

Medical Writing



ALSO IN THIS ISSUE...

- Artificial intelligence, natural language generation, and the COVID-19 Tracking Project
- What to expect from the revision to the Good Pharmacovigilance Practices Module XVI

Volume 30 Number 4 | **December 2021**



EUROPEAN MEDICAL WRITERS 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.

Medical Writing



THIS ISSUE December 2021 | Volume 30 Number 4

Medical journalism

“Knowledge is wasted when it isn’t shared.”

J.M. Cornwell

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Medical journalism in a new era

We are living at a time when the general public is increasingly interested in scientific and medical advances. Medical journalism is therefore becoming more important to medical writers, although it is a subject that few of us are familiar with. To be able to write effectively for the general public, we need to understand their needs and how to efficiently reach them. It is therefore with great pleasure that we bring you this amazing issue packed with information on a variety of aspects of medical journalism and writing for lay audiences.

The issue starts off with an infographic from **Michelle Guillemard** and **Daniela Nakagawa** on the timely topic of how to write about coronavirus.

GUEST EDITORS



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Our first feature article is also from **Michelle Guillemard** in which she discusses how to combat anti-vaxxers through medical journalism entitled, “Addressing vaccine hesitancy in writing: How has COVID-19 changed hesitancy communication, and what works?” This article examines practical ways to put yourself in your reader’s shoes,

demonstrate an understanding of their hesitancy about vaccines, and respond effectively using evidence-based writing techniques, clear communication, courtesy, and empathy.

Next, **Era Mae Ferron** brings in an aspect not so common for most of us: the use of comics in the medical and scientific world to communicate content to a variety of audiences, not just kids. In her article “Comics aren’t just for kids: Using cartoons in medical communications”, she shares five authentication strategies to gain the audience’s trust using this promising medium.

Our dear **Amy Whereat** shares her experience with “Tweeting publications... A short DIY guide to Twitter copywriting for



medical writers". Her article is about the five main lessons learned from having to write a Twitter post about a clinical study, for a peer-reviewed journal, in the eleventh hour.

Then, **Leesa Klich** enlightens us with "How to write for health websites". She explains that there are many strategies that medical writers can employ in creating health websites that make them more likely to capture and keep readers' attention and to encourage them to interact or engage with the content.

Lisa Chamberlain James and **Rachel Beeby** cover a related and increasingly relevant topic, "Plain language summaries of publications". The article explores what plain language summaries are, the approaches taken to date, and the challenges that remain. Moreover, the authors address the question, "What has COVID-19 taught us?"

Surayya Taranum writes about health on social media, another aspect of medical journalism, and shares with us her article "Science communication: A guide to creating online scientific content that engages". This article discusses the challenges and opportunities for science communicators in creating content for social media and other online platforms.

Finally, **Archana Nagarajan** covers an increasingly relevant topic, "Sustainable development, climate emergency, and journalism: The emerging role of medical writers". Her article, which gently introduces our upcoming issue on sustainable communications, provides a brief overview of reporting on sustainable development, the role of medical journalists and medical writers, and more.

We hope that you enjoy this issue of *Medical Writing*.

Happy reading!



Evguenia Alechine is a Biochemistry PhD and a science communication specialist based in Argentina who has been an active EMWA member since 2016. She's currently the co-editor of *Medical Writing* and the chair of the Getting into Medical Writing group. She's a globetrotter teaching science communication worldwide and helping PhDs get into medical writing.

Phil Leventhal is Editor Emeritus of *Medical Writing* and Manager of Publications and Scientific Communications at Evidera-PPD.



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From the Editor

On journalism, the Nobel Peace Prize, and the paths we travel by

The road to a Nobel Prize is not easy and journalist Maria Ressa can attest to that. I am both awed and inspired by her journey and find it fitting to pay tribute to her achievement in this issue on medical journalism. I must admit I am biased due to several reasons. Not only was she the first Nobel laureate of Filipino ancestry, she was also the sole female recipient in 2021. And she knows science.

Maria is not a medical writer, she is an investigative journalist, a human rights advocate, and a climate activist. But she started her tertiary education in biology before shifting to journalism and theatre. Her famous quote, “Don’t be afraid – if you don’t exercise your rights, you will lose them”, may sound political, but I read evolutionary biology between the lines.

Maria is a strong opponent of the weaponisation of social media. She calls out tech giants, especially Facebook, and seeks redress for the ongoing infodemic. Her continuing battle against misinformation and disinformation (“... so a lie told a million times becomes a fact...”) resonates in our struggle as medical communications professionals to defend science in a highly skeptical world. “The virus of lies is highly contagious. They infect real people, who become impervious to facts. It changes the way they look at the world. They become angrier, more isolated. They distrust everything.”¹

Maria’s journey from life science to writing underlines the importance of the choices we make in life. Too often “two roads diverge... and sorry [we] couldn’t travel both.”²

This brings back memories of my own journey when I received that life-changing letter at age 16 offering a full scholarship at the state university hundreds of kilometers away. Based on my test results, my aptitude gauge pointed me to major in either science or English. I chose Biology.

The second crossroads came 10 years later as a fax message. Should I pursue a master’s programme in Japan or Belgium? I chose Europe.

And though “one way leads on to way,”² I did go back. Fifteen years later, I reached the next junction and had to choose between academia



By awarding the Nobel Peace prize to two journalists, the committee highlights the importance of journalism and the responsibilities that come with the power of the pen.

and industry. Only this time the two roads converged in medical writing. I felt like I had come full circle – I need not choose between science and English anymore. I even wrote an article about it.³

So here we are, another 15 years hence.

I never imagined the impact that article made. As many life scientists reach their point of divergence, they reach out to me for tips on how to go “from academia to medical writing.”³ I used to keep track,⁴ but I have stopped counting. There was no secret map, just a combination of luck, determination, and patience. I am glad that many found their own path and made similar transitions.

In our life and career journeys, only a very select few will be honoured with a Nobel Prize. Despite our job title, a medical writer is highly unlikely to win the Nobel Prize for Medicine or Literature. But many of us have successful and fulfilling careers based on the choices we made.

I do not fully know Maria’s journey and the motivations behind her decision to go from science to journalism. But to many of my fellow travelers on this road of life, here is another one of Maria’s quotes that I live by each time I reach another fork:

“All through my life, when faced with a difficult decision, I always ask myself – where can I learn more? Make the choice to learn.”⁵

By awarding the Nobel Peace prize to two journalists, the committee highlights the importance of journalism and the responsibilities that come with the power of the pen. This issue contains an excellent collection of articles that supports this message. Thank you Evguenia Alechine and Phil Leventhal for putting this together.

Finally, I would like to wholeheartedly thank Jennifer Simmons for her valuable contributions to the journal; she is stepping down as Section Editor of Regulatory Matters as she follows other pathways.

This is my fourth issue as editor-in-chief and marks 1 year since I took on this role.

To our members, readers, contributors, collaborators, and especially the editorial board members, thank you very much for all your support and trust this last year and I look forward to working with you in 2022.

References

1. Wire Staff. Filipino journalist Maria Ressa receives UNESCO award, questions big tech’s impunity. 2021 May 04 [cited 2021 Oct 31]. Available from: <https://thewire.in/media/filipino-journalist-maria-ressa-receives-unesco-award-questions-big-techs-impunity>
2. Frost R. The road not taken. [Cited 2021 Oct 31]. Available from: <https://www.poetryfoundation.org/poems/44272/the-road-not-taken>
3. Billiones R. From academia to medical writing – And staying there. *The Write Stuff*. 2007;16(4):166-7.
4. Billiones R. Wives, mothers and medical writers. *The Write Stuff*. 2010;19(4):286.
5. Office of Communications. Princeton University. 2020 Commencement remarks by Maria Ressa. May 31, 2020 [cited 2021 Oct 31]. Available from <https://www.princeton.edu/news/2020/05/31/2020-commencement-remarks-maria-ressa>



Raquel Billiones
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President's Message

#EMWATogetherApart

Dear colleagues, friends, and EMWA community,

We hope you all had an exciting and educational 52nd EMWA conference. On behalf of the EMWA Executive Committee, I had great pleasure in welcoming you to the first Hybrid Opening Conference Day on Thursday, Nov 4, 2021. Conference attendees, 390 in total, had the possibility to join this conference either virtually or face-to-face. Twenty-five of you joined the face-to-face conference day in London, with an opening ceremony, presentations, and, not to forget, our legendary face-to-face networking event. For those who could not travel, we streamed the opening day across Europe and beyond. Thanks to the support of several networking groups, we were able to offer in total 64 EMWA and non-EMWA members local networking events in London, Zurich, Amsterdam, Warsaw, and Potsdam. Clare Forestier, the moderator of the hybrid day, did a fantastic job of connecting us all. Together with Clare, we all

took great pleasure in welcoming our new EMWA members. We also celebrated the commitment of our 182 volunteers who organised conference sessions and several events outside the formal education programme, including the traditional Introduction to Medical Writing seminar, the Freelance Business Forum, a session on Getting Into Medical Writing, Special Interest Group (SIG) presentations, Mindfulness, and Yoga.

The EMWA Professional Development Committee prepared a comprehensive education programme, with 29 online workshops covering a broad range of topics. This year, 38 workshop leaders offered 19 foundation workshops and 10 advanced workshops. Thank you for your commitment to the professional development of our members!

The organisation of the conference would have not been possible without the support of the Head Office. A special thank you to Editors, Candi, Amy, Debra, Carrie, and Claire who have

already dedicated more than 2000 hours to EMWA this year.

We hope that this year's unique conference setup allowed you to get the most out of your EMWA experience.

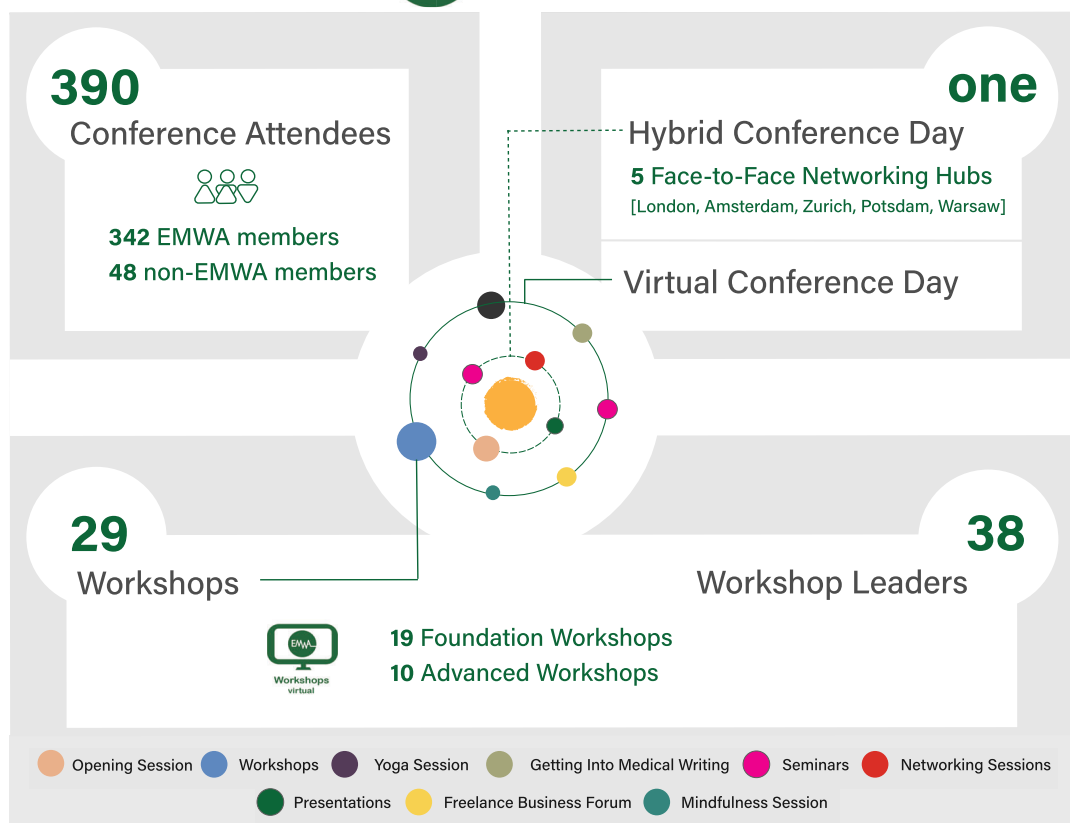
By attending this conference, you have contributed to EMWA's sustainability initiatives. For every registrant, the EMWA Sustainability SIG (#EMWASUSSIG) has pledged to donate 1€ to plant trees at <https://www.iplantatree.org>. That is approximately 100 trees planted for this conference.

We look forward to welcoming all of you to an exciting conference in Berlin in May 2022.



Carola Krause
president@emwa.org

SUMMARY of EMWA's 52nd CONFERENCE (2021)



Design@EMWA Creative Team: Carola Krause



EMWA supports collective editorial calling for emergency action to limit global temperature increases, stop the destruction of nature, and protect health

In September 2021, the editors-in-chief of over 200 biomedical and scientific journals from all geographic regions issued a call for Emergency Action to Limit Global Temperature Increases, Restore Biodiversity, and Protect Health.¹ This editorial was published simultaneously in several international journals, including the *New England Journal of Medicine*, *Lancet*, *BMJ*, and *PLoS*.

The EMWA journal *Medical Writing*, with the endorsement of the EMWA Executive Committee and the support of the Sustainability SIG (SUS-SIG), has declared full support for this collective and concerted editorial.²

The call for action is for everyone, but the editorial focuses particularly on what needs to be done by countries, world leaders and health professionals. For more information about EMWA's sustainability initiatives, contact sussig@emwa.org.

Reference

1. Atwoli L, Baqui AH, Benfield T, Bosurgi R, Godlee F, Hancocks S, et al. Call for emergency action to limit global temperature increases, restore biodiversity, and protect health. *N Engl J Med*. 2021;385(12):1134–7.
2. EMWA News. Oct 2021. Available from: <https://www.emwa.org/news/emwa-journal-supports-collective-editorial-calling-for-emergency-action-to-limit-global-temperature-increases-stop-the-destruction-of-nature-and-protect-health/>

Open Pharma collaboration calls for plain language summaries of peer-reviewed medical journal articles

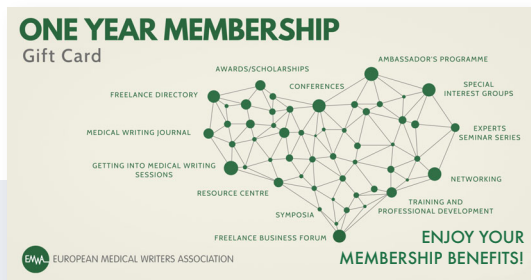
Open Pharma is a multi-sponsor collaboration of pharmaceutical companies, publishers, patients, editors, and other stakeholders that seeks to improve the pharma publications model.

The collaboration has recently developed new recommendations for plain language summaries of peer-reviewed medical journal publications. These recommendations, published in *Current Medical Research & Opinion*, were presented by lead author Adeline Rosenberg during the 52nd Annual EMWA Conference and feature EMWA's Slávka Baróniková among the co-authors.

The recommendations outline that, as a minimum standard, plain language summaries should be “in the style of an abstract, understandable and readable, free of technical jargon, unbiased, non-promotional, peer reviewed, and easily accessed”. This, the authors state, would make engagement with medical research easier for all intended audiences, from patients, patient advocates and caregivers, to healthcare professionals and policymakers.

Please refer to this link for the full recommendations:
<https://www.tandfonline.com/doi/full/10.1080/03007995.2021.1971185>





Membership gift card

You can now offer a 1-year membership gift card to a friend! For more information, email info@emwa.org.



New Chinese and Japanese translations of the Joint Position Statement Advocating for Pre-Publication Review

The American Medical Writers Association (AMWA), the European Medical Writers Association (EMWA), and the International Society for Medical Publication Professionals (ISMPP) announce the availability of translations into Chinese and Japanese of their **Joint Position Statement on Medical Publications, Preprints, and Peer Review**, published in *Current Medical Research and Opinion (CMRO)* in March 2021.

The Chinese and Japanese translations of the Joint Position Statement are accessible on the ISMPP website: <https://www.ismpp.org/position-statements-and-guidances>.

We want to acknowledge the following individuals and companies for their time and effort on the two translations:

- **Chinese:** Language translation provided courtesy of **Acurit Medical Communications Pty Ltd**, with review by **Yutao (Ronnie) Lin** and **Yilin (Greta) Ge**.
- **Japanese:** Language translation provided courtesy of **ThinkSCIENCE K.K.**, with review by **Yoshiko Okamoto** of **inScience Communications (Japan)**.

EMWA collaborates with the Asian Council of Science Editors (ACSE) at the 7th ACSE Annual Conference

The **Asian Council of Science Editors (ACSE)** hosted its 7th Annual Conference, themed around "Pandemic Driven Scholarly Publishing: Ways to Ensure Future Resilience and Sustainability," bringing together industry and academic experts to discuss the current status and future challenges to the Asian publishing industry.

The conference was held on August 21, 2021. More than 200 people took part in it, including speakers, moderators, panel experts, and

participants, from countries including China, Korea, Japan, Thailand, UK, USA, Greece, Egypt, Oman, Saudi Arabia, Nigeria, Pakistan, India, Iran, Australia, Malaysia, Argentina, Indonesia, and Turkey.

EMWA was one of the collaborators in this conference, together with AMWA, ISMPP, and other professional organisations. Check out more about the ACSE annual conference at <https://blog.theacse.com/2021/08/28/7th-acse-annual-conference-highlights/>.

Call for ideas for journal covers

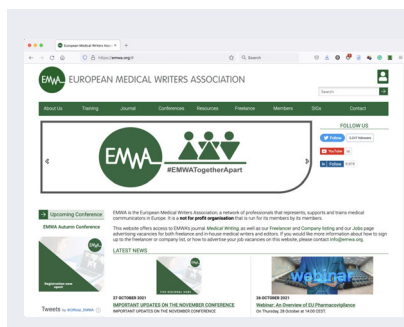
Put your creations upfront! If you are into visual communications, digital design, or photography, consider showcasing your work on the front cover of our journal. Upcoming themes include sustainability, medical devices, working from home, and open science. Please contact editor@emwa.org with your ideas.

Professional indemnity insurance – 20% discount for EMWA members!

Did you know that EMWA members get a 20% discount on their professional indemnity insurance? Established in 1992, PIA Commercial works closely with their clients to provide a tailored range of specialist insurance products for individuals and businesses.

Please get in touch with PIA Commercial

at info@PIAcommercial.com with any queries or to receive a personalised quote. Or go to their brand-new, updated website at www.piacommercial.com to view their extensive range of personalised insurance plans for businesses and individuals in the life science, biotechnology, and healthcare industries.



Have you updated your EMWA profile and preferences recently?

We have been working behind the scenes on an improved Member Directory. However, EMWA members need to actively opt-in to be listed in it. Please login to your account to opt-in. There you can also set your specific preferences for which information to show.

We will be providing more information and guides soon, but you can assist us in populating the directory by updating your preferences now.

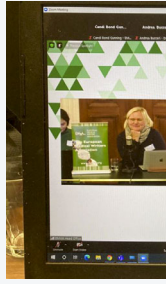


Amsterdam

“Great to see other delegates in person! And to connect with the regional hubs in London, Potsdam, Zurich and Warsaw.” – Sally Hill



London Backstage



EMWA's hybrid day

As the F2F part of the European Medical Writers Association (EMWA)'s 52nd home conference came to an end and it was time to return home, I was left with a wonderful feeling as memories from the event keep playing back in my head. How magical is human touch, to be in the presence of friends and

colleagues and to see and hear them in person? How much have we missed this salve in the last 2 years?

And so I wish to thank each and everyone who participated in planning, organising, and attending this new hybrid mode, the first in EMWA's history, showing that we can adapt,

and adapt well. Not only did we make it work but, I daresay, we made it a success. So again, a big thank you to EMWA's army of volunteers, our brilliant staff at the Head Office, the attendees at five hubs across Europe, and all those who helped make this a success.

Of course, we all owe a huge thanks to the

Potsdam

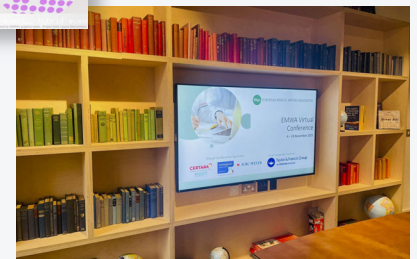
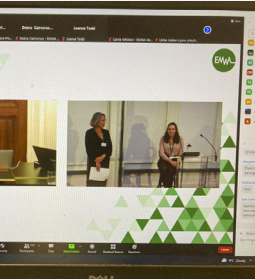


“The palatial scale of the venue was found to be directly proportional to the number of photographic opportunities.”

Satyen Shenoy



London



one thing that has given us a shot in the arm, literally – the vaccine. We marvel at the power of science, which has developed vaccines enabling us to return, slowly, to normalcy. As science communicators, it would be worth our time and effort to get involved in vaccine advocacy.

Satyen Shenoy, EMWA Vice President

"I really felt part of the EMWA community. It was exciting to meet some EMWA members face-to-face and others in the hubs, while knowing we had so many others joining us virtually. In London, I was able to see all the amazing behind-the-scenes expertise that went into making it all work."

Marian Hodges

Zurich

"Today was a refreshing break from our daily routine and we finally got a taste of what an EMWA F2F Conference is like. Looking forward to the next conference in Berlin."

Jhoy Benz



"Small but perfectly formed hub."

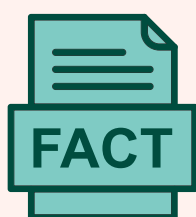
Urzula Agnieszka



Warsaw

HOW TO WRITE ABOUT CORONAVIRUS

Best Practices for Health Writers

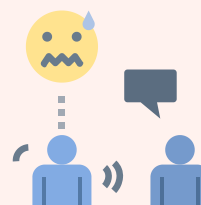


FOCUS ON FACTS AND EVIDENCE-BASED REPORTING

what we know, not what we think might happen

AVOID FEAR-MONGERING

watch your language

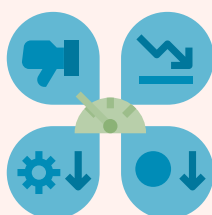
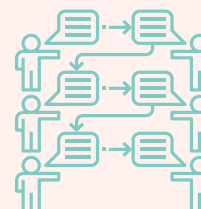


DON'T ENCOURAGE IRRESPONSIBLE ACTIONS

eg stockpiling

TELL STORIES THAT NEED TO BE TOLD

don't contribute to hysteria with irrelevant information

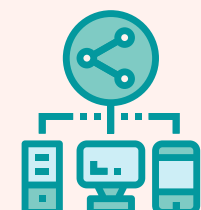


DON'T WRITE ALARMIST HEADLINES OR ENCOURAGE FEAR

like the classic: "Here's why you should be worried ..."

AVOID THE PRESSURE TO WRITE AND SHARE FOR THE SAKE OF IT

you don't always have to have a voice among the noise





TALK TO EXPERTS

consult with people who work in a relevant field and share their opinions

REMAIN OBJECTIVE

you don't need to have an opinion on the future



CONSULT A RANGE OF QUALITY SOURCES

different experts know about different topics

FOLLOW WHO'S ADVICE

read their dedicated coronavirus page



REMEMBER THAT NEW INFORMATION IS NOT NECESSARILY TRUE INFORMATION

in many cases, the newer info hasn't been verified yet

UNDERSTAND STATISTICS

use them sparingly and responsibly



WRITE USEFUL CONTENT THAT IS HELPFUL

consider your reader's needs, wants, fears and questions

REFER TO QUALITY, RELIABLE SOURCES

always question your information, and think before you share



EDUCATE PEOPLE IN THE WRITING PROCESS

explain the reasons why we don't have answers yet.

Source: <https://www.healthwriterhub.com/health-communication-best-practices/>
Author: Michelle Guillemard Infographic by Daniela Nakagawa

Addressing vaccine hesitancy in writing: How has COVID-19 changed hesitancy communication, and what works?

Michelle Guillemard

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Abstract

To address vaccine hesitancy in writing, it is important to put yourself in your reader's shoes, demonstrate an understanding of the hesitancy, and form an effective response using evidence-based writing techniques, clear communication, courtesy, and empathy. This article examines practical ways to achieve these objectives.

Eighteen months before the COVID-19 pandemic began, I wrote about vaccine hesitancy for the March 2018 issue of *Medical Writing*.

Back then, health communicators were concerned about hesitancy and the MMR vaccine.

We were furious at Andrew Wakefield and frustrated with mothers who spread misinformation online while choosing not to vaccinate their newborns.

How the world has changed.

COVID-19 and hesitancy

As outbreaks and infection rates continue to soar, vaccination – while not a silver bullet – is the only weapon we have against COVID-19. But poor messaging has hindered rollouts and uptake in countries like Australia. For example: our over-60s have had access to vaccines since March – but rates remained low for months. Why? Access issues aside, there are two likely reasons: mixed messaging and a lack of communication specifically addressing hesitations – both of which have created a perfect storm of hesitancy.

In Queensland, where I live, health experts told under-60s not to get the AstraZeneca

vaccine¹ due to concern about blood clot risks. In other states, experts encouraged under-60s to get whatever vaccine they could access. Months later, Queensland's message changed;² under-60s could get AstraZeneca if they first spoke to their doctor. Critically, health experts did not specifically address their earlier comments and why they changed their message, creating even more public confusion.

Consistent public health messaging is the key to alleviating fears. Reliable communications that address hesitancy will help to avoid mixed messaging around safety. Messaging needs to be strong enough to motivate behaviour change, too. One of our first consistent public health messages was to get vaccinated to do the right thing and protect your community,³ but it has since changed to focus more on “returning to normal”.

This perfect storm of hesitancy is, of course, worsened by media fearmongering. Journalists love to spread fear through speculation, sensationalist headlines, and language use. But fear doesn't change behaviours – it creates confusion, which makes hesitancy worse. And, to recap my 2018 piece: knowledge, facts, and evidence alone don't help to address vaccine hesitancy any more than fear does, unfortunately.

The first step towards addressing hesitancy is putting yourself in your audience's shoes. Demonstrate an understanding of the hesitation, and then form an effective response.

Putting yourself in your reader's shoes

Targeted communication is more effective than generic communication. Putting yourself in your reader's shoes and thinking about what they need to know helps you to communicate clearly, giving you a better chance of achieving your desired result. Asking questions that explore people's reasoning behind their decisions is a useful first step. (See the Appendix for a related writing exercise.)

I recently asked my Instagram followers why they got the vaccine, and one astute reader responded with a simple question: Why wouldn't

you? The answer requires a big-picture approach. Why do people do things that are bad for them, and why don't they do things that are good for them?

It's not because of stupidity or ignorance, writes emergency physician Edwin Leap, in *MedPage Today*.⁴ “Human decisions are far more complex, nuanced, and personal than most of us realise.” He added, “We needn't agree with a choice to understand it,” before offering a few logical reasons why people don't do things that are good for them, including:

- science is hard to understand
- an understanding of science is not innate
- people distrust pharma companies and the government in general
- poverty

But importantly, not all people who are hesitating feel and think the same. Vaccine hesitancy is a complex spectrum,⁵ from consideration right through to outright denial. Different stages require different messages, and each fear requires a targeted, consistent response. If a hesitant reader reads a different answer every time they express their specific hesitation, they'll likely feel more confused and hesitant.

