct object, by a transitive verb.

Part 2 – Introduction section: Objective

Example: Plural modifier – singular subject

The root mice development model at the bell stage was used to identify normal DLx3 gene expression and protein localisation.

Revision

The root **mouse** development model at the bell stage was used to identify normal DLx3 gene expression and protein localisation.

Notes

Why doesn't *mice development* sound right? Maybe because *mice* convey the nuance of a specific group of mice rather than the generic singular (*mouse development*). Some other examples are *tooth* (not *teeth*) development; *transition* (not *transitions*) frequencies.

Part 3 – Introduction section: Research problem pertinent background

Example: Plural subject – singular modifier

Different types of fibre are components of connective tissue.



Revision 1

Different types of **fibres** are components of connective tissue.

Revision 2

Different **fibre types** are components of connective tissue.

Notes

In Revision 1, the plural modifier of *fibres* matches the plural modiffee *types* as would *these fibres* rather than *this fibres*. Probably, the adjective *different* necessitates a plural: either *types of fibres* or *type of fibres*.

In Revision 2, when the modifier *fibre* appears before the modiffee *types*, the singular seems to be the only choice (not *fibres types*).

Summary

Modifier-caused misagreement in number is more common (n=4) than either complement (n=2) or referent-caused (n=1) misagreement. Most of the misagreements result in a dissonance, but the misagreement in number resulting from the coordination of subjects or modifiers is more severe resulting in impeded immediate comprehension.

Options for revision involve changing the number of the subject or the constituent, usually to the singular – maybe for its simplicity.

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Schematised misagreement in number distractions and preferred revisions

Between modifier and subject

Transporter clones 2 and 3 expression was correlated to the uptake of free neutral amino acids.
→ Transporter **clone** 2 and 3 expression **each** was correlated to the uptake of free neutral amino acids.

In patients with MHC class II deficiency, symptomatic and prophylactic treatment of infection prevented continued organ dysfunction.
→ In patients with MHC class II deficiency, symptomatic and prophylactic **combined treatment** of infection prevented continued organ dysfunction.
→ In patients with MHC class II deficiency, symptomatic and prophylactic **sequential treatment** of infection prevented continued organ dysfunction.

The root mice development model at the bell stage was used to identify normal DLx3 gene expression and protein localization.

→ The root **mouse** development model at the bell stage was used to identify normal DLx3 gene expression and protein localization.

Between subject and modifier

Different types of fibre are components of connective tissue.

→ Different **fibre types** are components of connective tissue.

Between subject and direct object

All patients had an enlarged heart.

→ **Each** patient had an enlarged heart.

Between subject and subject complement

The second indication of apoptosis is changes in morphologic features.

→ The second indication of apoptosis is a **change** in morphologic features.

Between subject and referent

Before data acquisition, each individual was instructed about how to move their centre of gravity.

→ Before data acquisition, each individual was instructed about how to move **his or her** centre of gravity.

My First Medical Writing

Editorial

For this issue, I had the pleasure of working with Spanish science writer Clara García-Gorro. Clara received a PhD in cognitive neuroscience at the University of Barcelona and studied science communication at the University of

Cambridge. She communicates to a lay audience on topics like neuroscience and psychology on her YouTube channel, *Cerebrotres*, and on her podcast, *Mentes Covalentes*. She is also a freelance science writer who explains scientific concepts to

different audiences. In this article, Clara shares scientific research on how spending time in nature keeps us healthy. Food for thought!

Evguenia Alechine

Spending time in nature every day keeps the doctor away

Humans have long known intuitively that spending time in nature is beneficial for our health without understanding exactly how or why. Forty years of research has repeatedly shown that exposure to nature is indeed associated with a variety of positive health outcomes, including lower mortality from cardiovascular disease, reduced blood pressure, less frequent allergies, improved mental health, and better self-perceived feeling of general health.¹

Besides reducing air pollution and regulating air temperature, vegetation might itself have an indirect positive effect on our health. Green spaces can encourage people to engage in physical activity, which in turn helps to reduce the risk of obesity, diabetes, mental health issues, and other health conditions associated with a sedentary lifestyle.