Over the past months, I've read many perspectives online to understand more about the spectrum of COVID-19 vaccine hesitancy. Two of the main themes underlying hesitancy seem to be:

- **Fear of the unknown** – fears related to long-term side effects, unfamiliar ingredients, and pregnancy risks
- **Loss of control over choice** – fears related to loss of ownership over one's body, which also relates to losing control of freedom

Anger and frustration, two highly emotional states, are closely related to these themes. So, it's not surprising that many of us end up in arguments when discussing hesitancy. Putting yourself in your reader's shoes helps you avoid arguments, communicate clearly, and engage in respectful debate.

When I asked a friend about her reasons for hesitation, she was more than happy to discuss



her feelings rationally. It was like I was the only person who had taken the time to have a civil discussion about hesitation with her. And by understanding and acknowledging her perspective, I was able to learn more about hesitation. “Treat [people who are hesitant] as potential allies rather than enemies,” concludes Dr Leap. “Try to learn from them and apply that information to future situations. But do not, under any circumstance, treat them as simpletons or dismiss their concerns out of hand.”

Understanding the reasons for hesitation helps you form an effective, relevant response.

Forming an effective response

An effective response should be targeted, evidence-based, and considerate. And we can look to other public health campaigns to see which communication tactics have successfully changed people’s behaviours. For example, health communication research⁶ has shown that, while fear alone doesn’t change behaviours, messages

of fear combined with messages of hope help to inspire behaviour change.

An effective response should be targeted, evidence-based, and considerate.

This effect worked well in a 2017 skin cancer prevention public health campaign. Therefore, a consistent fear-hope vaccination message might work well – as long as it’s not too menacing. Comparably, research into smoking prevention⁷ has shown that “short and sweet” messages focused on immediate gains work better than highly threatening or fear-eliciting messages.

A separate study⁸ found that negative messages containing deception and disgust pushed readers into defensive responses – making them best avoided. Narratives and real-life success stories are persuasive tools, too. Embedding facts in a story is more persuasive⁹ than simply presenting facts alone. Incorporating stories about hesitant individuals who have changed their minds may work well.

Engaging particular groups through targeted communication is important as well. Speaking to News GP,¹⁰ Associate Professor Holly Seale, an

infectious disease social scientist also at the UNSW’s School of Population Health, said: “By being activated, by being primed, the research shows people are more likely to go in to see their GP and their health provider with a more positive mind frame.”

The final word

If you’re communicating about vaccine hesitancy and you want to discuss the benefits of vaccination, here are the key points to keep in mind:

- **Put yourself in your reader’s shoes** – understand your reader’s reasons for hesitation
- **Form an effective, evidence-based response** – use health communication tactics, such as:
 - Fear-hope messages (but avoid frightening messages)
 - Short and sweet messages focused on immediate gains
 - Narratives and real-life success stories to persuade
- **Keep your communication targeted** - use relevant messages in susceptible communities or age groups

6 tips to help you write clearly about COVID-19

To alleviate pandemic-related anxiety, aim to provide clear, factual communication that supports health literacy.

1 Clearly define unfamiliar COVID-19 medical terms

Think of the words and phrases that could be unfamiliar to your target audience and define them before using them in a sentence. To determine which terms are unfamiliar, you'll need to research your target audience and gather your requirements in detail. The clearest way to define an unfamiliar medical term is to define the term first, and then use it in a sentence.

- **CORRECT:** The time after exposure and before having symptoms is called the incubation period. The average incubation period for COVID-19 is 4.9–7 days.

Sometimes, you may not be able to define the term before using it in a sentence. While it's best to define the term first, including a definition in the second sentence is better than not including a definition.

- **EXAMPLE:** The average incubation period for COVID-19 is 4.9–7 days. The incubation period is the time after exposure and before having symptoms.

2 Differentiate between similar-sounding terms

Many pandemic-related terms sound similar and can confuse your readers when misused. An essential aspect of writing clearly about COVID-19 is differentiating between common terms to avoid confusion. Here are just some of the many similar-sounding terms you may need to define or explain:

- Restrictions and measures
- Physical distancing and social distancing
- Quarantine and isolation
- Lockdown and self-isolate
- Medication and vaccination

3 Use key terms consistently

One of the fundamental rules of plain English writing is to use consistent key terms. Decide whether you're going to use the term COVID-19 or coronavirus, for example. If you



go with COVID-19, make sure your capitalisation is consistent.

Using consistent key terms is important, as it alleviates confusion. For example, if you use the terms physician, health professional, doctor, and GP interchangeably, your readers may think you're referring to different people.

Tip: SEO best practices tell us to use a range of synonyms for Google's algorithm, but there's a balance between substituting terms for variety and confusing your readers.

4 Define acronyms

Most abbreviations and acronyms need defining, except the ones you can assume everyone understands. For example, writing "Cable News Network (CNN)" is unnecessary. But your readers may not know what PPE or AZD1222 vaccine mean.

The correct way to use an acronym is to spell it out in full at first reference, then include the abbreviation in parentheses. You can then use the abbreviated term throughout your content.

- **CORRECT:** Personal protective equipment (PPE)
- **INCORRECT:** PPE (personal protective equipment)
- **INCORRECT** (no need to capitalise every word): Personal Protective Equipment (PPE)

Tip: You don't have to place an abbreviated term in parentheses if you're not going to refer to it in your content.

5 Be careful of redundancy

Redundancy is when your words and phrases repeat information unnecessarily. These extra words can confuse your readers and make sentences longer, contributing to

poor readability.

Here are some examples:

Global pandemic: Global is unnecessary, as a pandemic is, by definition, global or affecting multiple countries

COVID-19 virus: As COVID-19 stands for coronavirus disease 2019, virus is unnecessary

A total of 30,000 people: A "total of" is unnecessary.

Watch out for general redundant words and expressions, like:

- First and foremost
- My own opinion
- Past experience
- Exactly the same

6 Convey factual information

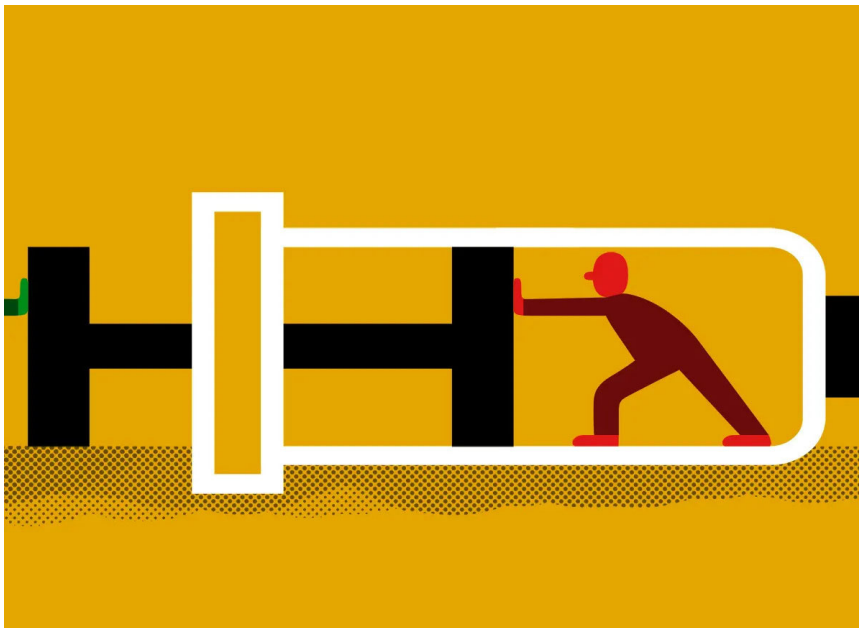
If your writing feels too emotional or threat-based, readers become anxious and may not understand. A review of media dramatisation of the H1N1 pandemic suggested that news content stressed threat-based information over accurate and factual information, creating artificial hype or hysteria around the new virus.

To avoid confusion and alleviate pandemic-related anxiety, focus on providing:

- Accurate information about the signs, symptoms, and risk factors
- Information on how to effectively prevent or control the disease

Practical, actionable information gives your readers a sense of control and reduces confusion.

An increasing number of people are reading about how viruses spread, how to prevent diseases, and how vaccinations work. By providing good-quality information, we can help our readers make informed choices and create better health outcomes.



Keep communication consistent, clear, and courteous.

Health writers should also continue to:

- Look at what has worked in previous pandemics and public health campaigns
- Look at what is helping to increase rates of vaccination now, in real time

Good scientific writing is about promoting a socially responsible message in line with the best available scientific evidence. And in the COVID-19 pandemic, that message is to get vaccinated. Our job is not to bring all views to the table, because not all views are backed up by evidence. Our job, as health communicators, is to help readers make the choice that leads to better health outcomes and is in the best interest of public health.

Disclaimers

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

Conflicts of interest

The author declares no conflicts of interest.

References

1. Zillman S. Queensland's Chief Health Officer rejects Prime Minister's comments on AstraZeneca's COVID-19 vaccine for under-40s. ABC News. 2021 [cited 2021 Sep 1]. Available from:

<https://www.abc.net.au/news/2021-06-30/qld-cho-rejects-morrison-astrazeneca-comments-covid-vaccine/100256022>

2. Layt S, Dennien M. Queensland CHO modifies AstraZeneca advice as case numbers rise. Brisbane Times. 2021 [cited 2021 Sep 1]. Available from: <https://www.brisbanetimes.com.au/national/queensland/queensland-cho-modifies-astrazeneca-advice-as-case-numbers-rise-20210803-p58fdz.html>
3. Why should I get vaccinated for COVID-19? Health.gov.au. 2021 [cited 2021 Sep 1]. Available from: <https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/getting-vaccinated-for-covid-19/why-should-i-get-vaccinated-for-covid-19>
4. Leap E. Vaccine hesitancy is complex. MedPage Today. 2021 [cited 2021 Sep 1]. Available from: <https://www.medpagetoday.com/opinion/rural/93783>
5. Leask J, Danchin M, Chad NJ. Australians' attitudes to vaccination are more complex than a simple 'pro' or 'anti' label. The Conversation. 2017 [cited 2021 Sep 1]. Available from: <https://theconversation.com/australians-attitudes-to-vaccination-are-more-complex-than-a-simple-pro-or-anti-label-74245>
6. Nabi R, Myrick J. Uplifting fear appeals: Considering the role of hope in fear-based persuasive messages. Health Commun. 2019;34(4):463–74. doi:10.1080/10410236.2017.1422847
7. Mollen S, Engelen S, Kessels LT, van den Putte B. Short and sweet: The persuasive effects of message framing and temporal context in antismoking warning labels. J Health Commun. 2017;22(1):20–28. doi:10.1080/10810730.2016.1247484
8. Leshner G, Clayton RB, Bolls PD, Bhandari M. Deceived, disgusted, and defensive: Motivated processing of anti-tobacco advertisements. Health Commun. 2018;33(10):1223–32. doi:10.1080/10410236.2017.1350908
9. Krause RJ, Rucker DD. Strategic storytelling: When narratives help versus hurt the persuasive power of facts. Pers Soc Psychol Bull. 2020;46(2):216–27. doi:10.1177/0146167219853845
10. Attwooll J. Is there enough public data on COVID-19 vaccine hesitancy? NewsGP, RACGP. 2021 [cited 2021 Sep 1]. Available from: <https://www1.racgp.org.au/newsgp/clinical/is-there-enough-public-data-on-covid-19-vaccine-he>



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Appendix. Vaccine hesitancy writing exercises

1. Addressing common fears

Consider these common hesitations, and write an empathetic, “short and sweet” response that includes a fear-hope message:

Hesitation	Your response
The AZ vaccine isn't as effective	
The vaccine won't stop me from getting the virus	
Why get vaccinated if you can give it to other people?	
I'm scared of the blood clot risk	
I'm scared of the risk of immediate death after receiving the vaccine	
Nobody I know has had COVID	
I want to wait and see what happens	
I'm worried the vaccine will affect my fertility	
It's an experimental vaccine that was rushed to market	

2. Common reasons why people get vaccinated

Sharing reasons why others choose to get vaccinated may help to persuade hesitant individuals. Consider these common reasons why people have been vaccinated and write a response to a hesitant individual.

Justification	Your response
Keeping family safe	
I don't want to die of COVID-19	
I care about the community and public health	
I want to travel again and live normally	
I've seen the multitude of benefits of vaccines over so many years, can't see why this is different	
Worried about spreading the virus	
I want the peace of mind	
I want to live without anxiety and fear	
Protection against long COVID-19	

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Comics aren't just for kids:

Using cartoons in medical communications

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Abstract

Comics aren't just for kids. They're a provocative, entertaining, and storytelling medium powerful enough to captivate people of all ages, all languages, and all cultures – no small feat in today's era of instant gratification. To engage our audience, medical writers and journalists can use *graphic medicine* – the intersection of comics and healthcare discourse. I produced a graphic medicine comic about a cosmetic procedure, the Vampire Facial, and applied five authentication strategies to gain my audience's trust in this promising communication medium.

I still remember the day that I got my first comic book. It was an *Archie and the Gang* double edition from my older, cooler cousin. When he handed it to me, I couldn't stop the corners of my mouth from curling up to my ears in a goofy, toothy grin. I cradled my new comic book and closed my eyes to imagine all the time that we'd be spending together. ("So this is what it feels like to be in love," I thought.) But as my joy soared, my father's displeasure grew. Comic books, he admonished, are junk that belonged in the junk pile. But to my surprise, he didn't toss it in the trash with the apple cores and crumpled juice boxes. Instead, he hid it. With the unbridled boldness that comes with an 11-year-old youth, I rolled up my pink jumper sleeves and started sleuthing. I scoured drawers, ransacked cupboards, and turned over beds. At last, I found it – up high on a shelf in my parent's tiny walk-in closet, under my dad's sweaters. I grabbed my beloved comic book and slinked

Visual literacy is now a required skill for communication.

away to a corner in my bedroom and devoured every word and every drawing in every panel from bright-coloured cover to bright-coloured cover. Until recently, I have left my love of comics with my youth. But now, when I muse about how best to capture my audience's attention about health and medical topics, I'm taken back to comics – my fondest memories of reading. I wonder, can medical writers (and journalists) use comics to captivate their audience the way that Archie and his gang of far-out friends captivated me?

Information in our back pocket 24 hours a day

We are forming expanding seas of information, propelling us into once unthinkable frontiers like the recent CRISPR gene modification technology. And we are enthralled with our seas of information. Our culture of immediacy and our iPhone mini-computers entice us to jump into the info waters, prepared or not, in search of answers to each one of our burning questions. Waiting a week for our dermatologist to tell us what this new rash is, is a week too late.

Like our audiences, medical writers and medical journalists (herein referred to as medical writers) are fixated with information. Our fixation, however, lies in how we construct knowledge to convey information in plain language and visuals.¹ Comics – a hybrid of text and image, presented as two narrative tracks in sequential order² – supports our aim to engage the public. In some contexts, particularly in the US, comics are perceived as juvenile and simplistic;^{3,4} literature relegated to children. And yet, our (everyone, including medical writers) frenzied obsession with comics (think of the X-Men franchise) demonstrates how magnetic they really are. Comics

have the power to convey complex information using text and visuals through narrative and storytelling. It's the combination of text and narratives presented in panels and purposeful

spacing that allows comics to transcend language and socioeconomic barriers,⁵ inviting a broad audience.³ They increase attention to, and recall of, information – and provide enjoyment to the viewer^{6,7} (I use the descriptor, *viewer*, instead of *reader* to take into account that some may not understand the text but can understand the pictures). It is also important for medical writers to be aware that literacy is changing.⁸ Unlike previous years, visual literacy is now a required skill for communication and "comics are at the centre of this phenomenon."⁸

Comics are known by different names: *graphic novel*, *sequential art*, *graphic literature*, *comics journalism*, and *graphic narrative*. On the

health and medical frontier, comics are often referred to as *graphic medicine* – the "intersection of the medium of comics and the discourse of healthcare."⁹

Graphic medicine has emerged in three categories: instructional, personal stories, and therapeutics.¹⁰ Graphic medicine is an ideal instructional medium as the hybrid of text and visuals aptly explain complex

concepts and may encourage behavioural change.⁵ For example, comics can transport a reader to invisible places like depicting how coughs spread clouds of infectious material^{4,5} (for example, *Be aware of droplets and bubbles!!*¹¹). By using graphic medicine to tell personal stories, the writer or illustrator documents their personal health experiences which can be a space to voice anxiety and fears (for example, *Inequity in the time of pandemic*)¹²; sometimes with an interjection of humour (see, *Creativity in captivity*).¹³ Comics have expanded from a solitary viewing experience to a collaborative, therapeutic production.¹⁰ The Graphic Medicine International Collective, for example, has been hosting "Drawing Together" sessions where comic artists assemble virtually and draw together.¹⁴

Can graphic medicine be authentic?

Authenticity and reliability are integral to medical writers' work. But if comics are a hybrid of text and visuals, fact and fiction, *can graphic*



medicine be authentic? The answer is a resounding yes. The journalistic standards of reliability and authenticity are central to the comic output that fuses “aspects of hard news and entertainment, factual reporting and fictional storytelling, accuracy and exaggeration, and credibility and creativity”.¹⁵ Authenticity in media, however, is a paradox. The information that the writer or illustrator presents to the world is mediated. Reality is represented thus constructed, manipulated, or even faked.¹⁶ It’s important to remember that writers, journalists, and/or photographers take creative liberties, from minor to major, with photographs and text also.¹⁶ For instance, with text, an article that a journalist wrote based on an interview is a true story, but only part of the true story. Certain details were the focus while others were not. With photographs, choosing one photo over another or editing by cropping is a representation of reality. However, in the case of drawn visuals as opposed to photographs (which we assume are authentic), the viewer accepts that the visuals are subjective and may therefore be misleading because, by their nature, they are artifacts of the writer or illustrator. It’s this unknown degree of the writer or illustrator’s interpretation that may chase away a prospective viewer. Therefore information in comic form may prevent the public from trusting health information.

Medical writers can create comics that their audience can trust

Medical writers can help their viewers distinguish fact from fiction and assess the level of subjectivity by being transparent about how the comic was created. Transparency builds authenticity. Journalistic transparency, according to Weber and Rall,¹⁶ involves being transparent about research strategies, methods, and sources. It’s about showing the viewer where the information comes from and how the comic was created.

Applying authentication strategies to a comic about vampire facials

In 2013, Kim Kardashian introduced the world to the Vampire Facial with a photo of herself sitting regally as if she were waiting for a cup of matcha green tea – her face covered in what appeared to be blood.¹⁷ Only the rich – we thought – do such kooky treatments in their privileged quest for youth. But as I get older and have somehow found my feet on the same path to reclaimed youth, I consulted with aesthetic nurse Jessica Varga, to learn if a fountain-of-youth procedure exists. It apparently does. Jessica is a gracious nurse with a velvety voice that matches her velvety skin, who loves her job so much that she works at three different medical spas, including her own, which she recently opened in London, Ontario, Canada. The infamous Vampire Facial, or PRP (platelet-rich plasma) treatment, she told me, is a popular, non-invasive,

and relatively affordable treatment (compared to a surgical face-lift for example). PRP involves two main steps. The first step is microneedling – pricking the skin with sterilised needles using the SkinPen[®] to make hundreds of microscopic wounds (i.e. tiny holes). This controlled wound-making procedure triggers the body’s natural healing process in which collagen is generated, rejuvenating the skin. The second step is applying the client’s own PRP onto their face which, courtesy of the tiny holes, drinks it in. PRP, one type of blood cells, contains growth factors that can speed up healing and stimulate tissue regeneration.¹⁸ I interviewed Jessica because her passion filled the treatment room and her expertise converted me into a PRP believer. I turned the interview into an 8-panel comic (Figure 1, panels 1–3).

In their article about comics journalism, Weber and Rall¹⁶ outline five authentication strategies which medical writers can use in graphic medicine.

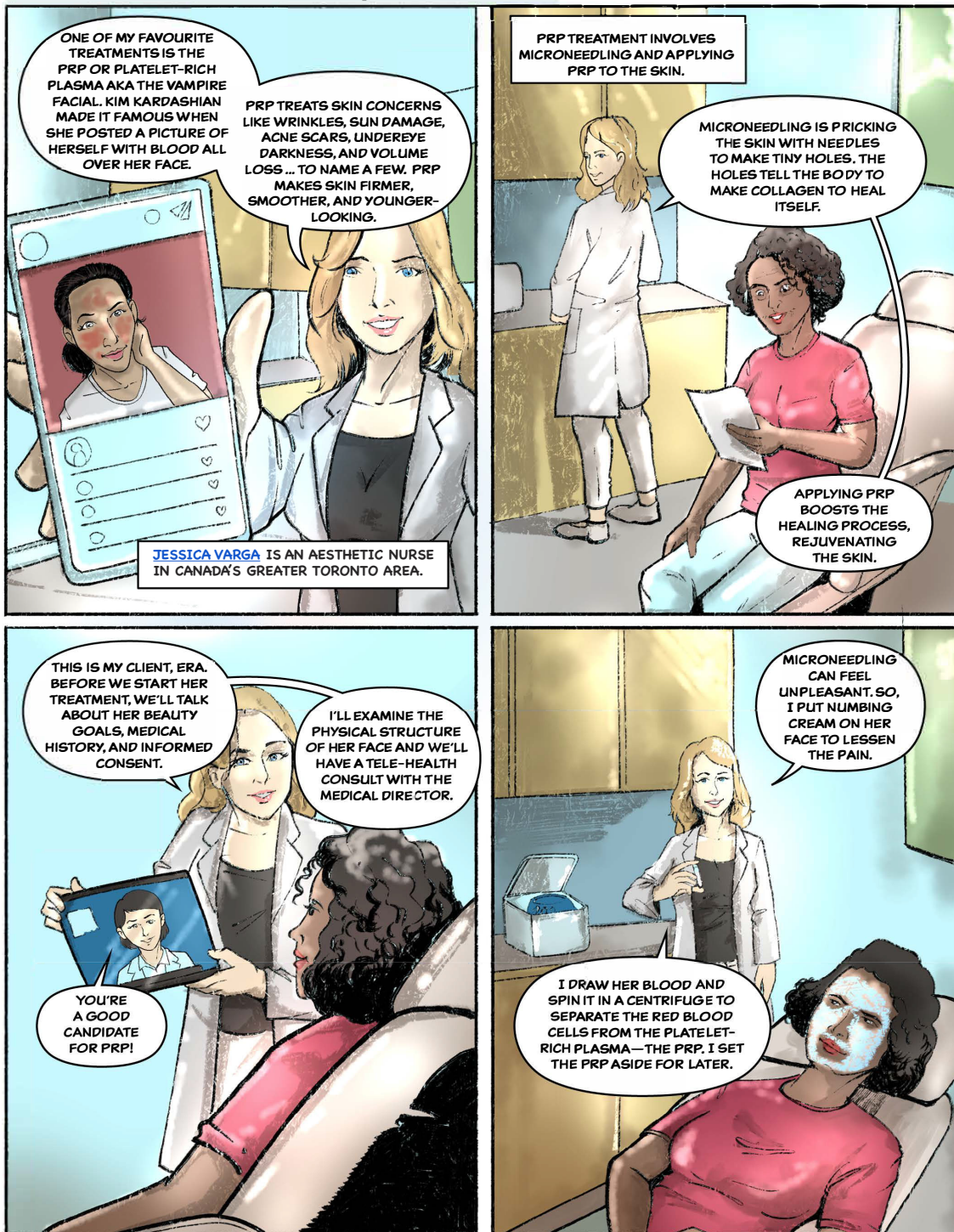
Strategy 1: The writer’s presence

In the comic, I’m the client. In reality, I didn’t have the PRP treatment done; however, I had a similar facial treatment. I decided to take this creative liberty because I was able to draw from my experience with Jessica in the medical spa. This fictional element of the comic doesn’t change the truth of how Jessica conducts the PRP treatment.

Continued on page 22

PRP aka The Vampire Facial

Interviewed July 11, 2021



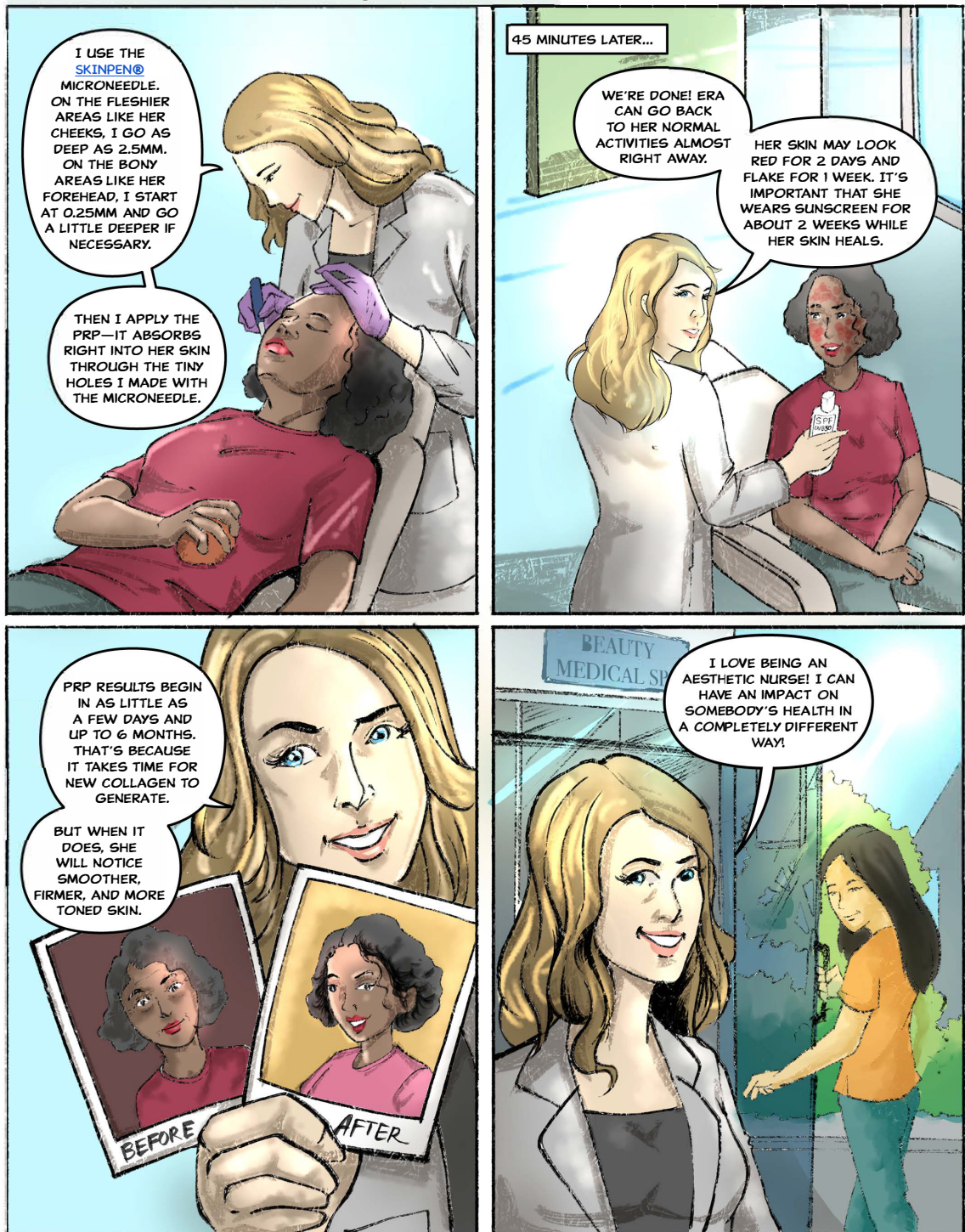
1

Figure 1, panel 1. Graphic medicine comic about the PRP (platelet-rich plasma) treatment aka the Vampire Facial.

Pictures and short bio data of comic characters show authenticity of information.

PRP aka The Vampire Facial

Interviewed July 11, 2021



2

Figure 1, panel 2

About the collaborators



(Above): Aesthetic Nurse and Interviewee Jessica Varga.

Jessica Varga started her career as a registered nurse in Alberta, Canada. She was a charge nurse and labour and delivery nurse in a rural hospital serving many surrounding reservations. Since relocating back to Ontario, Canada, she has trained extensively in aesthetic nursing. Jessica currently works in three medical spas, including her own. Jessica has a passion for women's health, skin health, and functional medicine.



(Above): Illustrator Rizqi R. Mosmarth.

Rizqi Mosmarth is an artist from Jakarta, Indonesia. He creates illustrations, comics, and simple animation. Mosmarth is an editor at BumiLangit and co-creator/founder and editor at FIGHT comic magazine.



(Above): Author Era Mae Ferron.

Era Mae Ferron is a PhD-prepared registered nurse based out of Toronto, Canada. For over 10 years, Era has been writing for academic, healthcare provider, and public audiences in nursing and occupational health and safety. Because of her love of writing and plain language communication, Era founded the health and medical communications company, The Writing Era Inc.

Published by The Writing Era Inc.

3

Figure 1, panel 3

Strategy 2: Physical resemblance

In the bio section at the end of the comic (Figure 1), I include headshots of the interviewee (Jessica), the illustrator (Mosmarth), and the writer (myself) so that viewers can see that we are real people.

Strategy 3: Style

In comics journalism, cartooning techniques such as motion lines, sound words (ouch! bam!), or thought bubbles are limited. Instead, the medical spa in the comic was drawn based on a photographic reference that I provided to the illustrator.

Strategy 4: Documentary evidence

I provided documentary evidence by including fact boxes such as a brief description of the main procedures of PRP (see Figure 1, panel 2) and hyperlinks to Jessica's Instagram business page (Figure 1, panel 1) and the SkinPen® website (Figure 1, panel 2).

Strategy 5: The meta-story

Elements used to create a comic are its meta-story such as the research methods, sources, interviewees, or the background of the writer or illustrator.

My comic's meta-story includes the date that the interview took place and the biographies of the interviewee, the illustrator, and the writer (see Figure 1, panel 3).

Conclusion

Our culture of immediacy propelled by 24/7 access to technology, and the changes in literacy from text to visuals make now an opportune time for medical writers to adopt graphic medicine as a communication medium. Graphic medicine – the hybrid of comics and healthcare discourse – is a provocative medium with the power to reach a broad audience of all ages, all languages, and all cultures. Medical writers can break the stigma that comics are for kids by being transparent about the creation process, from disclosing the writer's presence, to illustrating persons and places in their likeness, to divulging the behind-the-scenes procedures that brought the comic from concept to reality.

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References

- Costa AC, Bakker J, Plucinska G. How and why it works: The principles and history behind visual communication. *MEW*. 2020;29(1):16–21.
- Chute H. Comics are literature? Reading graphic narrative. *PMLA*. 2008;123(2):452–65.
- Ashwal G, Thomas A. Are comic books appropriate health education formats to offer adult patients? *AMA J Ethics*. 2018;20(2):134–40.
- Green MJ, Myers KR. Graphic medicine: Use of comics in medical education and patient care. *BMJ*. 2010;340:573–7.
- Kearns C, Kearns N. The role of comics in public health communication during the COVID-19 pandemic. *J Vis Commun Med*. 2020;43(3):139–49.
- Aleixo PA, Sumner K. Memory for biopsychology material presented in comic book format. *J Graphic Novels Comics*. 2017;8(1):79–88.
- Houts PS, Doak CC, Doak LG, Loscalzo MJ. The role of pictures in improving health communication: A review of research on attention, comprehension, recall, and adherence. *Patient Educ and Couns*. 2006;61(2):173–90.
- Eisner W. *Graphic storytelling and visual narrative*. Paramus, NJ: Poorhouse Press; 1996.
- Czerwiec MK, Williams J, Squier SM, Green MJ, Myers KR, Smith ST. *Graphic medicine manifesto*. University Park: Penn State University Press; 2015.
- Green MJ, Wall S. Graphic medicine – The best of 2020. *JAMA*. 2020;324(24):2469–71.
- Manna A. *Drawing the History of Science. Be aware of droplets and bubbles!* [Cited 2021 Aug 20.] Available from: <https://drawinghistoryofscience.wordpress.com/2020/03/25/be-aware-of-droplets-bubbles/>.
- Reveal. *In/Vulnerable: Inequity in the time of pandemic*. 2021 [cited 2021 Aug 12]. Available from: <https://www.revealnews.org/invulnerable/>.
- Correll G. *The Nib. Creativity in captivity*. 2020 [cited 2021 Aug 12]. Available from: <https://thenib.com/creativity-in-captivity/>.
- Comic Nurse. *Graphic Medicine. The drawing together archive* [cited 2021 Sep 30]. Available from: <https://www.graphicmedicine.org/drawingtogether/>.
- Weber W, Rall H. Comics journalism and animated documentary: Understanding the balance between fact and fiction. *ImageText: Interdiscipl Comics Stud*. 2019;11(1).
- Weber W, Rall H. Authenticity in comics journalism. *Visual strategies for reporting facts. J Graphic Novels Comics*. 2017;8(4):376–97.
- Instagram. Kimkardashian. Tonight on Kourtney & Kim Take Miami!!! #VampireFacial #kktm. 2013 [cited 2021 Sep 30]. Available from: https://www.instagram.com/p/WsspMAUS2A/?utm_source=ig_embed&ig_rid=abf89a27-a581-43c7-aa95-7a28e6047271.
- Dreher G. Johns Hopkins Medicine. Platelet-rich plasma (PRP) injections. 2021 [cited 2021 Aug 12]. Available from: <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/plateletrich-plasma-prp-treatment>.



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Abstract

The reach and impact of social media have made this communication channel the latest in a number of multidimensional communication tools to be employed in health research. Social media has become a communication tool to reach various audiences, recruit patients, develop engagement, and disseminate research. Currently, publication medical writers are being increasingly faced with producing research-based copy for social media. Luckily, as highly knowledgeable and flexible professionals, medical writers are well placed to support this challenge.

This article is about the five main lessons learned from having to write a Twitter post about a clinical study, for a peer-reviewed journal, in the eleventh hour.

It all started one gloomy afternoon in late winter as I was submitting a manuscript. Having entered the many author details and uploaded the manuscript, figures, and tables, I scrolled down the web page looking for the **next** button that would lead me to the final submission page and tea time. This is when I saw it. An empty, square box. A new, empty, square box, accompanied by a polite suggestion to “add an optional Twitter post text”. An *optional* Twitter post text? Of course, I didn’t want to add an *optional* Twitter post, I wanted to finish submitting my article and call it a day. Staring out the window, watching the last of the daylight fade, I had to admit that it was a good idea. It was an opportunity for more people to read about the research, another step towards making a difference, getting the message across. So, reluctantly, I reached for my phone, texted the lead author, secretly hoping he’d respond “not



necessary – submit now”. But he didn’t. Instead, he replied, “Great idea, Amy! thanks +++”. Oh. Thus started an adventure into the world of social media that I’d managed to circumnavigate until now. Being a publications writer, I thought that writing for social media was the realm of health science writers. Welcome back to Earth. This article is about five lessons learned with the guiding hand of a strategic communications consultant, Sabine Roziers, and that I hope to remember for the next time.

Lesson #1: Social media has gained unprecedented reach and impact in medical science

The reach and impact of the tentacular beast we know as social or, more precisely, information media has made this communication channel the latest in a number of multidimensional communication tools to be employed in health research. In health research, social media has become a communication tool to recruit patients, collect data, develop engagement, and disseminate research.¹ This is particularly true with health and medical science researchers who are concerned about demonstrating the impact of their work, although it is still not yet clear if social media posts increase citations.² Nevertheless, social media is important when the data has public health implications, may influence policy-making processes, improve

In health research, social media has become a communication tool to recruit patients, collect data, develop engagement, and disseminate research

health systems, or have a health-related socioeconomic impact.³ Interestingly, with the amount and spread of misinformation during the COVID-19 pandemic, social media platforms such as Facebook and YouTube have become acutely aware of the problems associated with social media as a communication channel for health research. To address this problem, Kang-Xing Jin, head of health at Facebook suggests “the long-term solution is to connect people to accessible, trusted information”. Equally, Garth Graham, MD, director and global head of healthcare and public health at YouTube suggests “plucking the weeds of misinformation and replacing it with good, engaging kinds of information.”⁴

So, it would seem the writing is on the wall, and medical writers are likely to be increasingly faced with producing research-based copy for social media. Luckily, as highly knowledgeable and flexible science communicators, medical writers are well placed to support this change! The tools that we use to turn a clinical study report into an article are those needed to write a Twitter post.

Lesson #2: A tweet is a very short story

A tweet, as the name implies, was originally coined to describe a product that delivered “a short burst of inconsequential information, kin

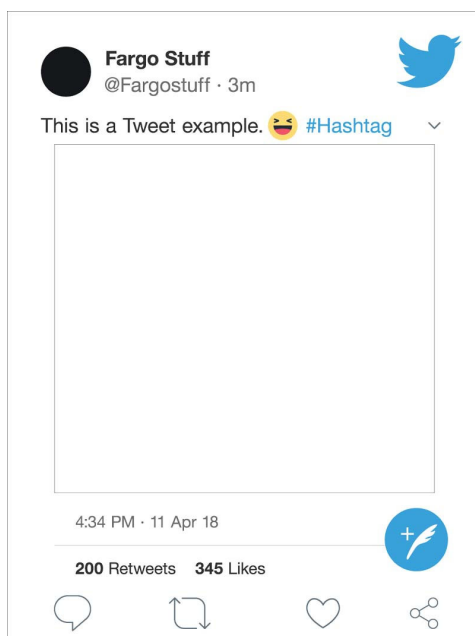
to ‘chirps from birds’ within only 140 characters” (Figure 1).⁵ That seems ironic now considering the power Twitter has gained in science communication. Nowadays, a tweet contains a luxurious 280 characters. So here’s a thing. How does one squeeze a 250-word abstract down to 280 characters? Simply, write very, very concisely and precisely. This means simple sentences and stick to the structure. Just as a publication has an established structure, so does a Twitter post.

The first line in a Twitter post is the catchphrase or title (Figure 2). This is the place to capture the reader’s attention. This usually appears on notification pop-ups on smartphones and computers.

The text that follows is a concise storyline that summarises the study conclusion and perhaps provides a bit more information with either a fact, some supporting data, or information presented in decreasing order of importance. The sole aim of this text is to engage with the reader by enticing them to click on the link, read more, or share your key data with someone else.

As each character counts, readable, concise, and precise writing is paramount. In short, the five useful (familiar?) writing tips are:

1. Choose active verbs.
2. Put the most important verb idea early in the phrase.
3. Ensure the vocabulary reflects the context, methods, and data accurately.
4. Consider presenting study design using PICO (population, intervention, comparator, and outcome).
5. Place key result data (with significance)
 - Superlatives such as: superior, better, but also improves, increases, decreases, faster, slower, etc. need to be associated with comparative data with appropriate significance.



Some good ways to capture Twitter readers’ attention in the first line are:

- Ask a question.
- State a fact.
- State the context.
- State the general problem in the domain the study addresses.
- Highlight the problem the study addresses.
- Place a key, attractive, alarming, or eye-catching figure.

Figure 1: A 280-character tweet looks like this example



Lesson #3:
Hashtags and tags engage readers to read, share, and comment on the content

Hashtags and tags come right at the end of the text. However, hashtags are usually placed at the end of the text, and are therefore included in the 280-character word count. Tags can be included in the legend of the central illustration. So, extra word count!

Hashtags are keywords that enable specific communities, who may be interested in or related to the research domain, to engage with your

content. For instance, #Alzheimers may be followed by anyone interested in Alzheimer’s disease, its management, and treatment.

Tags are aimed at specific Twitter accounts (@specific person) that target specific individuals and organisations to engage with the content and retweet or comment on your content (@Alzheimer’s France). Tags are also a useful technique to engage a first, corresponding author or another expert who supports the publication. By engaging these experts, they provide additional information, opinions or support for your research. However, if you are unsure about

the position or reaction an expert may have, you can start a private conversation with them (@specific person) on a Direct Message (DM) – this gives the expert the opportunity to retweet or engage without being public.⁶

Most often, a hashtag or tag will already exist. This means that someone has already coined a hashtag and used it to create a following. The only value in creating a new hashtag is if the subject is really new (e.g., COVID-19 in 2019) or if there is a reason to attract a specific audience (e.g., #maladie d’alzheimer for use in France). Both hashtags and tags for a given topic can be found simply by searching your research theme on Twitter (e.g., Alzheimer’s) or using specific software tools like (Tweetdeck or Google). Also, organisations and companies usually publish their hashtag on their websites – so scout around and see what comes up most often.

Lesson #4:
A central illustration completes the story

After the text, there is space to add a central illustration. This illustration is not counted in the 280-character count. It’s bonus text! The objective of the illustration is to support the



Figure 2: The catchphrase or title is the first line in a Twitter post

affirmation made in the tweet with complementary information that summarises or highlights the research data. Get creative! This can be anything from an image, a figure, a graph, a link to a webpage or PDF. It is also a good spot to add additional tags to authors, organisations, or associations concerned with the problem.

Lesson 5: Tweets can be planned!

Although journals request authors to provide a single tweet to promote their work, some organisations, patient associations, or authors will happily tweet a thread of posts. This is called Twitter planning. A plan of tweets covers the full content of the manuscript from background to discussion. A Twitter plan usually consists of up to 10 posts, each *chirp* about a part of the research story, which can be taken from any part of the manuscript. Of particular value are tweets about the discussion elements. Tweeting these discussion points can engage other experts to discuss the data or its implications with followers. As a medical writer, providing Twitter planning could be an additional service that you offer to your clients.

Conclusion

In summary, it would seem that social media has gained unprecedented reach and impact in medical science. Publication writers will be increasingly involved in promoting research data beyond the realm of the journal. As the last link between the author, who knows the data intimately and the reader who will discover it, it's up to the publication writer to carry their job a bit further and promote the value of the research at hand.

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Conflicts of interest

The author declares no conflicts of interest.

References

1. Dol J, Tutelman PR, Chambers CT, et al. Health researchers' use of social media: scoping review. *J Med Internet Res*. 2019;21(11)
2. Bardus M, El Rassi R, Chahrour M, et al. The use of social media to increase the impact of health research: Systematic review. *J Med Internet Res*. 2020;22(7):e15607.
3. Rivera SC, Kyte DG, Aiyegbusi OL, Keeley TJ, Calvert MJ. Assessing the impact of healthcare research: a systematic review of methodological frameworks. *PLoS Med* 2017;14(8).
4. Facebook, YouTube stamping out online covid misinformation much more than plucking [cited 2021 Aug 18]. Available from: <https://www.fiercehealthcare.com/digital-health/facebook-youtube-stamping-out-online-covid-misinformation-much-more-than-plucking>
5. Twitter [cited 2021 Aug 16]. Available from: <https://en.wikipedia.org/wiki/Twitter#>
6. How to send a Direct Message (DM) on Twitter [cited 13 Oct 2021]. Available from: <https://www.dummies.com/social-media/twitter/how-to-send-a-direct-message-on-twitter/>



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How to write for health websites

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Abstract

Medical writing for the internet is unique because of the way people find and consume online content. Unlike with a medical brochure handed to someone by their doctor or a hard copy of the latest health book that they've purchased, individuals are not invested in reading online content word-for-word in a distraction-free environment. There are many strategies medical writers can employ to create excellent content for health websites that makes it more likely to get readers' attention, keep it, and get them to interact or engage with the content. One of the main things to keep in mind is that each website has a unique goal and target audience that is often much more specific than simply the general public.

Writing for health websites

Finding and reading information published on a health website is quite a different experience from reading a printed patient information brochure or health book, which is why writing for websites needs different considerations. The main reason for this difference is that computer or smartphone screens offer a distraction-prone experience. The many health websites and accessible articles available online for free can distract the reader from finding and engaging with your medical content.

This article outlines some strategies that a medical writer can consider when creating content specifically intended for health websites so they have a better chance of getting their content found by the target audience and engaging the readers' attention.

A different reading experience

By keeping in mind how internet users find and consume content, medical writing can be tailored for websites. When faced with the vast amount of information available online for free in under a second, internet users are not usually invested in, nor are they motivated to, consume any particular posts that they come across. This is opposed to, for example, a patient with a new diagnosis who receives a handout from their physician or purchases a best-selling book who may be willing to carve out time in their day to be distraction-free and read their new health information. This means, for that website's content to be consumed it must be very easy to find, scan, and be both informative and engaging.

Different websites have different goals

Large companies, governments, universities, hospitals, and major health organisations often have large websites with hundreds, if not thousands, of web pages and blog posts. The goals of these websites is

usually to make conventionally accepted information easily accessible and consumable for the general public. For example, they might use general messaging around the topics of healthy eating, physical activity, or how to reduce the risk of disease. Alternatively, a website for a medical clinic, physician, or other health professional may use more targeted messaging as a marketing tool for the products, programmes, and services that they offer. These websites often aim to reach and engage with a particular audience with specific pains and goals. The content should be created to attract new potential clients and “convert” them into being loyal readers, email subscribers, and paying clients or patients. To do this, they use specific – and not general – health messages. For example, a midwife may target pregnant women in the surrounding metropolitan area, whereas a physiotherapist may target people interested in a particular sport. Unlike the website for a large health organisation, the main goal of a website for a clinic, physician, or health professional is *not* to

educate the general public, but rather to present themselves as thought leaders, educate their targeted audience, and encourage readers to take specified actions as they consume the content. Examples of these actions may be to share the post on social media, book an appointment, provide their email address, and permission to continue to email them (e.g., by offering something downloadable for free in exchange for permission to send emails – following all legal requirements including General Data Protection Regulation (GDPR)). Sometimes these health websites may offer readers the opportunity to make a purchase or investment right there online. All of these actions are encouraged by using “calls-to-action” which can look like pop-up windows, buttons, or specific requests made to readers (e.g., “leave a comment below”).

For website content to be consumed it must be very easy to find, scan, and be both informative and engaging.

Getting attention amongst 1.88 billion websites

Getting attention amongst 1.88 billion websites

As of August 6, 2021, there were an estimated 1.88 billion websites online.¹ Each of these websites can have anywhere between one and several thousand web pages and blog posts. Anyone with an internet connection can



haphazardly – or intentionally – come across your medical content online. So, how can you write a piece of content to attract the attention of your client’s target audience? While there are strategies to increase views (known as *traffic*) it is important to ensure that your content attracts the right people. This is where knowing your client’s target audience is key. Health internet users are presented with many distractions that entice them to click and view alternative content. So, to encourage them to click on your link, internet users need to know why they should, and when they do, they need to feel as though they’re in the right spot to get the right information for them or they will leave right away.

To ensure that your reader or internet user feels as though they are in the right place when they see your web page, the medical writer needs to take into consideration the target audience socioeconomic status, demographics, psychographics, trust in science and government, altruism, risk perception, etc.² One way to get this insight is to ask your client to describe their target audience in detail or even to share anonymised quotes or intake forms so you can more deeply understand who the website is trying to attract.

Once you understand the target audience for the health website, the next step is to set the post up to get found online. To get your website content found, consider two factors: getting as many of the target audience as possible to notice the content and enticing them to click through to see the content you’ve written.

Four ways to get in front of as many of the target audience as possible

The old adage that “if you build it, they will come” is long gone on the internet now. It is no longer sufficient to simply publish content online, so additional strategies that pull the internet users to your site are also needed. Some pull strategies that help content get noticed include optimising it to be found via search engines, sharing the link on social media and incentivising readers to do the same, investing in paid advertising to promote the content online, and getting other sites to link to your content (giving your content a “backlink”).

To get your health website content found, consider two factors: getting as many of the target audience as possible to notice the content and enticing them to click through to see the content you’ve written.

To make this strategy of being found via search engines easier, an entire field called search engine optimisation (SEO) has emerged. To do this well the writer would:

- Conduct “keyword research” to find a candidate keyword (the word or phrase that is typed into the search bar) that has an acceptable volume of monthly searches (e.g., over 1,000 or even 10,000) and is not too difficult to rank for.
- Review the top 10 or 20 posts currently ranking for that keyword to analyze the competition and see the content that search engines are putting upfront so that your health content is at least as comprehensive and high quality as those posts.
- Optimise your post for that keyword.

There are many pieces of software designed to help with each one of these steps in the SEO process.

In addition to search engines, a second avenue to get your post in front of as many of your target audience as possible is through social media. Different social media platforms appeal to (or are appropriate

for) different audiences, so ensure that your client provides direction on where they have the largest and most engaged following. Social media posts should be crafted with an image or video, enticing headline and “hook”, as well as the direct link to read your content on the health website. If the content is “evergreen” (will still be relevant 6 to 12 months later, or more), then creating multiple unique social media posts and scheduling them to go out on your client’s feed over the next 6 to 12 months is recommended.

The third way to get your website posts in front of your client’s target audience is with paid advertising. This may include boosting posts that have garnered some engagement or creating advertisements for them. I recommend testing a few options before investing significant amounts of money to boost social media posts or turn them into advertisements.

Finally, getting other websites to link to your content is the fourth way to get in front of the target audience. This is often done by directly emailing owners of high-volume websites who

also cater to the same target audience and requesting that they add your link to one of their related posts. There is software that can help find these websites for you, although I recommend that your outreach be very personalised.

Three considerations to entice your target audience to click through to your content

Now that a search engine, a social media post, advertisement, or a direct link from another site has brought your content in front of many people in your target audience, why should they click the link to see it in its entirety? The “clickthrough rate” depends largely on the headline, description, and image. A successful headline and description, and an eye-catching image should appeal to the target audience’s pain points or health goals, making it more likely to get clicked instead of being overlooked as readers are scrolling through their search engine results page or social media feeds.

For example, I recently wrote an article weighing the pros and cons of a certain type of health content and tried two different headlines: “...health content: pros and cons (the truth)” versus “...health content: pros and cons (an honest look).” The first example using the word “truth” got 18 percent more engagement than the one with the “honest look.” This example reiterates the importance of knowing the terminology that resonates with the target market and the difference an excellent headline can make.

Note that none of these strategies outright guarantees a specific result, but the more of these you as the medical writer can do, the higher the chance of getting your health posts found and clicked on.

How to keep readers’ attention on the post itself

People are now used to being entertained online, so once you have a reader’s attention – they’ve clicked through from a search engine, social media post, advertisement, or other website and have opened your post on their screens – you need to keep it. Readers quickly scan through a post before (if) diving into the content itself. Readers look for instant clues on how important and relevant the information on that post is to them. Did they find what they were looking for or expecting? Because if not, they don’t hesitate to hit the “back” button and look for another website. There are several strategies to use when writing medical content for the internet including

writing for “scanners”, using plain language, putting the most important points upfront, using headings and subheadings, using other formats, and linking to other relevant pages and posts.

Write for “scanners”

People rarely read long-form content word-for-word online, without first scanning it.³ Eye tracking studies show that people start scanning a page in the top left-hand corner, move to the right, then drop to the next line or header and continue their quick evaluation before deciding whether to consume the content.

Use plain language

Your terminology should be at the ideal reading level for your client’s target audience. While the “reading score” may not directly affect how well your post will rank in search engines, it does impact the readability, which is very important for your site audience’s user experience.⁴

Put the most important points upfront

While many other forms of content take a reader through a story or otherwise lead up to a conclusion, websites use the opposite structure. Because people are not invested in word-for-word reading unless their initial search and scan of your post looks promising for them, your message is more likely to come through if your main points are front and centre. Consider using a “hook” in your introduction and putting the key message upfront. Remember, people haven’t invested in a hard copy of your content to consume in a distraction-free environment. They often want to know the main points right away.

Use headings and subheadings

Headings and subheadings allow readers to easily scan to see an overview of the contents of a post. Use descriptive headers and subheaders to break the text into the main topical sections. Also, consider summarising the content under each

There are several strategies to use when writing medical content for the internet including writing for “scanners”, using plain language, putting the most important points upfront, using headings and subheadings, using other formats, and linking to other relevant pages and posts.



subheading in either the very first or very last paragraph. If you are optimising the post for SEO, then ensure your keyword is included in at least some of the headings and subheadings whenever you can naturally fit it in.

Use bullets, boxes, graphs, and other formats to clearly communicate

Well-designed sites cater to electronic screens because they can be difficult for people to see, so wherever possible, try to avoid creating a “wall of text.” The more skimmable we make the important content, the more easily it will be seen and remembered. This is why many popular sites include abundant “whitespace,” bullets, boxes, graphs, and several images to break up the text and keep the reader engaged.

Link to other relevant pages and posts

Websites are meant to create a web of content, not unlike a spider’s web. The idea is for the site to have enough relevant content to become a trusted information hub for its ideal target audience. Instead of a regular, linear flow of content similar to print magazines, most of the pages and posts on a given website should include links to other related pages and posts within that same site (called “internal” links). This encourages readers to spend as much time on that website as possible. The longer people stay on a website (called the “session duration”),⁵ the more valuable that website is deemed to be, so search engines may start to show it to more people when that topic or keyword is being searched for. This has a positive effect to possibly get it in front of more potential readers. To do this, consider looking through previously published pages and posts to find ones that are relevant to the current one you are working on and include topic-specific hyperlinks, avoiding linking through generic terms such as “click here.” When readers see the words that are linked (often they are eye-catching underlined blue text), if they are interested in reading about that topic, they can click through to find the additional related content. It is usually acceptable to include internal links right in the body of the content. Alternatively, the internal links can be used as references at the bottom.

A word of caution when you want to include external links (links to other websites, including PubMed). Linking to external sites may be discouraged as it can invite readers to leave that website. While this may be acceptable to do in

the references at the bottom of the post, keep this in mind for the main body of text. Confirm with your client how they prefer internal and external links to be handled.

How medical writers can find clients who need health website content

Rest assured, you do not need to become an expert in every single one of the elements described here to run a successful business writing for health websites. For example, you can specialise in creating engaging blog content and social media posts. Or you can copyedit website content and help clients get backlinks. Or you can focus on SEO-optimising posts to rank higher in search engines. All of these are valuable standalone skills.

When it comes to finding clients who need health website content, in my experience, this can be done by combining networking and referrals, as well as being found online when a potential new client is searching for health writers or copywriters (by having your website content SEO-optimised). Having a portfolio page on your website with examples of your work and compelling testimonials from happy clients are also encouraged.

When you have a potential new client inquiry, first investigate their site and look for clues as to the goal and target audience of their current website. When discussing the potential project with them, ask them to describe the challenges and pain points they’re experiencing, what their short- and long-term website goals are, and get some deeper insight into their target audience.

Knowing and understanding what your potential new client wants is key to negotiating a contract and delivering exceptional medical content for their health website.

Disclaimers

The opinions expressed in this article are the author’s own and not necessarily shared by EMWA.