A recent study found that children in Denmark who grew up with the lowest levels of

green space in their place of residence had up to a 55% higher risk of developing a psychiatric disorder in adulthood, after taking into account other risk factors such as the degree of urbanisation, socioeconomic status, parental age, and family history of mental illness.² Green space was quantified using satellite images covering the whole of Denmark between 1985 and 2013.

Notably, the psychological benefits of contact with nature are not exclusive to wild forests and mountains but are similar for both wild natural environments and urban green spaces.³ It seems, therefore, that urban parks could help address the public health problems posed by urbanisation. However, to ensure that investment in green spaces can help improve citizens' health, it is important to understand what types of natural spaces are most beneficial and whether frequency and time spent in nature play a role. Scientists have found that spending more than 2 hours in

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nature increases the likelihood of good health and well-being the following week.⁴ This is true up to 5 hours of nature exposure. Beyond that, more time in contact with green spaces is not associated with better health. Research shows that people who make longer visits to green spaces are less likely to suffer from depression or high blood pressure.¹ Specifically, visits to nature of 30 minutes or more at least once a week already show positive health effects, reducing by up to 7% the prevalence of depression and up to 9% the prevalence of high blood pressure.¹

However, it is important to bear in mind that correlation does not imply causation. It could well be that people with depression or high blood pressure – which are associated with other risk factors such as obesity – spend less time outdoors and, consequently, less time in contact with green spaces, as a result of their medical conditions. However, in this study, relevant factors such as activity levels and body mass index were included in the analyses.¹

We might also wonder whether all green spaces provide the same benefits. When directly comparing the effect of different green areas in New York City, the benefits of living close to a green area were greater in spaces with trees compared to grass-only areas.⁵

Curiously, nature can benefit our cognitive abilities even if we only look at it through a window or in pictures. For instance, university students in the United States who lived in rooms with views of green spaces performed better in cognitive tests measuring their attention capacity.⁶ Similarly, in another study in which participants were first mentally fatigued by





Photo by Steven Shaffer, available at <https://unsplash.com/photos/GYpzXl4bkUI>

performing a sustained attention task and then shown photographs of nature scenes, urban environments, or geometrical patterns, only those who had viewed the nature scenes improved their attention scores.⁷

But do we know why nature has so many benefits for our health? It is easy to understand that plants can contribute to our physical health by absorbing pollutant gases such as carbon monoxide, sulphur dioxide, nitrogen dioxide, and ozone, as well as particulate matter. In addition, parks provide a pleasant environment where we can walk and exercise. But, what about the restorative effect of exposure to nature for our mental health and attention capacity? Different theories try to explain this phenomenon.³

The biophilia hypothesis proposes that, since human beings evolved in natural environments, we have an innate need to interact with other forms of life.⁸ On the other hand, according to the stress-reduction theory, exposure to environments with water, plants, expansive views, and other elements that helped our ancestors to survive reduces our physiological and psychological response to stress.⁹ Finally, according to the attention restoration theory, natural environments contain elements that fascinate us, such as scenic views, trees, flowers, or water, which draw our attention in an involuntary manner.^{10,11} This allows our voluntary attention mechanisms to be restored, which is important, given that we need voluntary attention to achieve focus, but it requires effort and is susceptible to fatigue. In contrast, urban environments present us with stimuli that require our voluntary attention in order to act accordingly, such as traffic lights and other pedestrians, while trying to filter out

distracting stimuli such as traffic noise and ads, which drain us mentally.

Whatever the underlying cause may be, science shows that spending more time in nature can have multiple benefits for our health and cognitive abilities. Thus, we should take this into account for public policies when deciding how much to invest in the provision, management, and enhancement of public green spaces. In the meantime, though, we can take care of ourselves by ensuring we have our weekly dose of exposure to nature.

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Getting Your Foot in the Door

Editorial

In early 2020, Namrata and I found ourselves in between jobs when COVID-19 entered our lives. In this edition of Getting Your Foot in the Door, we share our experiences and learnings while searching for employment in the midst of a global crisis. This might not be entirely fitting

with the usual theme of “getting that first job”, but we feel this is very relevant in the current landscape. We are happy to report that after a few months of persistence, we have landed industry roles that are keeping us busy, sane, and happy.