Conflicts of interest

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References

1. Statista. Number of websites online. 2021 [cited September 1, 2021]. Available from: <https://www.statista.com/chart/19058/number-of-websites-online/>
2. Giuliani M, Ichino A, Bonomi A, Martoni R, Cammino S, Gorini A. Who Is willing to get vaccinated? A study into the psychological, socio-demographic, and cultural determinants of COVID-19 vaccination intentions. *Vaccines (Basel)*. 2021;9(8):810. doi:10.3390/vaccines9080810
3. Nielsen Norman Group. How people read online: New and old findings. 2020 [cited September 1, 2021]. Available from: <https://www.nngroup.com/articles/how-people-read-online/>
4. Ahrefs. Flesch reading ease: Does it matter for SEO? (Data Study). 2021 [cited September 1, 2021]. Available from: <https://ahrefs.com/blog/flesch-reading-ease/>
5. Google Analytics Help. How a web session is defined in Universal Analytics [cited September 1, 2021]. Available from: <https://support.google.com/analytics/answer/2731565?hl=en#zippy=%2Cin-this-article>



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Sustainable Communications

Sustainability is a key focus area across all economic sectors, including the pharmaceutical and healthcare industry. This issue will focus on where and how scientific and medical writing can contribute to current debates on scientific and environmental problems and their impact on human health. The issue will also cover emerging career opportunities for medical writers in this area.

Guest Editors: Surayya Taranum and Elisa Sala

Plain language summaries of publications: What has COVID-19 taught us?

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Abstract

The COVID-19 pandemic has significantly impacted the whole world, and the public has had to struggle with understanding scientific data on a daily basis. The impact of scientific misunderstanding became painfully apparent with the decline in vaccine uptake, so the need for clear, understandable scientific information has never been more vital. Plain language summaries of publications (PLSPs) could be an elegant and much-needed solution to this problem. This article will explore what these documents are, the approaches taken to date, and the challenges that remain. Moreover, the authors will aim to answer the question – what has COVID-19 taught us?

The development, approval, and dissemination of COVID-19 vaccines has been in the forefront of our lives for a long time now. The discussions around potential side effects and efficacy of the vaccines have been many and varied and have sometimes been delivered with a startling lack of scientific evidence or even basic understanding. The resulting public mistrust and ensuing reluctance to have one or any of the vaccines was swift and devastating and undoubtedly cost lives. This has highlighted the need and demand for scientific research to be delivered accurately and plainly.

The public's demand for more and better scientific information is not new, and the regulatory agencies have already responded with an increase in transparency and patient engagement. The most recent and largest changes from a documentary point of view have been the

inclusion of a new patient-friendly part of the Risk Management Plan (mandated by the EMA in 2013),¹ which was closely followed by the introduction of Regulation (EU) 536/2014, which mandates the production of a lay summary of clinical trial results.² This is not currently mandated by the FDA, but patient-friendly summaries of clinical trial results are recommended.

With this in mind, it is unsurprising that there is a growing demand for plain language summaries of publications (PLSPs).

What are PLSPs?

PLSPs are short summaries of research papers written in plain language, a language that is understandable to a non-specialist audience. A PLSP aims to improve access to the results of an original research article so that non-specialist healthcare professionals, patients, and consumers of healthcare without a medical background can readily understand the findings and recommendations. It is not specifically aimed at patients or the general public, but it is likely that these audiences will take a keen interest in PLSPs.

Although there is a growing demand for PLSPs, there is no requirement to produce or publish one alongside a manuscript in peer-reviewed journals. There is also no standard guidance available on how to prepare a PLSP. Cochrane Methods in 2013³ and the Canadian Frailty Network in 2017⁴ issued helpful guidance, but even PLSPs following the Cochrane guidance remained highly heterogeneous with very low adherence to these standards.⁵ However, other guidance and best practice documents have been (or are currently being) developed, for example, by Patient Focused Medicines Development and Open Pharma. The update to the Good Publication Practice Guidelines is also expected to include a new section on information for the patient. With increasing guidance being made available, it is hoped that the awareness and quality of these documents will increase.

Why should we care about PLSPs?

PLSPs not only benefit the general public and patients, they also benefit researchers, study sponsors, healthcare providers, and healthcare professionals. For the general public and patients, these patient-centric documents can help the lay audience understand complicated issues so that they are empowered to actively participate with their healthcare provider about their treatment: “No decision about me without me” has been a mantra in the UK since 2010, supported by government and the NHS.⁶

For time-poor and overstretched healthcare professionals, it can be difficult and time-consuming to extract key messages from scientific papers. Therefore, PLSPs are a good way to increase scientific learning by assimilating complex information quickly and easily, in turn promoting good evidence-based medicine. Both patient empowerment and evidence-based medicine are also likely to promote patient engagement, meaning that patients are more likely to comply with their treatment, which ultimately improves clinical outcomes.

In 2019, participants in a US survey rated the pharmaceutical industry lowest in a list of 25 industries, ranking lower than the oil and gas industry, the federal government, and the US healthcare system.⁷ For researchers and study sponsors, PLSPs are a key way of communicating research results to a wider audience, increasing accessibility to their work, and aiding transparency, which in turn may help ease negative

opinions of the pharmaceutical industry.

A survey among physicians, patients and caregivers showed that scientific journals were the third most common source of health-related information online (47%).⁸ It also identified the value of PLSPs in facilitating a patient-physician dialogue. In the US, a survey identified that 73% of Americans obtain health-related information from the internet,⁹ and in the EU, another survey showed that within 3 months, 52% of EU citizens aged 16 to 74 reported they sought online health

Plain language summaries of publications not only benefit the general public and patients, they also benefit researchers, healthcare providers, and healthcare professionals.

information.¹⁰ As the demand for information about health-related topics continues to rise, it is important to optimise its dissemination and reach.

However, despite the benefits related to the availability of health-related information, one survey showed that respondents had concerns about the credibility of the information: fears that it was false or misleading (52%), that it was trying to sell products or services (47%), confusion over research studies that seem to contradict each other (43%), difficulty understanding the information (31%), and that companies were tracking the information being searched for (29%).⁹ Despite roughly two-thirds of respondents reporting that they see health information on social media, the majority (83%) were concerned that this information was incorrect or misleading. These surveys highlight that the quality of health information available to patients is a major concern and increasingly important. When the public searches for information, it is vital that it is accurate, reliable, and presented so that they understand and can engage with it. This will aid clarity and help to avoid misinterpretation. This

growing demand for clear and unbiased information is pushing the drive for PLSPs.

What is out there and what approaches are being taken?

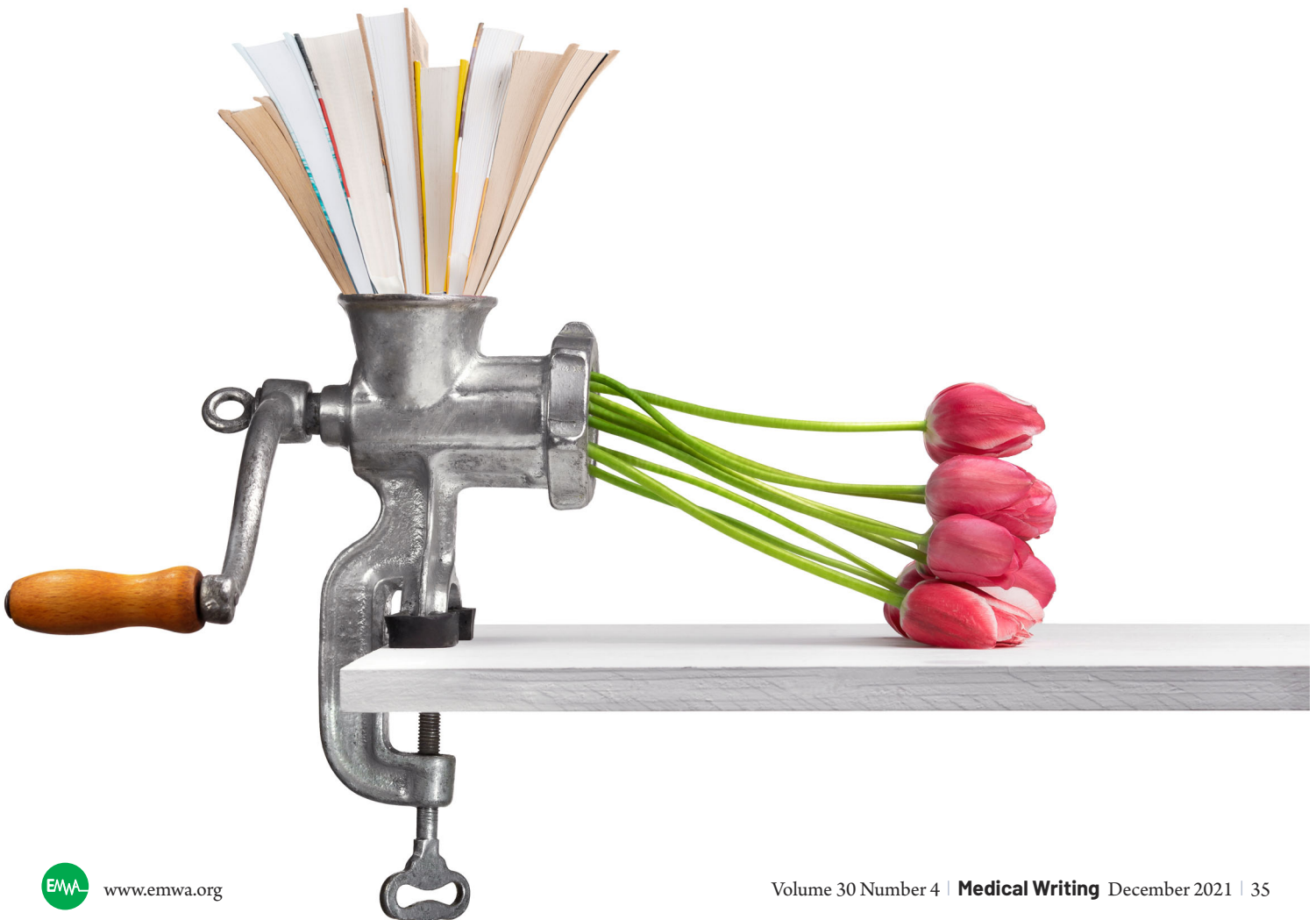
PLSPs are increasingly being considered as part of the publication plan.^{11–13} In recent years, there has been an increase in the number of PLSPs produced, an increase in journals including PLSPs in their requirements, and a more visible inclusion in their guidelines for authors. Although journals such as *Autism* have been producing PLSPs since 2011, and *PLOS Medicine* since 2004, prior to 2016, there were only approximately 100 PLSPs available on PubMed. This number slowly began to grow year on year to over 400 available in 2018 and then doubled to approximately 800 by 2020.¹⁴

Various approaches are being taken to communicate these clinical data to a wider audience. These include text-only PLSPs, a combination of text and visuals, infographics, videos, and podcasts. Gardner et al.¹⁵ investigated patient format preferences of PLSPs and identified that infographic style summaries were the first choice

followed by medium complexity PLSPs (reading age of 14–17 years) in all patient groups investigated.

Bredbenner and Simon¹¹ found that original abstracts and graphical abstracts are not as successful as video abstracts and plain language summaries at being understood, giving a feeling of understanding, or enjoyment. However, visual PLSPs are more expensive and difficult to produce. There are also problems with visual PLSPs being “found” by search engines since these engines search by text. The importance and effectiveness of infographics has been demonstrated most recently during the COVID-19 pandemic, when they were the medium of choice to convey important messaging quickly to the public, whether related to COVID symptoms, handwashing, or results of clinical trials and vaccinations. However, even when it was of the most importance – in a pandemic – governments struggle to use data visualisation well.¹⁶

Publishers and individual journals vary dramatically in how they approach PLSPs. Some journals include a PLSP as part of the manuscript submission process or on acceptance of the main



article; for others, it is optional or not required at all. Some companies have developed their own guidelines,¹⁷ and some publishers have produced short articles on how to write PLSPs (e.g., Elsevier's "In a nutshell: how to write a lay summary"¹⁸ and Wiley's "How to write a lay summary for your research"¹⁹). However, the majority still provide little to no guidance for authors.

In general, journals most frequently specify the length of the PLSP and target audience only, and the guidance itself varies widely. The target length of the PLSP can vary from 60 to 80 words²⁰ up to 250 words.²¹ The target audience for the PLSPs varies among journals, with some aiming to be "understandable by media and educated patients", "someone in high school", or "an interested person without a scientific background".²² Others advise to "pretend you're trying to explain your article to a distant family member who works in retail/fashion/hospitality".¹⁸ Generally, most journals target a higher reading age or ability than is expected in the general population.

Very few journals give guidance on language, and when it is offered, the guidance varies dramatically from journal to journal. One journal recommended using a readability analyser²⁰ to get an indication of the reading age level of the given text, but in general, the content and structure of the PLSPs is based on the abstract of the manuscript, and the advice is to simply summarise the impact/importance/relevance/key findings of the study.

Challenges

Non-specialists have access to a vast amount of medical content online, but how discoverable and easy is it for them to find peer-reviewed content of published research? Despite publishers increasingly publishing PLSPs, their availability, accessibility, visibility, and discoverability are still challenging.

Most journals have tried to make PLSPs easily accessible and open access; however, there are some that do not make them available at all or place them behind a paywall. For the general public, who may not be aware of publishers' websites, PLSPs are generally not publicly available or easy to find.²³ Journals and databases rarely have a dedicated PLSP category, and Fitzgibbon et al. in 2020 identified that only 2 out of 11 PLSPs were visible on PubMed.²⁴ Another factor that may contribute to the difficulty in

discovering PLSPs is the lack of standardisation of terminology, making searching difficult. PLSPs are referred to by a number of different terms, including lay summary, plain language summary, plain English summary, patient summary, author summary, general scientific summary, non-technical abstract, significance statement, highlights, or blog. Some journals have also been found to use more than one term for a PLSP,²⁴ and these terms also have different meanings for different people.

This lack of visibility and discoverability is a huge challenge and is frustrating for the general public. Patients feel that there is not enough open access material online to be useful and that it is difficult to find.²⁵

The challenges for medical writers and the value they bring

Many medical writers have been trained in the scientific writing of complex documents that convey information to specialist audiences who are experts within their fields. However, writing for a non-specialist audience requires far more than a translation of difficult vocabulary into simpler terms. It requires a completely different skill set, necessitating training and practice. Once the documents have been produced, the teams reviewing them must also be aware of, and skilled in providing for, the needs of a non-specialist audience so that their review is meaningful and helpful, and most review teams are far more used to reviewing highly complex documents aimed at regulatory agencies. It would help both writers and review teams to have the PLSP available as part of the manuscript and peer-reviewed alongside it.

The lack of guidance on the content of PLSPs drives the huge variation in the quality and length of the current offerings. Medical writers are trained to provide documents complying with a variety of requirements, but best practices are needed to help provide standardisation of PLSPs across the industry. In particular, guidelines are needed on the best format to use, text length, structure of infographics, reading age, and where the information should be made available.

Beyond this, even stand-alone PLSPs should not contain more information than that presented in the main manuscript but should include some context to allow non-specialist readers to fully understand the messages. Therefore, it is important that the main manuscript is also written well!

Conclusion

It is clear that there is a growing demand and need for information for non-specialist audiences, and it is equally clear that we face many challenges to be able to provide fit for purpose information in the form of a PLSP. However, this effort is vital, for without it, the PLSP will not be read or understood, and the monumental effort will be wasted.

Although many publishers have responded and are making great strides towards this goal, more can be done to help industry, authors, and ultimately the non-specialist audience. If journals require PLSPs and insist on high quality, fit for purpose documents, this will drive uptake and PLSP quality. The journals' demand for PLSPs may also ease company compliance issues and the danger of companies being accused of cherry-picking journals with no requirement for PLSPs. Whatever the decisions made by publishers on this issue, it is clear that PLSPs should be made available free of charge and should be a routine part of publication planning.

Medical writers are uniquely placed to bring data to life and help non-specialists to visualise them and put them into context. Writing for non-specialists is part of the evolution of the medical writing profession, and as communication experts, medical writers should be involved in the production of PLSPs right at the start of publication planning. The lack of PLSP availability and visibility could in part be due to the lack of standardised guidance on terminology, language and content of PLSPs, all of which have been called for by the medical writing profession.

Perhaps this is a simplistic view, but many of the challenges could be solved by simply producing the abstract in plain language. In this way, non-specialist audiences would have an easily accessible summary of the paper in a language they can understand, which would also be appreciated by time-poor healthcare practitioners. This would have the added advantage of having more in-depth detail available (directly attached to the abstract) with no risk of decoupling detailed scientific information from the summary and a much lower chance of misunderstanding and confusion.

This should be the ultimate aim. If we are to learn any lesson from COVID-19, surely it is this.

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References

1. European Medicines Agency. Guidance on format of the risk management plan (RMP) in the EU Part VI: Summary of the risk management plan by product. [cited 2021 Oct 1]. Available from: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-format-risk-management-plan-european-union-part-vi-summary-activities-risk-management-plan_en.pdf
2. European Medicines Agency. 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, Version 2. Amsterdam: European Medicines Agency; 2017. [cited 2021 Oct 1]. Available from: https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf
3. Plain Language Expectations for Authors of Cochrane Summaries (PLEACS) Committee. Standards for the reporting of Plain Language Summaries in new Cochrane Intervention Reviews. 2013. [cited 2021 Oct 1]. Available from: https://methods.cochrane.org/sites/default/files/public/uploads/pleacs_2019.pdf
4. Canadian Frailty Network. Guidelines for writing a lay summary. [cited 2021 Oct 1]. Available from: <https://www.cfn-nce.ca/wp-content/uploads/2017/09/cfn-guidelines-for-lay-summaries.pdf>
5. Kadic AJ, Fidahic M, Vujcic M, Saric F, Propadalo I, Mareljija I, et al. Cochrane plain language summaries are highly heterogeneous with low adherence to the standards. *BMC Med Res Methodol*. 2016;16(61):61.
6. Department of Health. Liberating the NHS: No decision about me, without me. Government response to the consultation. 2012 [cited 2021 July 7]. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/216980/Liberating-the-NHS-No-decision-about-me-without-me-Government-response.pdf
7. McCarthy J. Big pharma sinks to the bottom of US industry ranking. 2019 [cited 2021 Oct 1]. Available from: <https://news.gallup.com/poll/266060/big-pharma-sinks-bottomindustry-rankings.aspx>
8. Pushparajah DS, Manning E, Michels E, Arnaudeau-Bégard C. Value of developing plain language summaries of scientific and clinical articles: A survey of patients and physicians. *Ther Innov Regul Sci*. 2018;52(4):474–81.
9. The great American search for healthcare information. 2018. [cited 2021 Oct 1]. Available from: <https://www.webershandwick.com/wp-content/uploads/2018/11/Healthcare-Info-Search-Report.pdf>
10. Eurostat. 53% of EU citizens sought health information online. 2020 [cited 2021 Oct 1]. Available from: <https://ec.europa.eu/eurostat/web/products-eurostat-news/-/ddn-20200327-1>
11. Bredbenner K, Simon SM. Video abstracts and plain language summaries are more effective than graphical abstracts and published abstracts. *PLoS One*. 2019;14(11):e0224697.



Writing for a non-specialist audience requires far more than a translation of difficult vocabulary into simpler terms.



12. Chapman SJ, Grossman RC, FitzPatrick ME, Brady RR. Randomised controlled trial of plain English and visual abstracts for disseminating surgical research via social media. *Br J Surg*. 2019;106:1611–6.
13. Gardner J. Poster presented at ISMPP Annual Meeting 2019.
14. Havran LM, Morgan CH. Lay and plain-language summary trends in the medical literature. Poster presentation at ISMPP Annual Meeting, March 2019.
15. Gardner J, Silvagnoli LM, Shepherd C, Pritchett J. Evaluation of plain-language summaries (PLS): optimising readability and format. *JPLS*. 2019;1(1):1–10.
16. Cheshire J. Analysis: data visualisation expert on what's wrong with the UK government's coronavirus charts. *UCL News*. [cited 2021 Oct 1]. Available from: <https://www.ucl.ac.uk/news/2020/nov/analysis-data-visualisation-expert-whats-wrong-uk-governments-coronavirus-charts>
17. Rees T, Richter CA, Dennis N, James J, Gokool N. Development of a framework for publishing patient lay summaries in medical journals. Poster number 3 2017. European Meeting of ISMPP, 17–18 January 2017, London, UK.
18. Tancock C. In a nutshell: how to write a lay summary. *Elsevier Connect*. 2018. [cited 2021 Oct 1]. Available from: <https://www.elsevier.com/connect/authors-update/in-a-nutshell-how-to-write-a-lay-summary>
19. Green S. How to write a lay summary for your research. *Wiley*. 2019. [cited 2021 Oct 1]. Available from: <https://www.wiley.com/network/societyleaders/research-impact/how-to-write-a-lay-summary-for-your-research>
20. Author guidelines. *Autism Research*. [cited 2021 Oct 1]. Available from: <https://onlinelibrary.wiley.com/page/journal/19393806/homepage/forauthors.html>
21. Author Services Taylor & Francis. How to write a plain language summary. [cited 2021 Oct 1]. Available from: <https://authorservices.taylorandfrancis.com/publishing-your-research/writing-your-paper/how-to-write-a-plain-language-summary/>
22. Wiley Online Library. Author Guidelines. *British Journal of Dermatology*. [cited 2021 Oct 1]. Available from: <https://onlinelibrary.wiley.com/page/journal/13652133/homepage/ForAuthors.html>
23. Penlington M, Silverman H, Vasudevan A, Pavithran P. Plain language summaries of clinical trial results: A preliminary study to assess availability of easy-to-understand summaries and approaches to improving public engagement. *Pharm Med*. 2020;34:401–6.
24. FitzGibbon H, King K, Piano C, Wilk C, Gaskarth M. Where are biomedical research plain-language summaries? *Health Sci Rep*. 2020;9999:e175.
25. Nunn E, Pinfield S. Lay summaries of open access journal articles: engaging with the general public on medical research. *Learn Publ*. 2014;27(3):173–84.

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Rachel Beeby started her career as a medical writer in 2014 and joined Trilogy Writing & Consulting in 2017, where she supports Trilogy's clients on a wide array of clinical documents. The focus of her work has been writing and coordinating study protocols, study reports, common technical document submission dossiers, manuscripts, plain language summaries and other regulatory and patient related documents.

The June 2022 edition



Medical devices

The implementation date of the EU Medical Device Regulation has arrived, marking a new era of heightened attention to medical device safety and performance.

This issue will explore the experiences, challenges, and lessons learned over the last years preparing for the MDR requirements as well as potential opportunities these changes bring. Moreover, we touch base on the implementation of the EU In-Vitro Diagnostic Regulation and on other aspects of writing for medical devices.

Guest Editors: Kelly Goodwin Burri and Beatrix Doerr

Science communication:

A guide to creating online scientific content that engages

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Abstract

Science communication plays an important role in educating the public about scientific knowledge. Until recently, publishing in research journals and presenting at science conferences were the only options available to scientists for sharing their work. Now, technological advances have created several online platforms, including social media, that can be used for communicating science. This article discusses the challenges and opportunities for science communicators in creating content for social media and other online platforms.

Science communication is an overarching term to describe the practice of informing and educating the public about scientific knowledge. It plays a critical role in educating the public and policymakers about the world's most urgent issues (e.g., the COVID-19 pandemic, climate change), improving public understanding of science, and inspiring the next generation of scientists. The award of the 2021 Pulitzer Prize in Explanatory Reporting to Ed Yong, a science writer with *The Atlantic*, "For a series of lucid, definitive pieces on the COVID-19 pandemic that anticipated the course of the disease, synthesised the complex challenges the country faced, illuminated the U.S. government's failures and provided clear and accessible context for the scientific and human challenges it posed," underscores the importance of science writing in facilitating public outreach and engagement.^{1,2,3}

Until recently, publishing in a research journal and presenting at scientific conferences were the only avenues available to scientists for sharing

their work. Today, online platforms offer a multitude of options to communicate science to diverse audiences without the need for intermediaries (e.g., the press). This can be achieved through documentaries, blogs and articles, videos, podcasts, public talks, cartoons, infographics, and social media campaigns. However, relatively few scientists have embraced social media tools for sharing their work. This article discusses the important role of science communication in public health and provides an overview for creating and disseminating effective science content online.

Science communication: a public health imperative

Social media has changed how people interact with content and with each other online. More than 4.5 billion people are social media users.⁴ Internet users worldwide spend an average of 2.5 hours per day on social media.⁵ With such a vast user base, social media can be used to communicate science to the general public, increase public interest, and improve science literacy. However, a major disadvantage of any online platform is that information can be published online without rigorous fact-checking or peer review.⁶ This is evident in the number of websites and social media channels dispensing health-related advice or treatments with no scientific basis or evidence of effectiveness.^{7,8,9} The speed of information sharing on social media often contributes to the faster spread of such misinformation. Also, the cognitive overload resulting from large amounts of (often conflicting) information makes it hard for the non-expert reader to differentiate between scientifically sound vs. unreliable sources.^{10,11}

Misinformation on social media has now reached epidemic proportions, undermining public trust in science, and poses a risk to public and planetary health.^{12,13,14} Sources of

misinformation and disinformation may include news media,¹⁵ politicians,¹⁶ fiction,¹⁷ and word-of-mouth. Recent research has examined the public consumption of misinformation in the context of political elections, social network effects, and dynamics of misinformation spread.¹⁸ The impact of misinformation is evident in the lack of public support for policies to control the spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), leading the World Health Organization (WHO) to declare an "infodemic".^{19,20} Recent incidents of cyberbullying and online harassment of journalists, physicians, and scientists working to counteract misinformation underline the scale of the problem.^{21, 22, 23, 24, 25}

A recent report²⁶ found that 50% of US adults searched the internet for information regarding their health issues, with 77% using popular search engines (e.g., Google, Yahoo, and Bing) to search for health and medical information. Another report²⁷ found that 89% of Americans looked for medical information online before consulting their healthcare providers.²⁸ Seeking health information may contribute to a patient's

knowledge about their health condition and treatment options, and make them more involved in health decision making. However, given a large amount of inaccurate and potentially harmful information available online, it is easy for people to be misinformed.²⁹ It may also "change the way how patients interact with and participate in consultations with their physicians and how they feel about their relationship with their physicians,"³⁰ with detrimental consequences for patients' health.

Public confidence in science has remained stable since the 1970s;³¹ 76% of individuals report having confidence in scientists in general, and people trust scientists to provide reliable scientific information.³² Even so, improving the accuracy of information shared by science communicators, correcting errors, being trans-

A major disadvantage of any online platform is that information can be published online without rigorous fact-checking or peer review.



parent about funding and other disclosures, and taking advantage of social media tools are critical in countering the effects of misinformation and disinformation.³³ Several studies have found that health education materials exceed the eighth-grade reading level of the average American,³⁴ indicating a need for effective science communication practices and improved science literacy. As Nobel Laureate Dr Jennifer Doudna emphasises, “Science literacy is more important than ever before, and we need more innovative ways to inform, engage, and inspire the public around critical discoveries and technology.”

Science literacy is more important than ever before, and we need more innovative ways to inform, engage, and inspire the public around critical discoveries and technology.

Dr Jennifer Doudna
Nobel Laureate



Science communicators who got it right

While the explosion of science misinformation on the internet and social media are a cause for concern, there are plenty of stellar examples

where social media has served science communicators in sharing information with the public. Some of the most recent examples are discussed below.

Ed Yong was famous for his brilliant storytelling skills in science long before his coverage of the COVID-19 pandemic earned him the 2021 Pulitzer Prize in Explanatory Reporting.^{1,2,3} In his words, “If you do it well, science writing trains you to grapple with uncertainty, to embrace nuance, to run toward complexity, to try to make sense of the world.”

Dr Anthony Fauci’s media interviews during the COVID 19 pandemic are case studies in effective science communication. His simple, consistent approach of *what we know, what we don’t know, and what we should do*³⁵ focuses on the key data, translates the latest research into everyday language, and inspires public trust in science. “The purpose of your communication is not to impress people about how smart you are. The purpose is to get them to understand what the heck you’re talking about,” says Fauci, the director of the US National Institute of Allergy and Infectious Diseases (NIAID) and President Joe Biden’s chief medical advisor.



The purpose of your communication is not to impress people about how smart you are. The purpose is to get them to understand what the heck you’re talking about.

Dr Anthony Fauci
Director NIAID

Patients are also science communicators. Long-term effects of the coronavirus, or “long COVID”, is a term now used to describe the lingering symptoms that persist or worsen over several weeks or months after infection.³⁶ However, long COVID came to be recognised by the scientific and medical community only after patient-led groups collected evidence and advocated for themselves on social media. Several Facebook groups and Twitter handles were created to share information about long COVID symptoms and offer support to patients. A YouTube video on long COVID made by patient advocates captured the WHO’s attention.³⁷ Patient advocacy eventually led the WHO and medical community to accept long COVID as a diagnosis. The US Congress has now



authorised more than \$1 billion for research on long-term consequences of coronavirus infection and the US National Institutes of Health has launched a \$470 million initiative to study the condition. This story of long COVID is an excellent example of patient-led activism and involvement in research, and shows how social media can be harnessed to advance public health initiatives.

There are plenty of other examples of innovative science communication. Consider Adi Utarini, who pioneered a dengue prevention technique that used mosquitoes carrying the *Wolbachia* bacteria.³⁸ A randomised clinical trial where researchers from the World Mosquito Programme released the infected mosquitoes into an Indonesian city saw a 77% drop in dengue cases. This ground-breaking research placed

According to Aristotle, rhetoric is the art of effective or persuasive speaking or writing, intended to inform, persuade, or inspire audiences.

Utarini on the *Time* list of 100 Most Influential People of 2021.^{39,40} The clinical trial was made possible due to the support of the public and policymakers. Utarini’s team used media announcements, wall paintings, movie competitions, and in-person meetings to educate the local community and to drive public engagement and support for their research.

David Attenborough joined Instagram for a brief time to communicate science to a younger audience, “because, as we all know, the world is in trouble”.⁴¹ His debut earned him a place in the book of *Guinness World Records* for the fastest time to reach 1 million followers. Attenborough’s first Instagram message, “Continents are on fire. Glaciers are melting. Coral reefs are dying. Fish are disappearing from our oceans. The list goes

on,” was a call to rally the young audiences on Instagram into taking action to improve planetary health before it is too late.

The late Nadia Chaudhri, a professor of neuroscience at Concordia University in Montreal, Canada, used Twitter to share her palliative care journey with ovarian cancer to raise awareness about the disease to an audience of more than 143,000 followers.⁴² She also launched the Nadia Chaudhri Wingspan Award to provide funding to neuroscientists from minority and historically marginalised communities, raising over \$615,000 from a record 8,600 donors. Chaudhri passed away on October 5, 2021, leaving behind her a lasting legacy as a fine scientist and humanitarian.

Raven Baxter, also known as Raven the Science Maven,^{43,44} is an acclaimed science communicator, TEDx speaker,⁴⁵ and the founder of Black in Science Communication,⁴⁶ an organisation dedicated to advancing diversity in science and technology. Baxter is recognized as

one of *Fortune* magazine's 40 under 40 in *Healthcare*.⁴⁷ Her research focuses on the media representation of scientists and combines science-themed music with rap wordplay to drive public engagement with science.

How you can, too

According to Aristotle, rhetoric is the art of effective or persuasive speaking or writing, intended to inform, persuade, or inspire audiences.⁴⁸ A speaker's or writer's ability to persuade an audience depends on how effective they are in three areas that form the rhetorical triangle: *logos*, *ethos*, and *pathos*. All successful science communicators employ these rhetorical pillars, and you can also use them to craft your story.

1. **Logos** is the logic behind your content. Is your message clear and specific? Is there credible scientific evidence to support it? Are you logically building your story?
2. **Ethos** is about establishing your credibility and building trust with your audience. Where do you stand with your audience? How are you connected to the topic you are discussing? Are you using language or vocabulary that is appropriate for your audience?
3. **Pathos** is the appeal to the emotions, imagination, beliefs, and values of your audience. What are you doing to engage the audience's emotions or imagination? Are you using examples and language that the audience can understand and identify with?

Then, use the framework below to create your content.

Define your goal

You must be clear about your goal before you begin writing.⁴⁹ What is the topic you will focus on? Why is it relevant to the audience? What would you like to achieve? Who is your audience (e.g., scientists, policymakers, the public)? Where are they based (e.g., Twitter, TikTok, LinkedIn)? What do they know already about the topic? How much information do they need? How can you build trust with your audience? What should you do to gain their interest and engagement?

Choose your platform

A multitude of social media and online platforms are available, with more being added regularly. To find the platform that fits your needs, you

need to think about who your target audience is (e.g., scientists, policymakers, the public). Which social media platform do they use the most (e.g., YouTube, Twitter, LinkedIn)? What are the best ways to use the platform? How would you like to engage with your audience (e.g., writing, collaboration, discussions)?

Use the principles of persuasive communication to refine your story.

Persuasive communication is based on five principles: *clarity*, *brevity*, *context*, *impact*, and *value*.

1. **Clarity:** The purpose of science communication is to inform and engage the public. It respects the readers' time, intelligence, and attention. Don't make the reader work hard to understand your message!
2. **Brevity:** There is a reason that TED talks are 18 minutes or less. Brevity forces you to cut all unnecessary information and keep your content to the point. Use the inverted model of sharing information (most important content at the top and details later). Don't make the reader scroll down to the end of the page to understand the message.
3. **Context:** While designing scientific content it is important to be aware that biases exist in the audience and will influence how they engage with new information. Effective science communication depends on building positive associations with the content you create. Does your audience grasp the relevance to them? If not, your message lacks context. Be sure to include the "why" and "why now" into your message to engage the attention and interest of the audience.
4. **Impact:** Do you understand who your audience is? Did you tailor your message to make it relevant to different audiences? What are the implications of your message? Is your message memorable? Does it have a clear call to action? Creating clear messaging and reinforcing key points is also critical in gaining and retaining the reader's attention. If not, it will be quickly forgotten.
5. **Value:** A message that is clear, brief, relevant to the audience, and memorable. A balance of the four other principles mentioned above (clarity, brevity, context, and impact) creates value for the audience, educates, and empowers them.

The ultimate goal of science communication is to inform the audience, build an appreciation for

scientific knowledge, and provide a platform for public engagement. Often when we are working on an important project, we assume that the audience will understand and agree. This is not always the case. Asking "So what?"⁵⁰ at each stage of the writing process will make your writing concise and interesting to the audience.

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Conflicts of interest

Surayya Taranum is a Scientific Writer at 4Clinics.

References

1. The Pulitzer Prizes. Ed Yong of The Atlantic. 2021 [cited 2021 Oct 11]. Available from: <https://www.pulitzer.org/winners/ed-yong-atlantic>
2. Yong E. How the pandemic defeated America. The Atlantic. 2021 Aug 4 [cited 2021 Oct 11]. Available from: <https://www.theatlantic.com/magazine/archive/2020/09/coronavirus-american-failure/614191/>
3. Poynter Staff. Q&A: How The Atlantic's Ed Yong navigated a year of deep coronavirus coverage. 2021 [cited 2021 Oct 11]. Available from: <https://www.poynter.org/reporting-editing/2021/a-qa-with-the-atlantics-ed-yong-on-journalism-that-matters-in-moments-of-crisis/>
4. Kemp S. Half a Billion Users Joined Social in the Last Year (And Other Facts). 2021 [cited 2021 Oct 11]. Available from: <https://blog.hootsuite.com/simon-kemp-social-media/>
5. Statista Research Department. Daily time spent on social networking by internet users worldwide from 2012 to 2020. Statista. 2021 [cited 2021 Oct 11]. Available from: <https://www.statista.com/statistics/433871/daily-social-media-usage-worldwide/>
6. Groshek J, Bronda S. How social media can distort and misinform when communicating science. The Conversation. 2016 [cited 2021 Oct 11]. Available from: [https://theconversation.com/how-social-media-can-distort-and-misinform-when-](https://theconversation.com/how-social-media-can-distort-and-misinform-when-communicating-science)

- communicating-science-59044
7. Addressing the challenges of cancer misinformation on social media. National Cancer Institute. 2021 [cited 2021 Oct 11]. Available from: <https://www.cancer.gov/news-events/cancer-currents-blog/2021/cancer-misinformation-social-media>
 8. Johnson SB, Parsons M, Dorff T, Moran MS, et al. Cancer misinformation and harmful information on Facebook and other social media: A brief report. *J Natl Cancer Inst.* 2021;22:djab141.
 9. Loeb S, Sengupta S, Butaney M, Macaluso JN Jr, et al. Dissemination of misinformative and biased information about prostate cancer on YouTube. *Eur Urol.* 2019;75(4):564–7.
 10. Morhead SA, Hazlett DE, Harrison L, Carroll JK, et al. A new dimension of healthcare: systematic review of the uses, benefits, and limitations of social media for health communication. *J Med Internet Res.* 2013;15(4):e85
 11. Bird C. Talking about science on social media. *The Brink.* 2016 [cited 2021 Oct 11]. Available from: <https://www.bu.edu/articles/2016/communicating-science-on-social-media/>
 12. Brennen JS, Simon F, Howard PN, Nielsen RK. Types, sources, and claims of COVID-19 misinformation. Reuters Institute. 2020 [cited 2021 Oct 11]. Available from: <https://reutersinstitute.politics.ox.ac.uk/types-sources-and-claims-covid-19-misinformation>
 13. Van der Linden S, Leiserowitz A, Rosenthal S, Maibach E. Inoculating the public against misinformation about climate change. *Global Challenges.* 2017;1:1600008.
 14. Salmon DA, Dudley MZ, Glanz JM, Omer SB. Vaccine hesitancy: Causes, consequences, and a call to action. *Vaccine.* 2015;33:D66–71.
 15. Bode L, Vraga EK. In related news, that was wrong: the correction of misinformation through related stories functionality in social media. *J. Commun.* 2015;65(4):619–38.
 16. Tucker JA, Guess A, Barberá P, et al. Social media, political polarization, and political disinformation: a review of the scientific literature. Rep., Hewlett Foundation, Menlo Park, CA. 2018 [cited 2021 Oct 11]. Available from: <https://hewlett.org/wp-content/uploads/2018/03/Social-Media-Political-Polarization-and-Political-Disinformation-Literature-Review.pdf>
 17. Marsh EJ, Fazio LK. Learning errors from fiction: difficulties in reducing reliance on fictional stories. *Mem. Cogn.* 2006;34(5):1140–9.
 18. Vosoughi S, Roy D, Aral S. The spread of true and false news online. *Science.* 2018;359(6380):1146–51.
 19. Zarocostas J. How to fight an infodemic. *Lancet.* 2020;395:676.
 20. Cinelli M, Quattrociochi W, Galeazzi A, Valensise CM, Brugnoli E, et al. The COVID-19 social media infodemic. *Sci. Rep.* 2020;10:16598.
 21. Al Jazeera. Female journalists facing growing online attacks: UNESCO. 2021 [cited 2021 Oct 11]. Available from: <https://www.aljazeera.com/news/2021/4/30/female-journalists-facing-growing-online-attacks-unesco>.
 22. Barry-Jester AM. 'We're coming for you': For public health officials, a year of threats and menace. Kaiser Family Foundation. 2021 [cited 2021 Oct 11]. Available from: <https://khn.org/news/article/public-health-officials-year-of-threats-menace-santa-cruz-california/>
 23. Arora V, Pendergrast T, Jain S. Doctors on social media are being cyberbullied and sexually harassed. It's time to change that. *Stat.* 2021 [cited 2021 Oct 11]. Available from: <https://www.statnews.com/2021/01/05/doctors-on-social-media-are-being-cyberbullied-and-sexually-harassed-its-time-to-change-that/>
 24. Planas A. Fired Tennessee vaccine official received a dog muzzle at work days prior to her ousting. *NBC News.* 2021 [cited 2021 Oct 11]. Available from: <https://www.nbcnews.com/news/us-news/fired-tennessee-vaccine-official-received-dog-muzzle-work-days-prior-n1274178>
 25. Patel NS, Rao A. Doctors have been whistleblowers throughout history. They've also been silenced. *The Guardian.* 2020 [cited 2021 Oct 11]. Available from: <https://www.theguardian.com/education/2020/apr/08/coronavirus-doctors-whistleblowers-history-silenced>
 26. Pew Research Center. About three-in-ten U.S. adults say they are 'almost constantly' online [cited 2021 Oct 11]. Available from: <https://www.pewresearch.org/fact-tank/2019/07/25/americans-going-online-almost-constantly/>
 27. Eligibility.com. The most googled medical symptoms by state. 2020 [cited 2021 Sep 27]. Available from: <https://eligibility.com/medicare/states-most-googled-medical-symptom>.
 28. Tan SS, Goonawardene N. Internet health information seeking and the patient-physician relationship: a systematic review. *J Med Internet Res.* 2017;19(1):e9.
 29. Swire-Thompson B, Lazer D. Public health and online misinformation: Challenges and recommendations. *Annual Rev of Public Health.* 2020;41:433–51
 30. Tan SS, Goonawardene N. Internet health information seeking and the patient-physician relationship: a systematic review. *J Med Internet Res.* 2017;19(1):e9.
 31. Funk C, Kennedy B. Public confidence in scientists has remained stable for decades. *Pew Res. Cent., Fact Tank.* 2019 [cited 2021 Oct 11]. Available from: <https://www.pewresearch.org/fact-tank/2019/03/22/public-confidence-in-scientists-has-remained-stable-for-decades/>
 32. Kennedy B. Most Americans trust the military and scientists to act in the public's interest. *Pew Res. Cent., Fact Tank.* 2016 [cited 2021 Oct 11]. Available from: <https://www.pewresearch.org/fact-tank/2016/10/18/most-americans-trust-the-military-and-scientists-to-act-in-the-publics-interest/>
 33. Jamieson KH, McNutt M, Kiermer V, Sever R. Signaling the trustworthiness of science. *PNAS.* 2019;116(39):19231–6.
 34. Eltorai AE, Ghanian S, Adams CA Jr, Born CT, Daniels AH. Readability of patient education materials on the American Association for Surgery of Trauma website. *Arch Trauma Res.* 2014;3(2):e18161.
 35. Kaebnick GE. Anthony Fauci shows us the right way to be an expert. 2020 [cited 2021 Oct 11]. Available from: <https://blogs.scientificamerican.com/>



- observations/anthony-fauci-shows-us-the-right-way-to-be-an-expert/
36. Khullar D. The struggle to define long Covid. *The New Yorker*. 2021 Sep 21 [cited 2021 Oct 11]. Available from: <https://www.newyorker.com/magazine/2021/09/27/the-struggle-to-define-long-covid>
 37. Huckleberry Films. Message in a bottle – long Covid SOS. YouTube. 2020 [cited 2021 Oct 11]. Available from: https://www.youtube.com/watch?v=IIeOoS_A4c8
 38. Utarini A, Indriani C, Ahmad RA, Tantowijoyo W, et al. Efficacy of Wolbachia-infected mosquito deployments for the control of dengue. *N Engl J Med*. 2021;384:2177–86.
 39. Gates MF, Adi Utarini. *Time*. 2021 Sep 15 [cited 2021 Oct 11]. Available from: <https://time.com/collection/100-most-influential-people-2021/6095805/adi-utarini/>
 40. Nature. Nature's 10: ten people who helped shape science in 2020. 2020 Dec 15 [cited 2021 Oct 11]. Available from: <https://www.nature.com/immersive/d41586-020-03435-6/index.html>
 41. BBC Entertainment and Arts. Sir David Attenborough breaks Jennifer Aniston's Instagram record. BBC. 2020 [cited 2021 Oct 11]. Available from: <https://www.bbc.com/news/entertainment-arts-54292947>
 42. Concordia University. Nadia Chaudhri (1978 – 2021): 'She was a force of nature'. 06 Oct 2021 [cited 2021 Oct 11]. Available from: <https://www.concordia.ca/cunews/offices/advancement/2021/10/06/she-was-a-force-of-nature-nadia-chaudhri-1978-2021-passes-away.html>
 43. Baxter R. Dr. Raven the science maven. 2020 [cited 2021 Oct 11]. Available from: <https://www.scimaven.com/about>.
 44. Fallik D. Black female biologist tests, entertains and explains science on TV, social media. *The Washington Post*. 2021 Sep 26 [cited 2021 Oct 11]. Available from: https://www.washingtonpost.com/science/raven-the-science-maven/2021/09/24/e3415e9a-155c-11ec-9589-31ac3173c2e5_story.html.
 45. Baxter R. You Don't Look Like A Scientist! TEDxGreat Mills. 2020 [cited 2021 Oct 11]. Available from: <https://www.youtube.com/watch?v=ehBwfH0p06I>
 46. Black in Science. Celebrating black excellence in science communication. 2020 [cited 2021 Oct 11]. Available from: <https://www.blackinscicomm.com/>
 47. Fortune. 40 Under 40 Healthcare. 2020 [cited 2021 Oct 11]. Available from: <https://fortune.com/40-under-40/2020/raven-baxter/>
 48. Fs Blog. Ethos, logos and pathos: the structure of a great speech. 2020 [cited 2021 Oct 11]. Available from: <https://fs.blog/2016/11/ethos-logos-pathos/>
 49. Taranum S. Social media, science communication challenges, and the role of a scientific writer in standing up for science. *Medical Writing*. 2021;30(1):50–3.
 50. Selwyn, N. 'So What?'... a question that every journal article needs to answer. *Learning, Media and Technology*. 2014;39(1),1-5.



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Sustainable development, climate emergency, and journalism: The emerging role of medical writers

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Abstract

The Sustainable Development Goals, set up by the UN in 2015, provide a framework for the policy makers in government and other advocates to work towards planetary health in a more holistic way. For the general public, these goals might not always be clear. Thus, conveying the climate emergency that we are in, its impact on health, the measures being taken, and what we as citizens can do, without causing panic among the audience, is of paramount importance. In this article, we provide a brief overview of reporting on sustainable development, the role of medical journalists and medical writers, the changes that have happened in terminology, and the resources available for medical writers who want to consider medical journalism (with special focus on sustainability) as a career option.

*"Humans have pushed the climate into 'unprecedented' territory, landmark UN report finds."*¹

*"It Rained at the Summit of Greenland. That's Never Happened Before."*²

*"We must act now for a fast, fair and sustainable COVID-19 recovery."*³

These were the headlines from a couple of months ago. Reporting on climate change, environmental health, equity, and accessibility to various resources has taken centre stage in recent years and is going to occupy this spot for the

foreseeable future. The independent media are at the centre of sustainable development as they can create powerful stories about sustainable development, influence government policies, create and raise awareness among the public, bring relevant research to the foreground and bring communities together for common sustainable development goals.

Roles and responsibilities of medical journalists and medical writers

Sustainable Development Goals (SDGs), set up in 2015, are a collection of 17 interlinked goals

developed by the United Nations to end poverty, protect the planet, and to ensure peace and prosperity for all by 2030.⁴ With the climate emergency that we are in, these goals have taken on a significant role for preserving planetary health. Conveying these goals, the measures and policies governing them, and our role in achieving them, has now fallen on journalists. In this information age when knowledge is available at the click of a mouse, it is important that journalists themselves understand the science and report responsibly.



Know your science and tell a story⁵

With the decline in print media and increase in online content, the distinction has blurred between medical journalists and medical writers interested in writing media articles, blogs, and creating other media content. Reporting science and creating environmental health stories does require due diligence from the authors. Understanding the science behind a story, not sensationalising the science, and conveying the climate emergency to your audience is a skill in itself. Science reported in scientific journals often uses technical and opaque terms, and jargon, that need to be presented clearly and simplified for the audience.⁵ This is where medical writers can shine as most have advanced science degrees and are used to writing science for a variety of audiences. In fact, some of the top science reporters who report on climate change and sustainability these days are scientists and advanced science degree holders who have

chosen the career of science reporting.

Talking about climate change and sustainability to children and young adults requires special skills, which many medical writers (particularly illustrators) are equipped with. Simplifying science and providing visuals that add to the text can engage children in dialogues relevant to these goals without overwhelming them or causing panic and hopelessness, which is important.^{6,7}

Guidelines on reporting sustainability and climate change

With evolving terminologies on reporting science and gender and the use of more inclusive language, most print and online magazines now recognise that reporting on sustainability as well as climate change needs to be standardised across the media. In 2018, the BBC came up with a crib sheet on reporting climate change.^{8,9} The most significant item here was to accept that climate

change is real and, thus, there should be no more debates on *if* climate change was happening. With this, came further guidelines on terminologies to use, providing training to the journalists on climate change, how to sensitively report on these topics without causing despair and hopelessness among the population, but still be able to get people to act.

Simplifying science and providing visuals that add to the text can engage children in dialogues relevant to these goals without overwhelming them or causing panic and hopelessness, which is important.

Similar guidelines have now been issued by most global news agencies. For example, guidelines from *The Guardian* (a British newspaper) included using the words *climate crisis* instead of *climate change*, *fish populations* instead of *fish stocks* and similar changes to reflect the crisis we are in and, to put the onus on us all, to come up with solutions.¹⁰

Medical journalism vs medical writing

Medical journalists need to cover climate conferences, climate accords, and SDG meetings as well as report on pandemics, epidemics, ecological changes, and the latest research. This involves background research, talking to experts, and reporting in an unbiased manner. Thus, journalists are in a much more fast-paced and deadline-driven environment than medical writers. Medical writers, on the other hand, write science publications or online articles on the latest research or a topic, but do not report current events. Thus, they have more time to research and develop a story.

One of the biggest differences between the two is the human angle.¹¹ Journalists almost always cover the human stories – how the changes affect particular communities, families, and individuals. There are always elements of storytelling in journalism, whereas medical writers tend to focus more on the science angle.

There is also a middle path to tread where one chooses to be both a medical writer and a medical journalist. However, it might not be easy-going as the work involved is different and intense in terms of deadlines.

Medical writing to journalism: how to make the move?

Medical writers who are interested in journalism can start by writing blogs for various online platforms on sustainability and climate crisis. For example, Medium (www.medium.com) is a great option.¹² However, for someone who wants to consider this as a career move, I have listed some courses in Table 1 that are offered, both online and offline, on reporting sustainability and climate science. There are now wonderful opportunities available through online education platforms and even the United Nations Educational, Scientific and Cultural Organization (UNESCO) and similar organisations provide



Table 1. Some of the courses available in medical and environmental journalism and communications

	Course offered; online or offline	Offered by; duration	Website URL
1.	Environmental communication – research into practice (online)	International, Environmental Communication, Association (10 weeks)	https://www.theieca.org/training/environmental-communication-research-practice
2.	Environmental journalism (online)	Thomson Foundation (self-paced)	https://www.thomsonfoundation.org/latest/environmental-journalism-why-local-matters/
3.	Strategic communication for sustainability leaders (online)	edX (self-paced)	https://www.edx.org/course/strategic-communication-for-sustainability-leaders
4.	Science communication – Master’s Programme (offline)	UC Santa Cruz (1 year)	https://scicom.ucsc.edu/about/index.html
5.	MSc in Science and Technology Journalism (offline)	Texas A&M University (flexible)	https://vibs.tamu.edu/stjr/
6.	Science, health and environmental reporting (offline)	New York University (16 months)	https://journalism.nyu.edu/graduate/programs/science-health-and-environmental-reporting/
7.	Graduate programme in science writing (offline)	MIT (1 year)	https://sciwrite.mit.edu/
8.	Environmental journalism programmes	Michigan State University (varied)	https://knightcenter.jrn.msu.edu/category/masters/
9.	MA in Journalism (Science and Environment). Offline	University of Lincoln (1 year full time)	https://www.lincoln.ac.uk/home/course/jouscema/
10.	Environmental journalism courses (online)	Poynter’s News University (varied)	https://www.poynter.org/newsu/
11.	Science journalism (online)	World Federation of Science Journalists (self-paced)	http://www.wfsj.org/course/
12.	Media as partners in education for sustainable development: a training and resource kit (online)	UNESCO. Toolkit – not a course	https://unesdoc.unesco.org/ark:/48223/pf0000158787
13.	Toolkit by FAIR	Forum for African Investigative Reporters (FAIR)	https://fairreporters.files.wordpress.com/2012/10/gwens-layout-proofed.pdf

toolkits on climate reporting.

Over the next few years, medical journalists will assume a greater role in reporting of climatic events happening around the world and other biological events that are triggered by the climate crisis. Furthermore, innovative sustainable solutions will also need to be reported. Thus, a medical writer and journalist has many hats to wear, including reporting the crisis responsibly.

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Disclaimers

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Conflicts of interest

The author declares no conflicts of interest.

References

- Dennis B, Kaplan S. Humans have pushed the climate into 'unprecedented' territory, landmark U.N. report finds. *The Washington Post*. 2021 [cited 2021 Sep 23]. Available from: <https://www.washingtonpost.com/climate-environment/2021/08/09/ipcc-climate-report-global-warming-greenhouse-gas-effect/>.
- Fountain H. It rained at the summit of Greenland. That's never happened before. *The New York Times*. 2021 [cited 2021 Sep 23]. Available from: <https://www.nytimes.com/2021/08/20/climate/greenland-rain-ice-sheet.html>
- Dhaliwal M. We must act now for a fast, fair and sustainable COVID-19 recovery. United Nations Development Program. 2021 [cited 2021 Sep 23]. Available from: <https://www.undp.org/blogs/we-must-act-now-fast-fair-and-sustainable-covid-19-recovery>
- Sustainable Development Goals. United Nations [cited 2021 Sep 23]. Available from: <https://sdgs.un.org/goals>
- Fischer D. Covering environmental health [cited 2021 Sep 23]. Available from: <https://centerforhealthjournalism.org/resources/lessons/covering-environmental-health>
- Rosen J. The science of climate change explained: facts, evidence and proof. *The New York Times*. 2021 [cited 2021 Sep 23]. Available from: <https://www.nytimes.com/article/climate-change-global-warming-faq.html>
- What is climate change? National Geographic Kids [cited 2021 Sep 23]. Available from: <https://www.natgeokids.com/uk/discover/geography/general-geography/what-is-climate-change>
- BBC issues internal guidance on how to report climate change. *Carbon Brief*. 2018 [cited 2021 Sep 23]. Available from: <https://www.carbonbrief.org/exclusive-bbc-issues-internal-guidance-on-how-to-report-climate-change>
- Nakagawa D. Inclusive language: A hidden power at the hand of medical writers. *Medical Writing*. 2021; 30(3): 118-23
- Zeldin-O'Neill S. It's a crisis, not a change: the six Guardian language changes on climate matters. *The Guardian*. 2019 [cited 2021 Sep 23]. Available from: <https://www.theguardian.com/environment/2019/oct/16/guardian-language-changes-climate-environment>
- Collins S. Elements of storytelling in medical journalism. *Medical writing*. 2015;24(4):222-4.
- Nagarajan A. A wonderful "Medium" for medical writers. *Medical Writing*. 2021;30(1):36-8.



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News from the EMA

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The articles included in this section, except the first article, are a selection from the European Medicines Agency (EMA) News and Press Releases archive. More information can be found on the Agency's website: www.ema.europa.eu.