Raquel Billiones

SECTION EDITOR



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Job search during the COVID-19 era

COVID-19 was a pandemic that was well predicted yet seemingly ignored by most world leaders – until it happened. From the next major global recession to the permanent damages caused by global warming, our world is full of predictions. We signed treaties to give the scientists a bit more due for their hard work yet forgot to act on them. So here we are, in a world on lockdown, itching to be released into the wild again like caged animals in a zoo.

As we applaud our doctors and healthcare workers facing the brunt of the disease, the scientists dedicated towards the research and development of a COVID-19 vaccine and the medical device industry focusing on mass production of necessary equipment, one of the many and most dreaded repercussions of the sudden halt of business is the prospect of losing one's job. Many are already in this boat, many may enter it in the coming days, and some may never have to enter it, yet fear it nonetheless.

Impact on business and the economy

Industries most severely affected by COVID-19 are those related to mobility and leisure, such as aviation, tourism, gastronomy, and sports. Sectors least affected are those that cater to our basic needs such as food, healthcare products, and technology.

We may wonder then why jobs in the pharmaceutical and medical device industries are endangered. There may be increased demand for

certain drugs and devices but manufacturing and distribution face challenges in manpower shortages that cascaded into supply chain and logistics. In addition, mobility restrictions resulted in disruption of clinical trials; many studies have been suspended or even terminated.

With every industry being directly or indirectly affected by this pandemic, companies are struggling to calculate the best routes possible for retaining their existing employees. Consequently, despite Q1 and Q2 being the best time to hire new personnel, this year it had been slow if not almost negligible. This is not to say that people are no longer required to fill those positions, rather the decisions on how to make it happen, plus the best time period to allow it, is burdening organisations. Q3 and Q4 saw an increase in open positions after the dry spell of Q1 and Q2. However, one may quickly see the after effects of the pandemic by most positions being offered as “remote”. Organisations have worked hard this year to figure out how to adapt to a remote work ethic. One might go as far to say that the “taboo” behind the “working from home” concept has been shattered for some organisations via this pandemic. As people decipher the logistics of working and managing teams from home, recruitment agencies have been forced to get creative and find solutions.

It may also be mentioned that recruiters and headhunters might have to eventually face the axe if the hiring freeze goes on and their revenue channels disappear.

Luckily, we were not at a complete standstill,

thanks to advancements in information technology. One may only wonder what the situation would have been had we not discovered the internet. Information technology is our saviour for now, vaccines the next.

Business works on predictions

The immediate response to this disease by businesses worldwide was large-scale hiring freezes

followed either by reduced pay, furloughing, or outright termination of employment. For those positions that were posted in Q1, some companies were, and still are, ghosting on candidates, unable to efficiently inform them on the status of their applications due to the handicap they themselves

face. The frustration is high on both ends. The solution? Patience (monk level).

Amidst this nature-caused recession, we have the utmost responsibility to network and to assist those who are jobless as a result of the pandemic. Despite the lack of clarity, it is paramount to assist those reaching out in search of job opportunities.

For the job seeker, being proactive and reaching out to their network is essential. Temporary positions and contingency contracts should be taken as an opportunity to showcase one's competencies that are worth keeping in the long-term. For the employer, creative stop gaps such as short term contracts are a means to maintain a work flow during this crisis. For the recruiters and talent acquisition specialists, transparency and empathy towards human capital are crucial.

As we wait anxiously to see how events unfold,

At the start of every disaster movie, there is a scientist being ignored.



This article was published first as a post on LinkedIn at:
<https://www.linkedin.com/pulse/job-search-during-covid-19-era-dr-namrata-upadhyay/?trackingId=QckNbU2%2FS7qCqzAgaCJLxw%3D%3D>

a positive approach would be to acknowledge the gift of time that has been given to many. Although it seems a cliché to say, never again would we get such an opportunity to work on personal and professional growth, develop personal business ideas and advance our time/energy management skills (and sleep management skills for those with young children). Enterprises and professionals are plunged into managing a kind of risk that they would have never intentionally put themselves through. Hence, as uncomfortable as it may be, the only outcome is growth.

As world leaders juggle the sensitive battle between prioritising the health of their people or the wealth of their nations, the people remain cautiously hopeful of a return to normalcy. Whatever circumstance one is to face professionally, it is paramount to use it as a means of self-growth rather than a reason to count one's losses.