EMA finds no evidence linking viral vector in Zynteglo to blood cancer

July 9 and 23, 2021

Zynteglo is a one-time treatment for a blood disorder known as beta thalassaemia in patients 12 years and older who require regular blood transfusions. It is a gene therapy that uses a viral vector (or modified virus) to deliver a working gene into the patient's blood cells. Zynteglo was granted conditional marketing authorisation in May 2019, which means that the company will provide more evidence about the

medicine to EMA for review.

EMA's Pharmacovigilance Risk Assessment Committee (PRAC), has concluded that there is no evidence Zynteglo causes a blood cancer known as acute myeloid leukaemia (AML). The PRAC reviewed two cases of AML in patients treated with another investigational medicine, bb1111, in a clinical trial for sickle cell disease. Although there have been no reports of AML

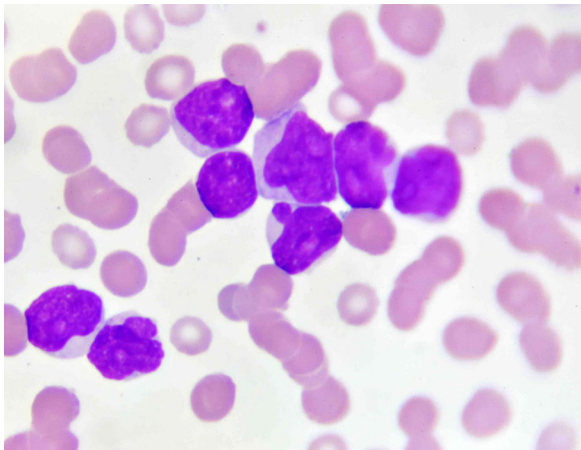
with Zynteglo, both medicines use the same viral vector and there was a concern that the vector may be implicated in the development of the cancer (insertional oncogenesis). The review found that the viral vector was unlikely to be the cause. In one of the patients, the viral vector was not present in the cancer cells, and in the other patient it was present at a site (VAMP4) that does not appear to be involved in cancer development.

After examining all the evidence, the PRAC concluded that more plausible explanations

for the AML cases included the conditioning treatment the patients received to clear out bone marrow cells and the higher risk of blood cancer in people with sickle cell disease. Patients having Zynteglo treatment for beta thalassaemia also need conditioning treatment to clear out their bone marrow cells. Healthcare professionals should therefore explicitly inform patients receiving Zynteglo of the increased risk of blood cancers from medicines used in conditioning treatments.

The Committee for Medicinal Products for Human Use (CHMP) has agreed with PRAC's recommendation that healthcare professionals should check their patients for signs of blood cancers at least once a year for 15 years.

The review of Zynteglo was initiated on February 18, 2021, at the request of the European Commission, under Article 20 of Regulation (EC) No 726/2004. The Committee, which worked closely with experts from the Committee for Advanced Therapies (CAT), concluded that the benefits of Zynteglo continue to outweigh its risks. As for all medicines, the PRAC will monitor any new data on its safety and update advice for patients and healthcare professionals when necessary.



Artificial intelligence in medicine regulation

August 16, 2021

The International Coalition of Medicines Regulatory Authorities (ICMRA) set out recommendations to help regulators to address the challenges that the use of artificial intelligence (AI) poses for global medicines regulation, in a report published today on ICMRA website.

AI includes various technologies (such as statistical models, diverse algorithms and self-modifying systems) that are increasingly being

applied across all stages of a medicine's lifecycle: from preclinical development, to clinical trial data recording and analysis, to pharmacovigilance and clinical use optimisation. This range of applications brings with it regulatory challenges, including the transparency of algorithms and their meaning, as well as the risks of AI failures and the wider impact these would have on AI uptake in medicine development and patients' health.

The report identifies key issues linked to the regulation of future therapies using AI and makes specific recommendations for regulators and stakeholders involved in medicine development to foster the uptake of AI. Some of the main findings and recommendations include:

- Regulators may need to apply a risk-based approach to assessing and regulating AI, which could be informed through exchange and collaboration in ICMRA;
- Sponsors, developers and pharmaceutical companies should establish strengthened

Six-month countdown to go-live for the Clinical Trials Information System (CTIS)

August 2, 2021

The European Commission has confirmed that the entry into application of the Clinical Trials Regulation and hence the go-live date for the CTIS will be on January 31, 2022.

As set out in the Clinical Trials Regulation, the entry into application of that regulation is set by the publication of a notice in the Official Journal of the European Union (EU), which confirms that the clinical trial EU Portal and Database, one of the main deliverables of the regulation and the key component of CTIS, has reached full functionality. The application of the regulation and the go-live of CTIS take place six months after the publication of this notice.

The Clinical Trials Regulation aims to harmonise the submission, assessment and supervision processes for clinical trials throughout the EU. CTIS will allow the streamlining of these processes, ensuring the EU remains an attractive region for clinical research.

CTIS will become the single-entry point for clinical trial application submission, authorisation, and supervision in the EU, and in the European Economic Area (EEA) countries Iceland, Liechtenstein and Norway. Currently, sponsors must submit clinical trial applications separately to national competent authorities and ethics committees in each country to gain regulatory approval to run a clinical trial.



With CTIS, sponsors can apply for clinical trial authorisation in up to 30 EEA countries with a single application. The CTIS will also, together with other EMA IT tools, support the coordinated assessment of safety reporting in the context of clinical trials and therefore contribute to the understanding of the benefits and the risks of medicinal products that are planned to enter or are already on the market of the EU.

The system will facilitate recruitment of trial participants by allowing sponsors and researchers to easily expand trials to other EEA countries, and will support collaboration across borders for better results and knowledge sharing. The system will contain a public website with detailed information on and outcomes of all clinical trials conducted in the EU, thus improving transparency and access to information for patients, healthcare workers, and other interested parties.

The Clinical Trials Regulation foresees a *three-year transition period*. Member States will work in CTIS immediately after the system has gone live. For one year, until January 31, 2023, applicants can still choose whether to submit their application to start a clinical trial according to the current system (Clinical Trials Directive) or according to the Clinical Trials Regulation. From January 31, 2023 onward, submission according to the Clinical Trials Regulation becomes mandatory and by January 31, 2025, all ongoing trials

approved under the current Clinical Trials Directive will need to transition to the new regulation and to CTIS.

While the authorisation and oversight of clinical trials is the responsibility of Member States, EMA will maintain the system. EMA has created an extensive training programme to help clinical trial sponsors, national competent authorities, and ethics committees prepare for using CTIS. The training catalogue consists of several modules, covering the full lifecycle of clinical trial submission, authorisation, and supervision. Modules are available for use on the CTIS training programme webpage. The CTIS training programme webpage is progressively updated as more training materials become available. EMA has also published a sponsor handbook to provide clinical trial sponsors with the information they need to get ready for, and use, CTIS.

governance structures to oversee algorithms and AI deployments that are closely linked to the benefit/risk of a medicinal product;

- Regulatory guidelines for AI development, validation and use with medicinal products should be developed in areas such as data provenance, reliability, transparency and understandability, pharmacovigilance, and real-world monitoring of patient functioning.

The report is based on a horizon-scanning exercise in AI, conducted by the ICMRA Informal Network for Innovation working group and led by EMA. The goal of this network is to identify challenging topics for medicine regulators, to explore the suitability of existing regulatory frameworks and to develop recommendations to adapt regulatory systems in order to facilitate safe and timely access to innovative medicines.



Photo: Freepik



Photo: Freepik

Interoperability of track and trace systems: key to public health protection

August 06, 2021

EMA has endorsed recommendations developed by the International Coalition of Medicines Regulatory Authorities (ICMRA) to facilitate the use of track and trace systems at the global level. A paper published today on ICMRA website identifies common technical denominators that allow different systems to exchange and use the available information on medicines and their supply chains in order to protect public health.

Production and distribution of medicines are globalised and rapid exchange of information among regulatory authorities is integral to the protection of supply chain integrity and patient safety. Track and trace systems are considered to be a useful tool to

mitigate the risk of shortages and fight production and marketing of falsified medicines. They provide visibility into the supply chain of medicines at any given time. However, until now, traceability systems have been designed and implemented with a local or regional focus, without taking into consideration whether they can exchange information with other systems at the global level.

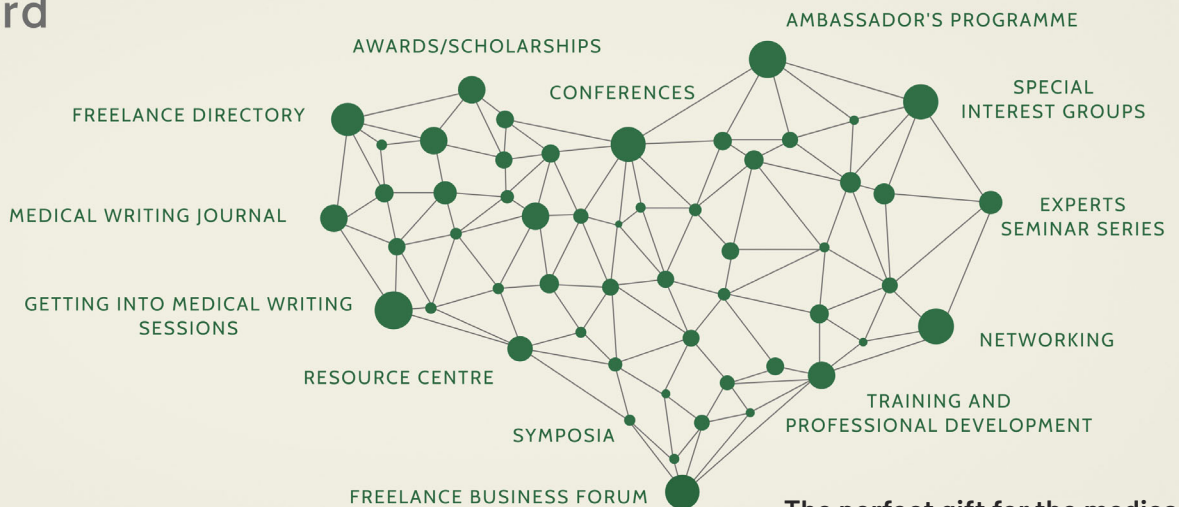
In this paper, international regulators emphasise that the interoperability of track and trace systems helps to protect public health by improving information sharing in case of quality defects, reducing shortages, contributing to the fight against falsified medicines and supporting pharmacovigilance activities. A common under-

standing of these potential benefits of interoperability is fundamental to promoting global planning and implementation of interoperable systems for medicines.

The ICMRA paper was open for public consultation from November 2020 to February 2021. The extensive and helpful feedback was carefully analysed and reviewed in order to refine and finalise the recommendations on common technical denominators for track and trace systems. More details on the comments received and the ICMRA analysis of these comments is available on ICMRA website.

ICMRA developed the recommendations in consultation with the World Health Organisation (WHO), representatives from international medicines regulatory authorities and experts from the private sector.

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Digital Communication

Navigating the COVID-19 pandemic: Artificial intelligence, natural language generation, and the COVID-19 Tracking Project

The past two years have confronted humanity with a variety of unprecedented challenges due to the far-reaching COVID-19 pandemic. In response to this tragedy have come monumental new advances in science and technology – namely the vaccines developed to prevent COVID-19 and curb the spread of the virus, as well as the detection methods used to identify it. However, an area that the public might not naturally associate with scientific and technological progress related to COVID-19 is artificial intelligence. Artificial intelligence (AI) is a subject matter with which most are already tangentially familiar. It is used every day when interacting with our mobile devices, or when deciding what film or TV programme to stream. Even marketing messaging is now produced using AI! But what one may not know is that a subfield of AI, called natural language generation (NLG), has played a pivotal role in our response to the COVID-19 pandemic. NLG has been essential in assessing massive amounts of COVID-19-related data to, among other things, provide accurate and easy-to-understand information to multiple stakeholders around the world.

Simply put, NLG is a computer software process that collects and transforms raw data into written natural human language. Though this technology is widely used by many businesses and organisations in a variety of sectors, it has proven particularly useful in the life sciences industry during these unprecedented times. To this point, the automation of clinical study reports, patient safety narratives, and electronic common technical documents, better known as eCTDs, have enabled medical writers to perform faster and improve efficiencies. Pharmaceutical companies have also substantially reduced costs and accelerated regulatory submissions, bringing

much needed new medical developments to the market quicker. With these and other useful applications in mind, the COVID-19 Tracking Project was created to further contribute to the COVID-19 response.

About the project

The COVID-19 Tracking Project is an international initiative that aims to facilitate the transformation of data about the virus into essential knowledge using NLG. It is a collaborative effort between Los Angeles-based Narrativa, one of the global pioneers in the NLG space, and several international partners including: the Spanish international news agency Agencia EFE; the Spanish public corporation for public radio and television services Corporación de Radio y Televisión Española (RTVE); the online news outlet Infobae; the information provider Applied XLabs; the location intelligence platform Carto; and the design experience and visual storytelling company DesignIt.

“Throughout the pandemic, it seemed as if everyone was drowning in data and did not fully understand what the data surrounding COVID-19 was actually saying. We sought to empower institutions, the media, and the public through natural language generation by giving them the critical knowledge they needed.

It’s our mission to better the world with technology and we saw an opportunity to help,” says Narrativa President Jennifer Bittinger.

More about the tool

Data are first independently collected and verified for accuracy by various health authorities themselves, including Germany’s Robert Koch Institute,¹ the Dipartimento della Protezione Civile in Italy,² and Johns Hopkins University in

Such easy access to accurate information about COVID-19 has been especially useful given the volume of inaccurate and false information that has been circulating among online communities.

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the United States.³ The tool then aggregates the verified data from these sources and structures it into a legible and interpretable format. Daily tests are performed to validate that the data extraction process is correct and in working order. For instance, if any data source changes its format in a way that negatively impacts the tool’s software, the tests fail, and the appropriate parties are notified so they can manually intervene and resolve the issue quickly. The software records every update in a database accessible via an application programming interface, commonly known as an API. Finally, and most importantly, AI and NLG convert the data into clear and intelligible text and a chart (Figure 1). The entire process happens automatically and 24/7. Other types of graphic content that can be generated include images and banners which, like the text and chart outputs, can be quickly disseminated and understood by multiple audiences, including the media and public.

Such easy access to accurate information about COVID-19 has been especially useful given the volume of inaccurate and false information that has been circulating among online communities. Moreover, the tool allows one to check the current COVID-19 statistics for any country on Earth, or, more granularly, for various regions, states, autonomous communities, and provinces. Aside from offering a general summary of the data, the information is represented visually through an interactive map

🤖 Post written automatically every hour by Narrativa technology from the Data API.

- Our automatically generated news feed: [XML](#) | [JSON](#)

Coronavirus outbreak latest: 788,781 new cases confirmed worldwide

Narrativa | Saturday, August 7, 2021

There are now **201,505,909 people infected worldwide**. Of these, **142,335,998** have already recovered, according to the data [provided by Johns Hopkins University](#). **The US** tops the list with **35,550,201** recorded cases, followed by **India, Brazil, and France** with **31,856,757, 20,108,746, and 6,324,215** cases respectively.

COVID-19 status across most infected countries

Currently Infected	Infected		Deaths		Recovered	
Total	Total	Last 24h	Total	Last 24h	Total	Last 24h
1. The US: 24,000,403	1. The US: 35,550,201	1. France: 186,267	1. The US: 615,856	1. Brazil: 2,155	1. India: 31,047,982	1. India: 40,020
2. The United Kingdom: 5,887,273	2. India: 31,856,757	2. The US: 109,713	2. Brazil: 561,762	2. Indonesia: 1,635	2. Brazil: 18,102,750	2. The US: 21,734
3. France: 5,796,167	3. Brazil: 20,108,746	3. Brazil: 82,213	3. India: 426,754	3. France: 1,342	3. The US: 10,933,942	3. Italy: 2,936

Over the last 24 hours, there has been a **0.39%** growth with **788,781** new infections. **France** is reporting the highest number of new cases with **186,267**, followed by **The US** with **109,713**. **Brazil** and **Indonesia** are not far behind, with **82,213** and **39,532** new patients respectively.

Since the coronavirus outbreak began, a total of **4,275,820 people** have died worldwide. **The US** is the country with the highest count so far with **615,856** deceased, followed by **Brazil, India, and Mexico** with **561,762, 426,754, and 243,165** deaths respectively.

The first news of this new strain of coronavirus appeared in **China**, in the city of **Wuhan**, on **31 December 2019**. Since then, the infection has spread across the Asian continent and the globe. At the moment, cases in China have grown to **12** new cases since Thursday. Overall, **1,499** people are infected with the virus.

Note: This article has been **generated automatically by Narrativa** from the data by [Dipartimento della Protezione Civile de Italia](#), [Robert Koch Institute](#) and [Johns Hopkins University](#).

** If you are interested in including these news or other automatic reports in your content, contact us: info@narrativa.com*

Figure 1. Screenshot of the COVID-19 Tracking Project tool.

The tool contains easy-to-comprehend text and a simple chart derived from the mass amounts of data related to the virus.

and shows the worst hit countries alongside the number of daily positive cases being documented. Another helpful feature of the project is the information alert system, which notifies users of the latest news on COVID-19. For example, if there is a notable increase or decrease in the number of cases within a region of interest, an alert is automatically generated. This feature is particularly helpful because accurate information and fixed content again reaches the public directly, eliminating the inevitable alteration of information as it passes from person to person and is taken as fact.

Narrativa continues to offer reporting that is updated at least every hour, as the insights provided by the COVID-19 Tracking Project have been vital in helping people make more informed decisions about COVID-19. "The efforts of the COVID-19 Tracking Project have left humanity better prepared when a global pandemic happens again," echoes Bittinger. To reach a vast amount of people, the simple yet comprehensive tool is currently directly available to the public in English, Spanish, and Italian. This endeavour is not-for-profit, so any person or institution can

freely use the information provided by the COVID-19 Tracking Project, which has become a large and expansive repository of data, reports, graphs, and images associated with the evolution of the virus. To interact with the tool from the COVID-19 Tracking Project, please visit covid19tracking.narrativa.com.

Conflicts of interest

The authors are associated with Narrativa, which has created and sells as a service the technology discussed in this article.

Data availability statement

For inquiries about data and other supplemental information, please contact info@narrativa.com.

References

1. GitHub. Robert Koch-Institut. 2021 [cited 2021 Aug 7]. Available from: <https://github.com/robert-koch-institut>.
2. GitHub. Presidenza del Consiglio dei Ministri – Dipartimento della Protezione Civile. 2021 [cited 2021 Aug 7]. Available from: <https://github.com/pcm-dpc>.

3. ArcGIS Online. COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU). 2021 [cited 2021 Aug 7]. Available from: <https://www.arcgis.com/apps/dashboards/bda7594740fd40299423467b48e9ecf6>.

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In QUEST of better science communication

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Reaching an audience has never been easier. Still, your message could be lost on your audience if not tailored to them. This is especially true when communicating important scientific topics to the public that could significantly impact their daily lives, like climate change or vaccines. Indeed, we observed the influence public health messaging can have on decision-making that drives population behaviour change throughout the COVID-19 pandemic. As such, science communicators may feel inspired to reassess how and to whom they convey information. But where to start?

Recognising the gap for effective dialogue between science and the wider public, a European Horizon 2020 project, Quality and Effectiveness in Science and Technology (QUEST), worked to develop tools, recommendations, and guidelines for communicators in the fields of journalism, social media, and museums. Focusing on vaccines, artificial intelligence, and climate change the QUEST team engaged with communication professionals across Europe to identify specific challenges and opportunities for skills development. The QUEST communication checklist for scientists: communicating science to the public represents one of several resources in the QUEST toolkit available for download at <https://questproject.eu/>.¹ Also of interest, is their *Checklist for science communicators on social media*.² With such handy tools and guidelines available, we can all look forward to more high-quality science communication.

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A special thanks to the QUEST team for permitting the reprint of the *Checklist for scientists: communicating science to the public* poster in our December 2021 issue.



quest

Checklist for scientists: communicating science to the public

Jacopo Pasotti, Ilda Mannino,
Alessandra Fornetti
Venice International University

1. Are you allocating enough **time** for preparation and improving your communication skills?
2. Do you know who your **audience** is?
3. Have you identified the key **messages** to deliver and kept the focus on them?
4. Are you **framing the message** so that it sparks curiosity and is compelling to the public?
5. Are you **linking to current facts** or events?
6. Are you communicating **something that you also care about**?
7. Are you **telling stories** or just delivering a list of facts or numbers?
8. Are you using **a simple explanation**, can it be understood by the public?
9. Are you using **short sentences**?
10. Have you strategically planned ways to open **a dialogue and interact** with your audience?
11. Are you carefully thinking about how to **keep your delivery or writing lively** and monitoring the public's reaction?
12. Have you set out strategies to **deal with scepticism or distrust**?
13. Have you **practiced** your communication with non-experts?
14. Are you in touch with your **communication (or press) officers**?

The above checklist developed within the H2020 QUEST project supports scientists in delivering their message and fine-tuning their communication skills to the public. It is the result of several focus groups and interviews with both scientists working in different fields and trainers experienced in science communication. The checklist also draws from the literature review of published studies on scientists' perception and from available guidelines on science communication. Some of the points in the checklist apply in specific contexts and not in others; scientists are encouraged to go through the list and choose those elements that apply to their circumstances.

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Conflicts of interest

The author declares no conflicts of interest.

References

1. The QUEST project. 2021 [cited 2021 Oct 12]. Available from: <https://questproject.eu/toolkits/>.
2. The QUEST project. 2021 [cited 2021 Oct 12]. Available from: <https://questproject.eu/checklist-for-science-communicators-on-social-media/>.



EMA guidance meets reality: An evolving story

One key point in 2012 to the Good Pharmacovigilance Practices (GVP) guidelines was mandatory consultation of all stakeholders before the first publication of GVP and after its implementation. Execution of these guidelines was influenced by public participation through means such as online forums. In addition, stakeholders such as patients and healthcare professional representatives now provide opinions to the European Medicines Agency (EMA) on pharmacovigilance matters through public hearings. Many modules – components of the GVP guidelines – underwent intensive revisions based on the discussions triggered by the stakeholders' feedback before their final publishing.

Revised Modules

The GVP modules that underwent significant revision to address stakeholders' feedback, collected experience, and evolving processes are briefly presented in the table below. The history of revisions is regularly updated by EMA;¹ the individual guidance documents (final or draft currently under public consultation) can be accessed from the EMA webpage on GVP guidance.²

From a regulatory pharmacovigilance writing perspective, the most significant revisions were applied to the documents as shown on the following page. (See Table 1 for an overview of all revisions.)

Conclusion

In the effort to streamline pharmacovigilance activities in the EU, the EMA has consistently sought stakeholders' feedback on the implementation of the GVP guidance. Discussions, proposals, and public consultations have led to either major updates or fine-tuning of the guidance. The increasing experience with pharmacovigilance processes and the dialogue between the EMA and all stakeholders contribute to a constant adjustment of the guidance. Further evolution is to be expected in the near future to account for a changing regulatory environment and the integration of digital tools in pharmacovigilance.

Disclaimers

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

References

1. Guidelines on good pharmacovigilance practices (GVP). Introductory cover note, last updated with revision 3 of Module XVI on risk minimisation measures and its Addendum II on methods for their effectiveness evaluation for public consultation. European Medicines Agency and Heads of Medicines Agencies. 2021 [cited 2021 Sept. 4]. Available from: <https://www.ema.europa.eu/en/>

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[documents/regulatory-procedural-guideline/guidelines-good-pharmacovigilance-practices-gvp-introductory-cover-note-last-updated-revision-3_en-0.pdf](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidelines-good-pharmacovigilance-practices-gvp-introductory-cover-note-last-updated-revision-3_en-0.pdf)

2. Good pharmacovigilance practices. European Medicines Agency. 2021 [cited 2021 Sept. 1]. Available from: <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/good-pharmacovigilance-practices>
3. Explanatory note to GVP Module VII. European Medicines Agency and Heads of Medicines Agencies. 2021 [cited 2021 Sept. 9]. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-module-vii-periodic-safety-update-report-explanatory_en.pdf



Module V-Risk management systems

Soon after the implementation of GVP Module V, it became clear that the definitions of safety concerns (i.e., important identified risks, important potential risks, and missing information) needed further clarification and pragmatic guidance. In many cases, based on the initial guidance, the Risk Management Plans (RMPs) included long lists of safety concerns and related pharmacovigilance and risk minimisation activities, leading to a significant burden on the risk management system of medicinal products and on the marketing authorisation holders. The second revision of GVP Module V was a long-awaited, major revision that provided guidance to critically review the list of safety concerns. The “importance” of identified and potential risks is now linked not only to the impact of the safety concerns on the benefit-risk balance of the product, but also on the need for further characterisation and management. Updated guidance was given to tailor RMPs to different types of initial marketing authorisation applications. Along with Module V Rev. 2, a major update of the related RMP template was published. The RMP is now a more risk-proportionate document that focuses only on those safety concerns that need further characterisation and management. Furthermore, following feedback from all concerned stakeholders, the public summary of the RMP underwent a major revision; the related template is now more structured, the content is rather technical, the language is plain but scientific, and definitions of the RMP terminology are provided.

Module VII-Periodic safety update report

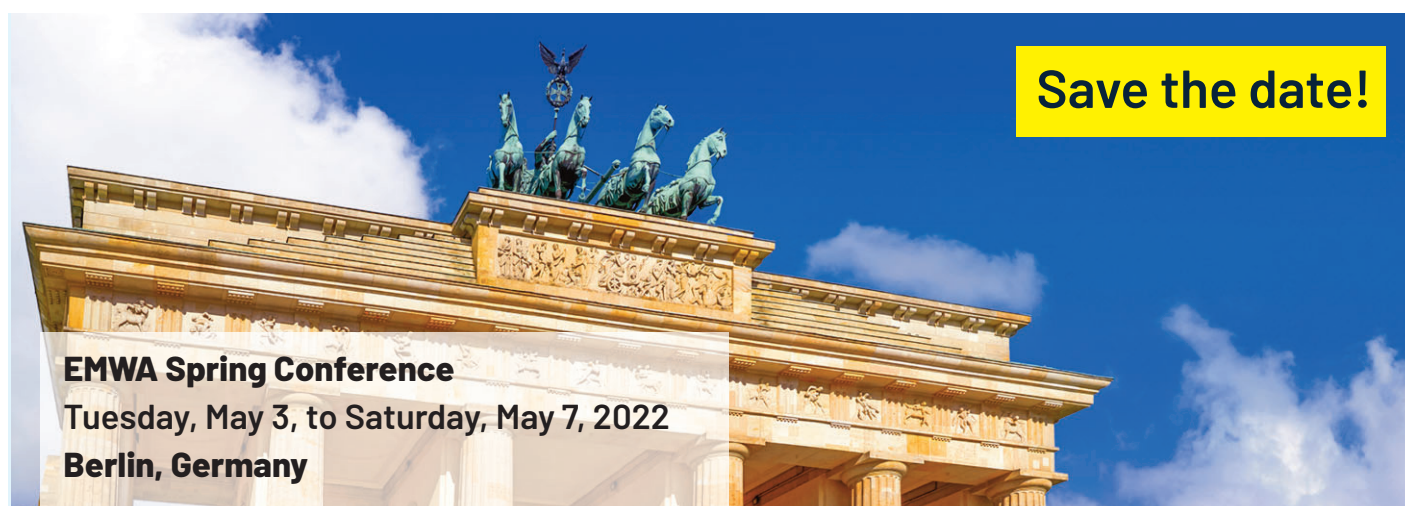
A new revision was announced for this module shortly after publication of Rev. 1. The need for a major update of the guidance is based on the challenges encountered since its first implementation, the experience collected with preparation and assessment of Periodic Safety Update Reports (PSURs), and the feedback received from the stakeholders. In particular, there appeared to be diverging expectations and guidance interpretations among stakeholders, including individual national competent authorities. For example, the appropriate presentation, level of detail, and discussion of safety data, monitoring topics, signals, and safety concerns in PSURs needed clarification and training. Furthermore, since publication of GVP Module V Rev. 2, there were outstanding questions related to the expected evolution of safety concerns in PSURs, such as, when these are revised in, or removed from, RMPs. To temporarily address the still unmet need of a major update of Module VII, the “Explanatory Note to GVP Module VII”³ was issued and has undergone three updates to further clarify the guidance expectations to the industry. Currently, this explanatory note must be read in conjunction with GVP Module VII, but will be replaced by a future, major update of the module.