Recruitment during and after COVID-19

Despite initial slowdown in the hiring process, several progressive companies picked up in Q2 and Q3 where they left off during the lockdowns. Companies and businesses, too, have to grow, and in order to grow, they need to hire. In the healthcare industry, there is definitely lots of work to be done once the initial setbacks in mobility have been addressed.

To circumvent the need to travel for face-to-face meetings, technology has become our best friend. Video interviews with several people across different time zones are not without their challenges, but they can be done. There are, however, some ground rules to be observed. The candidate has to exhibit flexibility but also the same commitment that one invests in a face-to-face interview. The minimum is to ensure a working technology and, if possible, freedom from interruptions from one's personal life.

The employer, on the other hand, should treat candidates with respect and consideration, taking into account time differences and biological need for food and rest. Instead of marathon interviews à la assessment centres, consider breaking up video sessions across 2 or 3 days. Allow breaks between virtual interviews. Don't leave the candidate traumatised, bruised, and battered at the end of a long virtual interview day.

COVID-flavoured interview questions

Any job interview now and post-COVID-19 will be flavoured by pandemic activities and mindsets. The question of "how did you cope with the lockdown" may not be asked openly but



For job seekers, an added mention that you would consider temporary positions and freelancing will go a long way to attract potential employers.

this would be in every interviewer's mind. Using one's learnings and experiences during the lockdown can demonstrate a candidate's resilience, crisis management skills, and resourcefulness.

The job seeker can also formulate questions around COVID-19 to ask a prospective employer. "How did the company support patients/clients/employees during the pandemic?" This will gauge a company's values and their commitment to people. The employer should not forget that candidates are also assessing them.

The bottom line

Facing unemployment is always taxing to the psyche of those affected, more so in these times. Ghosting from recruiters, empty promises from

employers, and shoddy recruitment practices are unnecessary yet resolvable hindrances. Empathy is paramount. Imbalance of power should be avoided. A candidate should not be coerced into accepting an offer out of desperation. We must keep in mind that employment is a partnership, preferably a long-term one that is mutually beneficial to all parties. If done right, recruiting and hiring during the COVID-19 crisis can be turned into a win-win situation and possibly create new trends altogether that may be here to stay.

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Save the date:

EMWA Conference in Latvia

RIGA

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**The 51st EMWA conference will be held
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The EMWA spring and autumn conferences provide a medium for networking, active discussions, and extensive cost-effective professional training. The conferences also provide an opportunity to benefit from the experiences of other medical writers.

The venues, facilities, and training programmes are chosen to offer the best possible learning environment. In addition to the formal training sessions, a relaxed, friendly conference atmosphere provides for ideal networking opportunities and enables all those attending to meet medical writers and communicators at all stages in their careers.

<https://www.emwa.org/conferences/future-conferences/>



Out on Our Own

Editorial

Welcome readers,

Over the years of being a freelancer, the Out on Our Own editor, and chair of the Freelance Business Group, I have met many freelancers from various walks of life, with different experiences and journeys. Personally, I find those that I've met extremely hard working, driven, positive, and passionate about their careers.

In this issue, our author has all these qualities and more. Shaun W. Foley is a

freelancer turned businessman. In previous issues, we have had other freelancers explain their journeys of setting up a business, and this issue complements those but offers useful tips for those likeminded readers.

In only a few years, Shaun has gone from freelancer (which he still does) to also being director of his business. He summarises key aspects that he has learnt along the way and gives our readers essential advice on how to juggle freelance work, bringing in a steady salary and

launching a business. "You need to be passionate about the business you're setting up" he states. So, if you want to challenge your work life, have a business idea, and want to take that leap of faith to get it off the ground then read his journey and advice, I'm sure you'll be inspired.

Happy reading.

I wish everyone a healthy and happy start to 2021. Farewell 2020!

Laura A. Kehoe

Setting up a business as a freelancer

I began freelance medical writing in 2017 after 5 years of medical writing at several agencies. During this time, I realised that I wanted to be a freelancer when I was constantly needing and searching for freelance support during what seemed like permanently busy periods. I also had access to the EMWA *Medical Writing* publication, through which the Out on Our Own section provided me with great advice on the requirements needed to be a freelance medical writer and the common challenges involved. Finally, I decided to take the leap of independence when my son was born, and I wanted to improve my work-life balance and spend more time at home.

Two busy years after I began freelancing, I launched my own business, Biome Professionals. In this article, I've shared my experiences and the challenges that I faced while freelancing and simultaneously running a separate business.

Initial planning for a new business

Refining your idea for a new business is an important step before investing many further hours into the idea. As a freelancer, you are the product, and even the most self-critical among us can speak positively about ourselves! But as a business owner, you need to be able to promote and advertise your services or product. Thoroughly consider the benefit that your product or service provides and refine your idea into a 30-second elevator pitch in which you can convey

your idea clearly and passionately.

Depending on the product or service, new businesses can be an expensive and financially risky venture. Therefore, careful financial planning is a key consideration for launching a new business. Will you be able to cover the expenses of launching and running the business yourself or will you need the help of a partner? If you do require investment from a partner, have you considered how this investment will be repaid? Being an online service, my business had minimal set up costs which were largely derived from profits from freelancing, and so there was no need for borrowing or further investment.

Developing and running your new business

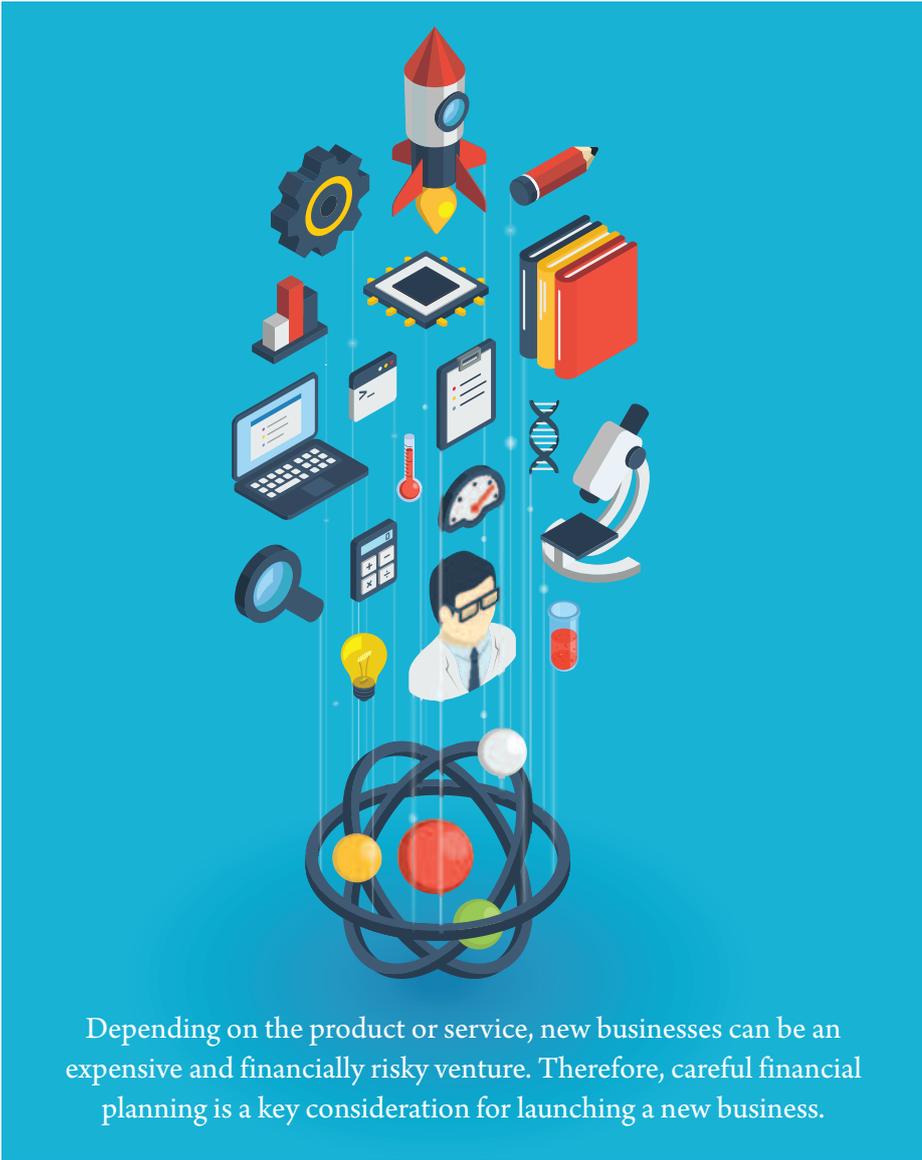
The freelance medical writers among us will appreciate the effort and input required to transition from an employee to going solo as a freelancer. In addition to freelancing, launching a new business is a huge time commitment, so prepare to invest maximum effort! Developing and running your new business with a partner will allow the workload to be split across multiple people. My wife and I designed and developed our new business, with some fantastic help from my own freelance clients, which minimised burnout while also performing our simultaneous day jobs. However, a business partner re-introduces something that many freelancers wanted to move away from in the first place: working with others! Therefore, it is important