Module XVI- Risk minimisation measures: selection of tools and effectiveness indicators

Since the first publication of this module, there were outstanding questions among the stakeholders related to guidance implementation. Particularly, the development of risk minimisation measures revealed unclear areas (e.g., design, target audience, objectives, and effectiveness measurements of risk minimisation tools). Module XVI Rev. 2 was issued along with GVP Module V Rev. 2. Since the latter included the description of routine risk minimisation tools, Module XVI Rev. 2 focused on additional risk minimisation measures. Therefore, the second revisions of Modules V and XVI complement each other and must be read together. However, Rev. 2 revealed a need for further practical guidance and clarifications. The third revision of Module XVI, which is still under finalisation, clarifies the role of risk minimisation for risk management planning and for the impact on the benefit-risk balance of medicinal products, as well as the role of the related effectiveness evaluation. Rev. 3 also includes further clarifications on the role of risk communication, dissemination, and implementation, and on the role of healthcare professionals and patients in risk minimisation. Furthermore, Addendum II to GVP Module XVI provides guidance to stakeholders to monitor outcomes of risk minimisation measures. Rev. 3 of this Addendum is currently under finalisation along with Module XVI Rev. 3.

Table 1. Overview of the revisions made to GVP modules to address stakeholders' feedback, collected experience, and evolving processes

GVP module / Topic	Overall no. of revisions	Contents of selected significant updates
V Risk management systems	3	Rev. 2: <ul style="list-style-type: none"> ● Explanation of the definitions of safety concerns and practical guidance on how to apply them ● Guidance on the expected changes in the Risk Management Plan (RMP) during the lifecycle of the product ● Updated requirements for different types of initial marketing authorisation applications, with the aim to create risk-proportionate RMPs ● Major template update to reflect risk-proportionality, including major revision of the public summary of RMP ● Parallel alignment revision of Module XVI
VI Reports of suspected adverse reactions to medicinal products	2	Rev. 2: <ul style="list-style-type: none"> ● Updated guidance on individual case safety reports (ICSRs) submission, follow-up, duplicate detection, validation, data quality management ● New guidance on electronic submission modalities of ICSRs and on management of reports on off-label use and from Post-Authorisation Safety Studies (PASS) ● Transfer of the guidance on emerging safety issues to Good Pharmacovigilance Practice (GVP) Module IX ● Parallel alignment revision of Module VIII
VII Periodic Safety Update Report	1	<ul style="list-style-type: none"> ● Major update pending based on experience in preparation and assessment of Periodic Safety Update Reports (PSURs). "Explanatory Note to GVP Module VII" published to complement Module VII until the next major update
VIII Post-Authorisation Safety Studies (PASS)	2	Rev. 2 of module and its Addendum: <ul style="list-style-type: none"> ● Clarification of link between legislation on non-interventional PASS and categories 1 to 4 ● Alignment with GVP module VI Rev. 2
IX Signal management	1	<ul style="list-style-type: none"> ● Clarifications of terminology, roles, responsibilities, and processes for signal management ● Updated guidance on the monitoring of EudraVigilance data ● Revised definition and process for emerging safety issues (transferred from Module VI Rev. 2)
XV Safety communication	1	<ul style="list-style-type: none"> ● Revision of guidance on safety communication, along with revision of the template for Direct Healthcare Professional Letters (DHPCs) ● Alignment with outcome of work package 2 on communication and dissemination of the Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action of the Member States
XVI Risk minimisation measures	3	<ul style="list-style-type: none"> ● Rev. 2: Alignment with GVP Module V Rev. 2 ● Rev. 3 + Addendum: Recommendations, clarifications, and details about additional risk minimisation measures and risk communication, dissemination, and implementation



Medical Writing Humour

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Cover letters and Santa Claus

To celebrate the festive season, we'd like to share with you the elves' cover letter. The target journal was the *The Polar Express*, which has an enviably high impact factor. Santa Claus is its editor-in-chief.

We run medical writing courses for PhD students at Copenhagen University,¹ and *Cover Letters* is one of the most popular sessions. To spark a lively discussion, we provide tips and tricks, useful phrases, and inspirational examples,² and then we ask participants to come with their own suggestions.

This cover letter from elves won the prize for this year's most entertaining suggestion.

The elves followed our guidelines:

- Keep it short and simple (max one page).
- Present the submission.
- Set the context and describe the current state of the field.
- Identify the knowledge gap.
- Describe the problem and how it was solved.
- Highlight the novelty and relevance for readers of the journal.
- State that the manuscript is not being considered for publication elsewhere.
- Suggest experts in the field qualified to carry out the review.

Dear Santa Claus,

We are pleased to submit this manuscript to be considered for publication in *The Polar Express*.

Since forever, Santa Clauses all over the world have struggled to deliver Christmas presents in time. The problem has only grown over the last decades with the increasing number of small children. We therefore feel our finding is timely and highly relevant.

We have developed a model for optimised gift wrapping, which will enable an elf to wrap a gift in less than one second, and with aesthetic perfection.

We genuinely believe that our finding will make the world a better place and that it would be of particular interest to all Santa-believers.

The paper is original work, has not been published before, and is not being considered for publication elsewhere either in printed or electronic form.

If the paper is to be considered for publication in *The Polar Express*, we would like to suggest Rudolph and the Grinch as reviewers of our work. We look forward to hearing from you.

With best wishes,
The Elves



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References

1. Moller C. New medical writing course in Copenhagen: Increasing chances of publication for non-native speakers. *The Write Stuff*. 2007;16(1):8–9.
2. Langdon-Neuner E. About cover letters for manuscripts submitted to biomedical journals. *The Write Stuff*. 2010;19(3):184–7.
3. Cover letters and “Arctic Monkeys”. Christine Møller: *Medical Writing*. 2020;29(1):82.

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Christine started her career as a Liberal Studies lecturer in the UK. After moving to Denmark, she taught English and worked for the British Council. Until recently she was Assistant Editor of *APMIS (Journal of Pathology, Microbiology and Immunology)*. She now teaches courses in medical writing.

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Bobby studied Biochemistry at the University of Glasgow and has a PhD in Plant Molecular Genetics. He worked for over 20 years as a technician and postdoctoral research scientist. Currently he is a freelance medical writer and regularly edits manuscripts written by non-native English speakers.

Veterinary Medical Writing

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Editorial

December is traditionally a time of reflection, with an old calendar year drawing to a close, a new one just around the corner, and many of us planning to spend the festive period with friends and loved ones. On top of that, 2021 brings to a close our second year living under the shadow of the Covid-19 pandemic. It is, therefore, fitting that reflection is the theme for this issue's article. In it, Henry Smith, our Veterinary Special Interest Group (vetSIG) committee co-chair, describes how he designed and conducted a survey of the group's membership. As the vetSIG is celebrating its

third year in 2021, the time was right to find out who vetSIG members are and what direction they want to steer the group into the future. From a very personal perspective, Henry recounts what he has learned from running the survey and reflects on the survey's exciting and sometimes surprising results.

In the second edition of *From the horse's mouth*, our quarterly news bulletin from the veterinary world, we report how legislation to reduce the number of antimicrobials available for the treatment of veterinary patients has been rejected by the European Parliament and

why this is a victory for One Health, "an approach . . . with the goal of achieving optimal health outcomes recognising the interconnection between people, animals, plants, and their shared environment," according to the CDC website.

(<https://www.cdc.gov/onehealth/index.html>)

Finally, we wish all our readers a very happy and peaceful holiday, and we look forward to seeing you in 2022!

**Louisa Marcombes and
Jennifer Bell**

Surveying a SIG: Profiling EMWA's veterinary medical community

EMWA's Veterinary Special Interest Group (vetSIG) turned three years old this year. There was no birthday party, of course, due to the pandemic; however, we were able to mark the occasion with a questionnaire. This questionnaire took the form of a survey aiming broadly to profile EMWA members currently working in the veterinary field (full- or part-time), and those interested in doing so in the future. As described below, the birthday questionnaire results were informative, but still left a gap in the profile. That gap was swiftly plugged using a shorter follow-up questionnaire, targeted more narrowly at established veterinary medical writers. The results of the two questionnaires were formally reported at our July 2021 quarterly meeting, and the full data are available in the report of that meeting, (please see data availability statement below), but here I will present a more personal viewpoint. In this short essay, I recount my experiences as a survey administrator, and the lessons learned – about EMWA's veterinary community, and about conducting surveys.

Designing the questionnaire

The survey's timing and choice of software were dictated by the terms of my subscription to SurveyMonkey, an audience-research solution provider. The paid subscription offers more options for question format and response analysis, so I was keen to wrap up the data collection and analysis while I still enjoyed access to these features. With little time to lose, I set about canvassing the vetSIG's active volunteers for possible questions to include in our survey, and we quickly generated a rather long list of what can best be described as super-multi-option survey questions. In retrospect, I realise this was a beginner's error by a novice survey administrator. I learned that questions should be created *after* objectives are set and the target audience identified, or else they quickly become unwieldy. The main survey objective originated as a rather vague idea of finding out something interesting from people who do, or may do, some veterinary medical writing (VMW). I managed to achieve a bit more clarity in my mind when one member asked me "You defined what a veterinary medical writer is before starting the survey, didn't you?" I could only answer in the negative, but inside my

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head I was thinking "That's what the survey should do: define the term *veterinary medical writer*!"

With the objectives clearer, a final list of seven questions could be finalised swiftly. Five of the seven questions were orientated towards the main term-defining goal; with these questions I aimed to elucidate areas of work, professional path into veterinary medical writing, current employment status, geographical work locations, and future career goals. Another question asked respondents to rank possible vetSIG meeting topics by preference, and the final question was aimed to solicit general comments through a free-text-entry box.

Distributing the questionnaire

With the questions decided, all I had to do was get our survey to the people we wanted to hear

from. I had some options for widespread distribution. Helpful suggestions from members included some large profession-based communities such as the relevant LinkedIn groups, and as a SurveyMonkey subscription holder, I could have availed myself of a marketing and messaging approach involving a target-audience-finding algorithm. However, a more modest approach seemed better suited to a first attempt to administer a survey. Furthermore, focussing on EMWA members and their immediate contacts seemed more likely to yield information from people who could benefit from our SIG's activities. So, I decided to rely on a digital "word-of-mouth" approach within the EMWA community. I publicised the link to the on-line survey through our SIG's mailing list, and EMWA's monthly Newsblast and social media outlets, inviting members to respond, and share the link with any other potentially interested colleagues. Launching the questionnaire was as simple as pressing a button on my personal software-subscriber web page, and copy-and-pasting the software-generated survey link into invitation mails and social media messages. All I had to do then was sit back and wait for the responses.

Round 1 responses: a diverse community emerges

The survey software was good at providing data updates and graphical breakdowns of the responses in real time, although "in real time" was perhaps a relative concept as the early response rate fell somewhat short of deluge proportions. In fact, it took quite a few pleading e-mails to get the number of respondents into double figures, after which there was a steady trickle to reach a final total of 34 responses.

Even though the wait for responses was agonising at times, I was able to spot some interesting patterns almost right away. My first three definition-orientated questions (work area, professional path, and current work status) had been rather heavily loaded with multiple choice items, to cater for every level of experience I could imagine. However, respondents seemed not to see themselves (solely) in terms of the pre-defined categories and provided a lot of information through additional comments, which allowed me to build up a far more detailed picture than I could have otherwise obtained.

The emerging picture threw up a number of interesting revelations. In the first place, the data intended to define veterinary medical writers showed that ... veterinary medical writers are not easily defined. I had expected to find a sort of mini-EMWA, with people engaged in one of the

work areas I labelled *The Big Three* (regulatory, journal articles, and communications, as I imagine them). Our survey did produce the same Big Three, but the proportions were almost the reverse of what I had expected: journal article-type work came out top (46%), with the comms area second (36%), and regulatory a mere third (25%). Veterinary medical writers also seemed to be inveterate category hoppers, with more than half of the respondents reporting work in multiple areas (thus the percentages adding up to more than 100 percent). In particular, many people described a range of work in the comms area (podcasts, vlogging, website material, etc.); maybe the term I was trying to define should have been "veterinary medical communicator" rather than "veterinary medical writer".

A similarly diverse picture emerged with regard to the professional paths into veterinary medical writing. Our community comprises:

- Veterinarians who have moved from clinical practice into medical writing.
- Veterinarians in clinical practice who do some medical writing as a sideline.
- Veterinarians who move (sometimes repeatedly!) between research and medical writing.
- One or two veterinarians who have (sadly) abandoned medical writing and gone back into practice.
- Research scientists who have moved into veterinary medical writing from fields like toxicology.
- Medical writers who are not veterinarians but do some work in the field (that is the category I belong to).

Of the three other definition-related questions, those related to current work status and future career plans also elicited varied responses. The only exception to this pattern of diversity concerned geographical location: our respondents (mainly EMWA members of course) appeared to be a rather Eurocentric group (Germany and Austria were the most commonly cited locations), with a smattering of members in North America, two members in Asia (one apiece in India and Japan), and an Australian respondent as the sole representative of the entire southern hemisphere.

Unsurprisingly, our diverse group of respondents produced a rather diverse wish list when it came to ranking preferred SIG activities. The survey software provided a sort of weighted



scoring system for the ranked options ("discussing my area of VMW", "discussing other areas of VMW", "career opportunities/ development", "specific VMW training", and "social contact"), but no clear, central tendency emerged. Although the survey was anonymous, the software does allow administrators to correlate the responses to different questions. Seemingly, writers with the most experience in the field were keener to discuss their own or others' areas of veterinary medical writing, whereas those with little or no experience in the field were more interested in careers and training-related activities. Perhaps this is an unsurprising finding (albeit not

statistically tested), but it has already had a direct effect on our SIG. We have prepared a grid for varied speakers and topics for quarterly meetings through 2022, and expanded the workshops the SIG offers to EMWA members (with a new workshop on "One Health" added for the 2021 autumn conference). Of course, it would be impossible to satisfy all

members all of the time, but over the course of a year, I believe the vetSIG truly does have something for everybody.

Round 2: The great species race

Fascinating as these results were, something was still missing. It took a while for the penny to drop,

Do our writers have to contend with pets one day and lab rats the next? Just how exotic is the work of a veterinary medical writer?

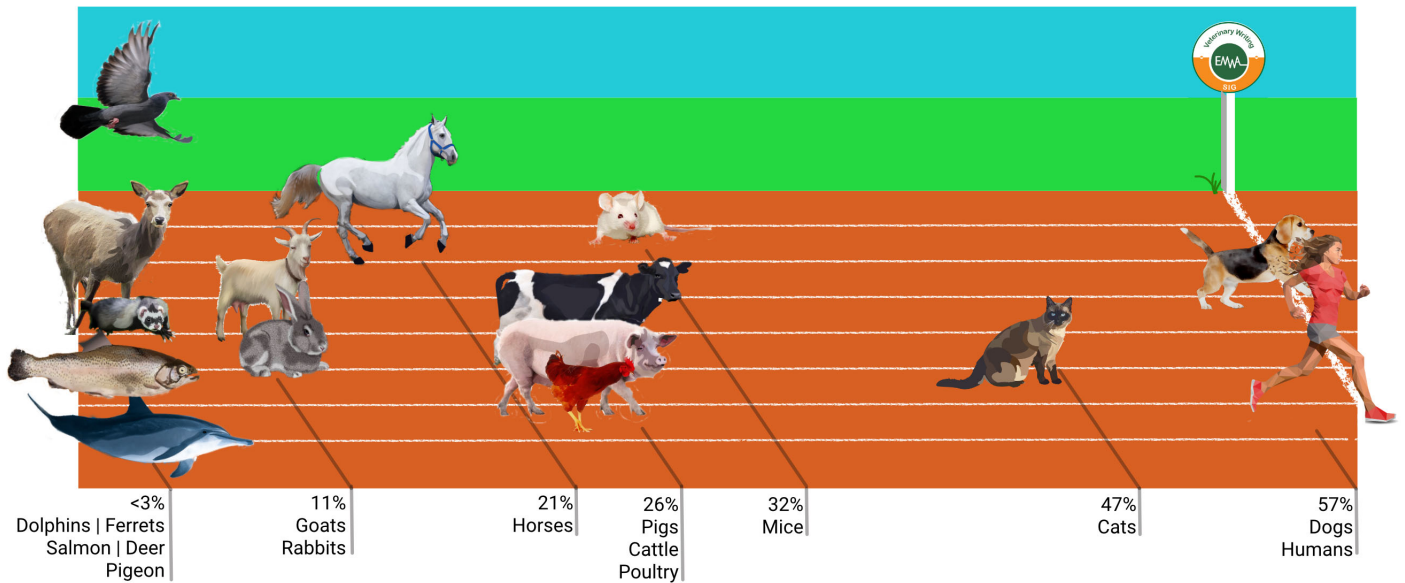


Figure 1. Which species do veterinary medical writers write about? Species that feature in EMWA vetSIG members' writing, percentages are expressed as the percentage of respondents that report writing about a given species in their work.

Figure created by Louisa Marcombes

but a crucial question had been overlooked in the initial survey: which animals do veterinary medical writers write about? Actually, this simple question could open the door to answering many others. Are veterinary medical writers divided along “small animal” versus “large animal” lines, as clinical veterinarians can be? Do our writers have to contend with pets one day and lab rats the next? Just how exotic is the work of a veterinary medical writer? To find out, we launched a one-question follow-up survey targeted more narrowly at those already working in the field to elucidate their species-writing habits.

The question was “What species feature in your medical writing?” I imagined I might get some vaguely interesting breakdowns by category, but I was unprepared for the excitement of watching the answers come in. The range of animals mentioned was intriguing (dolphins, deer, salmon, and ferrets all made early appearances), but the true excitement came from watching a desperately close race unfold as various members of the Animal Kingdom vied for the title of most written-about species. It was apparent that cows, pigs, and horses were running well but remained just behind the leaders. Cats got off to a flying start, but then faded in the latter stages. On the last day, I was able to watch a photo finish courtesy of the survey software real-time results page. Dogs put on a late spurt to finish in a dead heat with ... *Homo sapiens*, who had been leading pretty much from the first day (Fig. 1).

When the vetSIG discussed the results, this

thrilling race between species was our most talked-about finding. The presence of humans in writing about animal medicine might initially seem like an unwelcome intrusion. However, we interpreted it as a refreshing sign of the One Health times: growing recognition of the links between human and animal (and environmental) health. The wide species range also illustrates some of the fascination of working in veterinary medical communication: no one will get bored writing about the same study population.

Final thoughts

As stated on our website (www.emwa.org/sigs/vet-sig/) the vetSIG aims to “present and illuminate the broad and diverse area of Veterinary Medical Writing” and “encourage veterinarians and others to get in touch”. The survey results suggest we are achieving these objectives, and have informed our planning for 2021 and 2022. Our survey was not perfect, and perhaps questions would have been better designed if I had set the objectives and considered the target audience more clearly from the start. Even so, I found this survey to be a fascinating exercise, and it has been invaluable for the growth of our SIG.

In conclusion, EMWA's vetSIG can now be regarded as a profiled community, thanks to our birthday questionnaire and the follow-up species poll. The results demonstrate that veterinary medical communication encompasses a truly diverse range, free of species boundaries. However, I believe these questionnaires represent

a mere curtain raiser to our SIG's future: we have plenty of activities – and plenty of birthdays – to come.

Conflicts of interest

The author declares no conflicts of interest.

Data availability statement

Follow the link to the July 30th Q3 meeting in the Quarterly Meetings section at <https://www.emwa.org/sigs/vet-sig/>

Acknowledgments

I want to thank the many respondents, especially those who made extra comments, or even sent follow-up mails, because this helped us to get a far fuller picture than the rather crude categorisations in the original questions alone made possible.

Author information

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From the horse's mouth

The quarterly pick of the news from the veterinary world

A motion for resolution regarding the designation of antimicrobials to be reserved for the treatment of certain infections in humans has been defeated by a large majority in a plenary vote at the European Parliament, the *Federation of Veterinarians in Europe* reported on September 16, 2021 (<https://fve.org/fve-congratulates-the-european-parliament-for-taking-a-one-health-approach-and-voting-for-science-based-regulation-in-europe/>). The motion had sought to expand the criteria used for identifying antimicrobials reserved for humans (HRAM) through the presentation of a Delegated Act supplementing Regulation (EU) 2019/06. Critics of the motion feared that this would result in prohibiting antimicrobials that are crucial for the treatment of veterinary patients. An open letter was sent, coordinated by the European Platform for the Responsible Use of Medicine in Animals (EPRUMA), urging them to reject the motion. Heads of veterinary associations, deans of veterinary schools, and animal welfare organisations from all over Europe were counted amongst 9,000 signatories. The letter argued that the motion ignores currently accepted scientific evidence and that restricting access to antimicrobial treatment would pose an unacceptable threat to animal welfare.

Furthermore, the reduced spectrum of antimicrobials available for use in these species would favour the emergence of resistant microorganisms that could threaten human health. Finally, the motion goes against the One Health ethos, where healthcare for animals and the environment, as well as humans, is essential to protect the health of all. EPRUMA has hailed the result of the vote as demonstration that Members of the European Parliament “have understood the importance of animal health and its knock-on effects on public health, food safety, food security, and the environment.”

Researchers at the University of Guelph have found that veterinarians in the United States and Canada prescribed shorter antibiotic courses to treat dogs with urinary tract infections in 2018 than in 2016, it was reported in the September 19, 2021, edition of the *Humanimal Hub*. The study, by Weese et al. and recently published in the *Journal of Veterinary Internal Medicine* (doi: 10.1111/jvim.16246), reviewed the clinical records of 7387 dogs treated for urinary tract infection from 723 clinics in Canada and the US, the majority of which were first opinion clinics. The study directly compared the prescribing patterns of antimicrobials for urinary tract infections in dogs between 2016 and 2018, with reference to contemporary prescribing guidelines. The authors detected a significant difference ($P = .0002$) in the length of antibiotic treatment prescribed in 2016 (median = 14 days) and 2018 (median = 10 days) for treatment of sporadic bacterial cystitis. Furthermore, the authors found increased compliance with the recommended first-line treatment selection over the same period. The results show that awareness of antimicrobial stewardship is becoming more widespread, translating into a change in prescribing behaviour. However, the same study also showed an overall prevalence of 39% for using a “highest priority critically important” antibiotic as a first-line antibiotic treatment for canine urinary tract infection. This indicates a need to continue the work raising awareness of veterinarians in the responsible use of antimicrobials.

Vet Sustain, a not-for-profit social enterprise that aims to support the veterinary industry in adopting sustainable practice, and the veterinary pharmaceutical company Animalcare have announced a new partnership; it was reported at vetcommunity.com on August 25, 2021. In 2020, Animalcare was the first veterinary

pharmaceutical company in the UK to achieve carbon-neutral status. Vet Sustain was founded in 2019, providing support for individual veterinarians and organisations in improving their sustainable practice. The partnership has been forged with the collective goal of improving sustainability in the veterinary sector. A resource in high demand, as evidenced by a recent survey of British Veterinary Association members, found that 89% of respondents were motivated to play a more active role in the UK sustainability agenda.

In the previous issue of *From the horse's mouth*, we reported the unusually high incidence of feline pancytopenia cases presenting at veterinary clinics across the UK since the beginning of 2021. The cause was suspected to be exposure to mycotoxins, specifically T2 and HT2, which are hazardous to animal and human health. At the time, a possible link to a pet food production site in Lincolnshire, Fold Hill Foods, had led to a provisional safety recall of cat food lines manufactured at the site. Investigations that have since been undertaken by the Royal Veterinary College and the Food Standards Agency have found no link to the cat food manufactured by Fold Hill Foods, who are now working with local food safety authorities to restart production. Encouragingly, epidemiological data published on the RVC site (<https://www.rvc.ac.uk/news-and-events/rvc-news/feline-pancytopenia-update>) has shown weekly cases tailing off from a peak in mid-June, with the most recent update having been posted on September 13, 2021. Nevertheless, investigators continue to search for a dietary or possible non-food source of mycotoxins and updates are regularly posted on the site.

Medical Communications and Writing for Patients

Editorial

Dear All,

As I'm sure you are aware, EMWA's Special Interest Groups (SIGs) have been hard at work hosting "Meet & Share" sessions throughout the year. These sessions aim to encourage open and honest discussion between medical writers on a variety of topics (usually identified ahead of the session). It's an invaluable resource for EMWA members, since we are lucky enough to have a lot of very experienced and talented medical writers in our community, so I strongly encourage you to look out for the Meet & Share sessions and get involved!

The MedComm SIG's inaugural Meet & Share session delved into the issues surrounding acknowledgement of the support of medical writers/communicators in scientific publications. The intrepid reporters from the Meet & Share session are well known to EMWA members – our very own Beatrix Doerr and Thomas Schindler. They give a fantastic summary of a really interesting and educational session – guaranteed to whet your appetites for the next one!

As 2021 draws to a close, I hope that it has been a good year for you all, and that you and your loved ones remain healthy and happy.

SECTION EDITOR



Lisa Chamberlain James

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I also fervently hope that we will get to see each other in person next year at an EMWA conference.

Enjoy the upcoming Christmas break – may your socks stay snowball-proof and may Santa be kind.

See you in 2022!

Bestest,
Lisa

Ethics in publishing: First Meet and Share session of the Medical Communications Special Interest Group (MedComm-SIG)

The new Meet and Share sessions are intended to facilitate open discussions amongst peers and to offer a forum to dive deep into topics – well beyond the information that is provided in guidelines or books belonging to the daily practice of medical writers.

The first session was dedicated to acknowledging the support of medical writers/communicators (MW) in scientific publications. Like the Introduction, Method, Results, and Discussion (IMRAD) structure, it is almost common knowledge that medical writing support in the preparation of scientific articles needs to be acknowledged. So why dedicate a Meet & Share session to this topic?

The idea arose during medical writer Andrea Rossi's webinar on International Committee of Medical Journal Editors (ICMJE) guidelines. There, a newbie MW reported about her difficulties of having her medical writing support acknowledged. Kudos to the colleague who spoke up so openly. Many of us are established MWs and we have no problem with requesting acknowledgement for our work. However, the situation might be different for someone who is new to medical writing and is desperately looking

for work and pay to make ends meet.

We wanted to provide a forum for open discussion and practical advice to support peers and people who have just started their medical writing career. It is a good thing to develop ethical guidelines, however, we also need to support each other in implementing these. To summarise, these were the main recommendations:

- Even if it is hard at the beginning, it is much better to lose a customer than engage in ghost writing, i.e., accepting that medical writing support is not acknowledged. It will not pay off long term to work with somebody who obviously does not respect a medical writer's contribution.
- If somebody does not want to acknowledge medical writing support, it was suggested to initiate a discussion on the topic by asking for a reason for such a violation of guidelines and common practice. It is strongly recommended to familiarise yourself with the relevant resources, e.g., the various guidelines (ICMJE,¹ Good Publication Practices [GPP3],² EMWA guidelines³), and the publications that demonstrate the value of MWs.^{4,5}

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- Medical writers are well advised to state in their contract that they work according to the ICMJE and GPP3 guidelines and consequently expect acknowledgement of their work; this will clarify the situation upfront.