that roles and responsibilities are discussed and that you have a trusting relationship.

An important point to consider is whether you will continue freelance medical writing at the same time as running your separate business. As every freelancer knows, freelancing is epitomised by feast or famine. One month we are worrying about where our next job will come from, and the next we are wishing for more hours

Summary box

- **Refine your idea:** Thoroughly critique whether your product or service provides a benefit. Be able to convey your idea clearly and passionately.
- **Setting up:** Consider whether you will run your new business alone or with a partner, and how you will finance your new business.
- **Maximum effort:** Launching a business is a huge commitment, so prepare to work on your idea on weekends and evenings if you need to continue freelancing during "office hours".
- **Network, network, network:** Create accounts for your business on social media and post relevant content regularly to communicate with your customers and grow your business.



Depending on the product or service, new businesses can be an expensive and financially risky venture. Therefore, careful financial planning is a key consideration for launching a new business.

in the day to finish our work. If you need to continue freelancing during your feast periods to keep your clients happy, be prepared to develop and run your business on weekends and

evenings. I've been extremely fortunate to have several long-term clients as a freelancer, but this meant that developing my business was done entirely at evenings and weekends, and running

my business is usually done during quieter periods or lunchtimes.

Growing your business and communicating with customers

Think how you will identify and communicate with your customers and grow your business. Depending on your business idea, LinkedIn, Facebook, YouTube, and Instagram are all invaluable social media platforms that can be used to launch and grow your business. Find out which social media platform is best suited for your business and create an account (they are usually free). Posting regularly, at least a few times a week, will help with growing your business and keeping in touch with customers. I do almost all of my advertising and communication on LinkedIn. As an example, I update the company's LinkedIn page with content related to freelancing in medical communications which I hope will be of interest to our followers. I also ran a relatively inexpensive targeted advertising campaign on LinkedIn last year, in which I was able to specify that the content was seen only by freelancers, recruiters, and medical communications agency staff who may be involved in recruiting freelancers.

Summary

In summary, pick a business that you are passionate about and go for it! I found it very satisfying to completely create something from scratch and to work on Biome Professionals as a break from the day-to-day of freelancing and I aim to continue to do both in the long-term.

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Save the date:
EMWA Conference in Portugal
CASCAIS
 November 4-6, 2021
<https://www.emwa.org/conferences/future-conferences/>

Upcoming issues of **Medical Writing**



March 2021:

Social media

For many people social media has become a primary source of information, including that related to medicine and healthcare. This issue will include articles about this trend, how to leverage the different social media tools, and how to write for social media.

Guest Editor: Diana Ribeiro



June 2021:

Mentorship

No one is born a medical writer. This issue will explore the important role that mentorship plays in the professional development of medical writers.

Guest Editor: Clare Chang

The deadline for feature articles is March 8, 2021.



September 2021:

Medical decision making and health technology assessment

This issue will focus on medical decision-making and will address issues at both the population level (e.g., health policy, resource allocation) and the individual level (e.g., individualised patient treatment decisions, involvement of caregivers). It will give medical writers a broad perspective over current issues and trends in medical decision-making and provide information and practical hints for how to describe decision-making processes and report data for health technology assessment.

Guest Editors: Claire Gudex and Maria Kołtowska-Hägström

The deadline for feature articles is June 1, 2021.



December 2021:

Medical journalism

We are living at a time when the general public is increasingly interested in scientific and medical advances. Hence, for medical writers understanding our audiences and how to efficiently reach them is key. This issue will cover those insights.

Guest Editors: Evguenia Alechine and Phil Leventhal

The deadline for feature articles is September 1, 2021.

CONTACT US



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



<http://journal.emwa.org/>