We had a lively discussion that brought many different aspects to the attention of the audience and therefore this was a great first Meet & Share session. The collective brainpower and the open and respectful discussions were fruitful and refreshing and we all learned something about different work contexts of medical writers.

References

1. ICMJE. Recommendations for the conduct, reporting, editing, and publication of



- scholarly work in medical journals [cited 2021 Jul 21]. Available from: <http://www.icmje.org/icmje-recommendations.pdf>
2. Battisti WP, et al. International Society for Medical Publication Professionals. Good publication practice for communicating company-sponsored medical research: GPP3. *Ann Intern Med.* 2015;163(6): 461–4.
 3. Jacobs A, Wager E. European Medical Writers Association (EMWA) guidelines on the role of medical writers in developing peer-reviewed publications. *Current Medical Research and Opinion.* 2005; 21(2):317–21.
 4. Gattrell WT, et al. Professional medical writing support and the quality of randomised controlled trial reporting: a cross-sectional study. *BMJ Open.* 2016;6(2):e010329. doi:10.1136/bmjopen-2015-010329
 5. Hamilton CW, Gertel A, Jacobs A, Marchington J, Weaver S, Woolley K. Mythbusting medical writing: Goodbye ghosts, hello help. *Account Res.* 2016;23(3):178–94.

The September 2022 edition of *Medical Writing*

Working remotely/working from home has become the norm these days. This issue will focus on various aspects of working from home- the good, the bad, the ugly. We will have articles on the challenges of writing from home, managing teams and also, on how some of us overcome these challenges and enjoy this opportunity.

Guest Editor: Archana Nagarajan

Don't miss!

A virtual workforce

Gained in Translation

Medical translation basics: Insider tips to improve quality

Introduction

How do medical translators get their projects? Most of the time they come from translation agencies, whose end clients need medical documents translated. These documents can be as varied as summaries of product characteristics (SmPC), drug leaflets, informed consent forms, patient questionnaires, or drug marketing material.

There are fundamental aspects that need to be taken into account and agreed between the end client, the agency, and the translator to avoid misunderstandings and to ensure a translation of the highest possible quality.

This article is not an exhaustive guide for medical translators. It is based on examples of good practice that were gathered during discussions with fellow translators and from my own

experience. This article gives insider tips, which new translators might not be aware of when they start their career.

As in many cases, communication is key. By going through the different steps of a medical translation project, we will see how things can go either right or wrong. The following approach is from the perspective of a translator receiving a medical translation project from an agency.

1 The translator receives a medical translation project from a translation agency

Best practices:

Clearly define the client's requirements:

- Who is the end client? If the document contains confidential information, the

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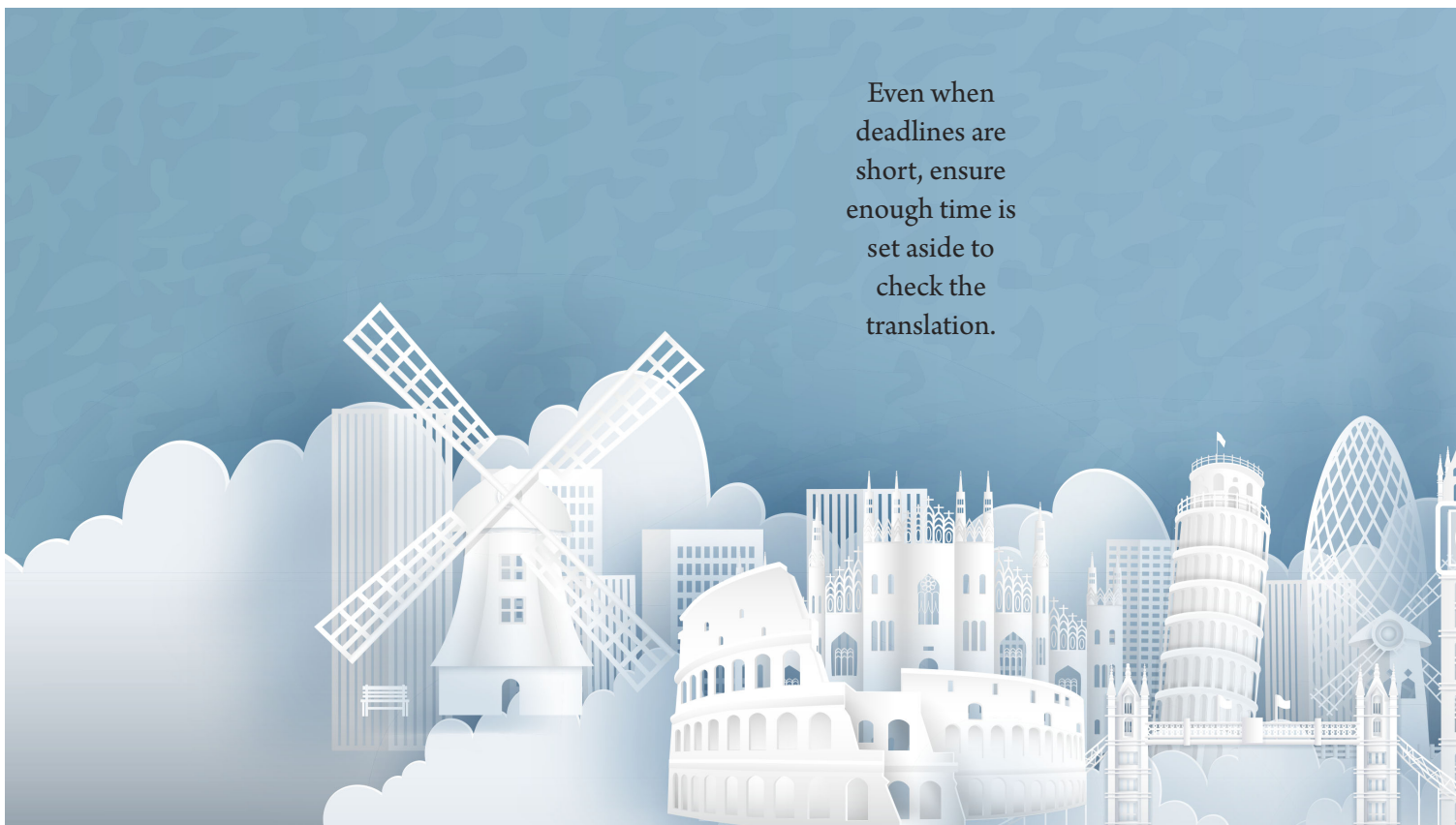


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translator may just ask for the type of client (e.g. pharmaceutical company, health agency, clinical research organisation, patient).

- Does the end client have any reference documents that could be useful for the project (e.g. translations of similar documents, glossaries, a multilingual website, a style guide, a feedback log)?
- What is the deadline for each step of the project involving the translator? Has the agency negotiated a suitable deadline with the



Even when deadlines are short, ensure enough time is set aside to check the translation.

end client to suggest a reasonable deadline to the translator?

- What level of quality does the end client want? Different clients and projects mean different criteria. Quality requirements are closely related to the purpose and the target audience of the translation. Sometimes, the high quality the translator wants to deliver does not match the quality requirements of the client, especially when the translation is for internal use only and is not going to be published in print or online. Getting more context and really knowing the end use of the translation is of great importance when it comes to adapting the translation to the target reader.

Advice for medical translators:

Translators should consider their agency clients as direct clients. Especially for new clients or new types of projects from an existing client, translators can have a list of questions ready and send it at the beginning of the project after reviewing any instructions provided. This helps save time for both parties. Furthermore, clearly written instructions can be used as proof in case of a future disagreement between the parties.

2 The translator starts the translation project

Best practices:

Open and read through all the files sent by the agency, including all reference files, instruction files and glossaries.

Read the source document and start a list of questions, if any, including the following:

- Is there anything else that needs translating first? There may be content directly related to the document to be translated, that was issued before or at the same time. For example, when a user manual for a medical software needs to be translated, if the document contains many screenshots from the software, the translator should ask if the software has already been translated. If the software will not be translated, common practise is to use the English format for user interface terms, for maximum user-friendliness.
- In case of doubts regarding the translation of a term, the translator should make suggestions to the client and ask for the preferred term.
- If a translator disagrees with the existing translation of a term, it is advisable to ask if there is a specific reason why this term is used. Before challenging it, it is best to have solid

references, such as the opinion of one or more doctors or specialists in the field. The translator may also ask for the term to be updated within the client's glossary so that the change can be taken into account for future projects.

Advice for medical translators:

In the end, a medical translator has to comply with the client's wishes and instructions. However, in case of a disagreement on the translation of a term, it is safer not to use another term without first asking the client's preferences. This shows the translator's involvement in the project and positions them as partners, rather than simple subcontractors.

This may also allow translators to figure out if the client is actually willing to communicate and establish a good working relationship. Indeed, it is more enjoyable for a translator to feel that a client, especially an agency, will be easy to communicate and work with.

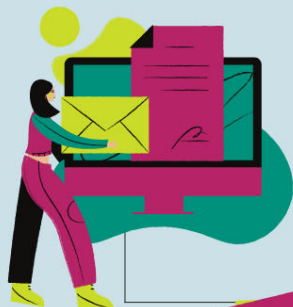
3 The translator has issues understanding a specific term: Ask for information and outside help

Best practices:

Even after looking thoroughly for the meaning or the translation of a term, a translator may not find



Medical Translation Project



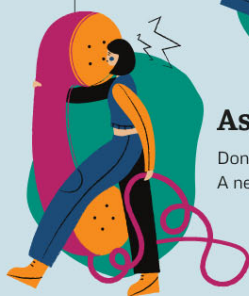
Receive project from a translation agency

Consider agency as direct clients. Get clearly written instructions and requirements.



Read through all the sent files

Review all reference files, instruction files and glossaries.



Ask for information

Don't be afraid to ask questions. A network of contacts is a great help.



Proofread the translation

Another pair of eyes is essential to ensure good quality of the translation.



Get feedback

Asking for feedback after a project shows the involvement in ensuring quality. It is also a smart way to get testimonials.



Keep collaborating with the client

Make suggestions to the client while taking their preferences into account.



the necessary information. If the document is a medical article, it can actually be a good idea to ask the author.

Also, translators should always make sure to review the instructions and the answers to their questions before delivering the project. This is a safe way to make sure that they have implemented all the changes they talked about with the agency. If uncertainties remain, they should be mentioned in the delivery email and the translator should offer to make final changes the client asks for after the delivery.

Advice for medical translators:

It might seem a bit bold at first, but authors are actually happy to see that other medical communication professionals have enough interest in their work to ask them questions. In most cases, they will gladly answer the translator's questions, especially if it helps publishing their article in other languages, which helps expand the reach of their message. Translators should not be afraid to ask authors questions directly. Of course, having a network of contacts in different medical specialities can also be of great help.

4 The translator proofreads the translation

Best practices:

- Have the translation proofread by another translator working within the same specialty. Another pair of eyes is essential, especially considering the very short deadlines translators are often asked to meet. This is common practice in the industry. Sometimes a second revision takes place. Workflows vary from one client to another, but as per the ISO standard related to translation services (ISO 17100: 2015),¹ there should be at least two pairs of eyes. If the agency does not take responsibility for this, ensure that you are allowed to subcontract this step under the terms of your agreement with the client.
- Even when deadlines are short, ensure enough time is set aside to check the translation.
- If the client is a translation agency, the translator should ask them if they have an internal reviewer who will proofread the translation once it is sent to the agency.

Advice for medical translators:

Networking is the best way to get to know translators working within the same area of specialty. Translators are encouraged to communicate with other translation and medical communication professionals about the types of documents they translate and the projects they have already done.

It is also very good practice to foster a spirit of mutual aid between translation professionals by taking part in discussions, meetings, and programmes organised through translators' organisations. One of these is the *Société Française des Traducteurs (SFT)*² in France. Recently, the SFT launched a mentoring programme called "Boussole" (translation: "compass"), in which

Figure 1. Main tips at different stages of a medical translation project

Graphic by Pavlina Cickova

experienced translators help newer translators with regular meetings and discussions.

It is not always possible to have translations reviewed when deadlines are tight. However, it is important not to give up on other ways to ensure quality, such as using the client's feedback for future projects.

5 After the project: getting feedback from clients

Freelance translators mostly work on their own and only contact their clients through emails and on the phone. This type of working relationship, associated with tight deadlines, does not leave much space for debriefing after a project. More than 9 times out of 10, translators only get a confirmation of safe receipt of the translation and no other type of feedback on their work. It may be difficult to get feedback from some clients, but asking for feedback after a project shows the translator's commitment to ensuring quality.

Feedback requests can range from general to very specific questions:

- Is the client happy with the translation?
- Are there any issues that were spotted? Is there anything that needs to be changed or improved?
- What's the final decision of the client regarding the capitalisation of this specific term we talked about?
- Do you confirm that the following abbreviations need to be kept in English for French readers in future projects?
- What is the final version of the file that was sent to the end client? This way the translators can compare it with the version they delivered.

Advice for medical translators:

Asking for feedback is also a smart way to get testimonials that can be used to promote medical translation services. Translators can use a post-project questionnaire. Louise Shanahan, health copywriter and messaging fixer, issued a very helpful podcast on how to get testimonials from clients for freelancers.³ This gives access to a free PDF guide full of useful advice.

6 Keep collaborating with the client

It is important to keep making suggestions to the client while taking their preferences into account, even when translators think that their translation would be more appropriate than the client's.

However, to make sure to keep a good working relationship with their clients, translators should be aware of the following:

- Arguing with the clients and wanting to have the final say on the translation of a term is not going to improve the working relationship. It might

only push the client to look for another translator.

- Translators can question their clients' requirements when they have solid references (doctors, specialists, etc.). Backing up a chosen term with evidence is better than relying on personal opinion.
- It is more rewarding to work with agencies who are happy to discuss specific matters about the translation of terms, the style, and the end client's preferences, even if things do not change in the end.

Advice for medical translators:

In order to have more time to produce their work, translators can try to reduce their workload and negotiate the real deadline that is necessary to work on the project in optimal conditions. If translators are able to negotiate fair rates for their services, taking more time to work on translations should not cause a loss of profit. Agencies will always try to ask for the earliest deadline but translators can and should negotiate on deadlines. This can also have an effect on end clients. By negotiating deadlines and prices, translators can become part of a virtuous circle. If translation agencies let end clients know that it is not possible to deliver a good translation in 24 hours for their 7,000 word-project, they can get a better idea of the time needed to deliver good quality and they will stop looking for the fastest, cheapest translator. A more realistic speed for specialised medical translation is 1,500 to 2,500 source words translated and reviewed per day. However, the speed is closely related to the level of specialisation of the source text.

Translators who negotiate on a regular basis are more aware of the actual needs and requirements of translation agencies and end clients. They can thus refine their services, deadlines and rates to better serve their clients. This can also allow them to actively search for clients whose quality criteria are in line with their own.

Bad practices

Here is a non-exhaustive list of bad practices in the translation industry. Whenever translators come across such practices, they should try to negotiate and if negotiations fail, consider refusing to work with agencies having such practices.

- Very short deadlines: more than 2,000–2,500 words translated and reviewed per day. This will not give the translator enough time to do all the necessary research and quality assurance steps to ensure good quality.
- Badly written source texts: some texts may be of low quality, especially when they are written by non-native speakers. This happened to a fellow translator, who had to translate texts

about rapid COVID-19 tests that were written by non-natives. Source texts did not make much sense and she had difficulty understanding and translating them.

- Bad communication: clients not answering questions or with great delay, having different project managers answering the questions so that the translator has to explain the issues over again.
- Clients who do not actually know what they want: they cannot tell who the target audience of the translation is going to be, they don't know the purpose of the translation, they cannot answer the translator's questions on the translation.
- Clients that change things once the translation has been delivered. Example: the client changes the translation before putting it online and the text no longer makes sense.

Conclusion

For each step of a medical translation project, quality assurance measures can be put in place to ensure better overall quality. Even though translation might seem like a solitary profession, translators have to become communication professionals in order to receive and comply with their clients' requirements, as well as conveying a meaningful and useful message while translating. A solid working relationship can be built between freelance translators and translation agencies. The work of both parties should be seen as a cooperation, rather than a fight where each party is only focused on their own interests.

This cooperation is in everyone's interest: the clients, who receive better quality translations; the agencies, who gain customer loyalty; and the translators, who negotiate fairer working conditions.

References

1. ISO 17100:2015 Translation services – Requirements for translation services [accessed on 2021 Sept 29]. Available from: <https://www.iso.org/standard/59149.html>
2. Société Française des Traducteurs 2021 [accessed 2021 Sept 29]. Available from: <https://www.sft.fr/fr/homepage>.
3. 15 Minute Freelancer. How to ask and use better client testimonials. 2021 [accessed 2021 Sept 29]. Available from: <https://www.15minutefreelancer.com/16240-18/8507502-18-how-to-ask-for-and-use-better-client-testimonials>.

Pharmacovigilance

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Editorial

Dear members,

I am delighted to launch the Pharmacovigilance (PV) section in this journal issue! Those of you who have been around for a while may know that, in the past, PV-related articles were published either as feature articles or as guest topics in the Communication section (and with this, I would like to thank Lisa Chamberlain James for making this possible over the past six years!) It is now time for a dedicated PV section to explore and highlight hot topics in the PV area or potential common interests

between the PV-Special Interest Group (PV-SIG) and other EMWA SIGs.

In this brand-new PV section, Sam Ramsden from Boehringer Ingelheim provides very interesting heads-up about the forthcoming revision of the EU guideline on additional risk minimisation. Sam recently coordinated the review of the draft good pharmacovigilance practices (GVP) Module XVI rev.3 guideline by the European Federation of Pharmaceutical Industries and Associations (EFPIA). While guiding medical writers through such a complex topic, he shows how national guidelines integrate growing experience and knowledge with the ultimate goal

to protect patients.

A further PV topic is included in this journal issue in the Regulatory Matters section (see p. 56): Joan D'souza, active supporting member of the PV-SIG, prepared with me an overview of the evolution of the GVP guidance since first publication in 2012.

This is another example of how public consultations and interaction with stakeholders contribute to improve implementation of the guidance.

I wish our members happy reading!

Tiziana

What to expect from the revision to GVP Module XVI

Within the European Union (EU), the Good Pharmacovigilance Practices (GVP) guidelines define the regulatory expectations related to pharmacovigilance (PV), including the risk management system of a Marketing Authorisation Holder (MAH). Risk minimisation is essential to ensure safe and optimal patient care. Respective activities are used as barriers in medical practice to prevent or mitigate risks to the patient, healthcare provider, or public health. In general, there are two types of risk minimisation recognised in the EU regulatory framework: (1) routine risk minimisation that includes the product information (e.g. Summary of Product's Characteristics [SmPCs]) and legal status (e.g. over-the-counter or prescription-only medicine); and (2) additional risk minimisation that includes activities such as educational programmes, restricted access, and pregnancy prevention. GVP Module XVI¹ deals exclusively with what is known as additional risk minimisation measures and the measurement of their effectiveness.

Within the Risk Management Plan (RMP)² and the Periodic Safety Update Report (PSUR),³

the evaluation of important risks provides a conclusion of their impact on the authorised patient population and the appropriate strategy to manage the risks in the post-marketing environment. Most of the time, routine risk minimisation is considered sufficient to manage

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risks; however, in situations where the seriousness and/or likelihood of occurrence is not sufficiently managed by routine activities, additional risk minimisation may be necessary as described in the applicable GVP Module XVI.¹ Furthermore, when additional risk minimisation is required, a detailed plan and periodic evaluation for measuring the effectiveness of the risk minimisation activity is required to ensure they meet the defined goals and objectives, and are not causing an unacceptable

burden on patients and healthcare providers. Therefore, GVP Module XVI¹ also details the requirements and approach to generate metrics to assess the effectiveness of additional risk minimisation.

On February 1, 2021, EMA issued a draft of the 3rd revision of GVP Module XVI⁴ for public

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consultation and this article will contextualise the proposed changes.

Regulatory history

The history of GVP Module XVI and supporting addenda is presented in Table 1.

Important changes with draft revision (Rev) 3

GVP Module XVI Rev 3⁴ went through a round of public consultation and is currently under finalisation, anticipated coming into effect in Q4 2021/Q1 2022. Therefore, the changes that are described below could be modified in the final version.

Dissemination Plan

In the draft Rev 3 guideline, there is a clear description of the need to prepare a risk minimisation dissemination plan. This plan complements the information, such as root cause, risk factors, and proposed measures to prevent



and mitigate important risks, which are included in the RMP Part II module VII and Part V.² The plan should provide in-depth details about the objectives, target audience, implementation strategy, and milestones. Plans for additional risk minimisation should be submitted to National Competent Authorities (NCAs) as part of the national negotiation prior to the launch of the product.^{1,4}

What does this mean for medical writers?

Medical writers involved in the preparation of RMPs and risk minimisation proposals should be aware of the need to submit the proposal to

NCAs. No standard template has been included by the EMA in the draft guideline for the dissemination plan. Therefore, MAHs can develop a company-customised template to support a harmonised approach for implementation of risk minimisation plans that acknowledges the company's situation and way of working. Furthermore, the information included in the RMP and Annex II of the European Public Assessment Report (EPAR) should be aligned with what is detailed in the risk minimisation plan in terms of root causes of risks, stakeholders that should receive the interventions, implementation strategy, and milestones.

Additional risk minimisation tools

The draft Rev 3 guideline⁴ further improves the clarification of types, objectives, and target audience of the different additional risk minimisation measures. Activities such as educational programmes, Direct Healthcare Professional Communication (DHPC), controlled access, and pregnancy prevention programmes, are addressed in detailed sections outlining considerations for the target audience, such as specific types of information relevant for physicians or patients. Situations where each risk minimisation measure should be considered are also described. This is helpful because it provides guidance on

Table 1: History of GVP Module XVI and supporting addenda

GVP module / Addendum	First publication	Revisions	Comments
GVP XVI risk minimisation measures: Selection of tools and effectiveness indicators ¹	Feb 28, 2014	Rev 1: Apr 25, 2014 Rev 2: Mar 30, 2017 Rev 3 ⁴ released for public consultation: Feb 3, 2021	Planned date for Rev 3 coming into effect: Q4 2021/Q1 2022
Addendum I – Educational materials	Dec 15, 2015	Not applicable	No revisions
Addendum II – Methods for effectiveness evaluation ⁵	First released for consultation: Feb 3, 2021	Not applicable	Planned date for coming into effect: Q4 2021/Q1 2022



how objectives of risk minimisation need to be aligned with the choice of tools. Educational materials are further stratified, and specific reference is made to guides, check lists, risk awareness forms, demonstration kits, patient diaries, and patient cards. Although the tools are not “new”, the specific mention of them and individualised considerations for each type is a welcome addition to help clarify the appropriate use of the different interventions. Controlled access programmes have also been stratified and include controlled prescription and supply systems, and centre accredited systems.

What does this mean for medical writers?

Medical writers working on respective materials (e.g., educational guides or check lists) should consider the objectives of the various tools defined in the guideline to ensure the inclusion of appropriate information. In terms of project management, they need to prompt project team members to provide their respective expertise to design the risk minimisation tool. Furthermore, the development of templates for use within the organisation can improve internal and external communication when creating and implementing the interventions.

Effectiveness measurements

The requirement of the evaluation of effectiveness of risk minimisation measures has been expanded and clarified. The Rev 3 draft guideline⁴ specifies that effectiveness evaluations should be focused, i.e. the approach to assess the effectiveness should be aligned with the objectives, target audience, and milestones of the risk minimisation activity. Furthermore, emphasis has been given on how and when risk minimisation evaluation should occur, which includes a close interaction between prospective planning in the RMP, targeted endpoints in the Post Authorisation Safety Study (PASS), and appropriate regulatory follow-up. The evaluation of effectiveness and regulatory follow-up also benefits from patient and healthcare provider input, which is also emphasised for the design and evaluation of risk minimisation.

Timelines for consideration are described, and the evaluation should take place at defined intervals of 1, 3, and 5 years after initial im-

plementation of the risk minimisation activity. These timeframes will be defined based on the type of intervention and agreed with the EMA and NCAs. The timelines will also have to be reflected in the RMP² and aligned with PASS⁶ activities. A detailed timeline for the measurement of effectiveness will also help support the appropriate approach to risk minimisation over the lifecycle.

Planned timelines for evaluation will help establish the relevance of risk minimisation measures through a timely demonstration if important risks and risk minimisation become routine knowledge and integrated into clinical practice.

The draft guideline includes a new section detailing the need to evaluate both the intended and the unintended outcomes of a risk minimisation activity.

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of a risk minimisation activity. MAHs must understand if the risk minimisation activity is having the desired effect, for example, if an appropriate change in clinical knowledge has been achieved about how to mitigate a risk. This desired outcome should be evaluated against any

unintended consequence of the risk minimisation. Evaluating intended and unintended consequences aims to ensure that risk minimisation is fit-for-purpose and does not lead to an unacceptable burden on the intended stakeholders. For example, patients might stop taking the medicine because it is too difficult to follow the requirement of the risk minimisation activity.

The approach to effectiveness evaluation has also been expanded. In the initial guideline, effectiveness evaluation could be categorised as either a process indicator (e.g. dissemination, changes in knowledge or behaviour) or an outcome indicator (e.g., actual change in the incidence of the risk). In the draft guideline, the concept of effectiveness evaluation is addressed in more depth, and the following hierarchy is used: dissemination and risk awareness, behavioural change, and health outcomes. The draft guideline includes relevant considerations and expectation with regards to the necessary data to be collected for qualitative and quantitative assessments of the three levels of effectiveness.

The measurement of effectiveness of risk minimisation can be considered a PASS and therefore, the respective expectations need to be fulfilled.⁶ In Addendum II⁵ of the draft guideline, a detailed consideration for study design and protocol preparation is provided.

What does this mean for medical writers?

Medical writers involved in writing protocols and study reports should be aware of the added requirements for studies used to measure the effectiveness of risk minimisation.^{4,5,6} The endpoints in study protocols should be focused and aligned with the objectives of the risk minimisation activity and any interim and final study reports should clearly describe if the objectives of the risk minimisation measure were met. This calls for close cooperation of medical writers and epidemiologists when developing the study-relevant documents, to ensure appropriate considerations. Different methodology is recommended within the guideline,^{4,5} which should be considered when a protocol is prepared.

Finally, the evaluation of effectiveness should be accurately and appropriately documented in the RMP² and assessed in the PSUR.³ The necessary milestones documented in the RMP should be carried into the organisation's lifecycle management plan. The key focus in the description of effectiveness in the RMP should be on how the outcome informs on risk minimisation and PV planning.⁴ In the PSUR, the effectiveness of risk minimisation should

focus on how the implemented measures impact the safety and benefit-risk balance of the product.⁴ The medical writer should ensure that there is a continuity between the objectives of the risk minimisation measures and the endpoints in the protocol, the conclusions in the study report, further planning in the RMP, and communication in the PSUR.

Conclusion

Rev 3 of GVP Module XVI is a welcome evolution of the regulations defining additional risk minimisation and measurement of effectiveness and reflects the experience gained since the coming into effect of the first version in 2014. Clarification through the inclusion of greater detail has helped resolve some of the outstanding questions MAHs faced with previous versions of the guideline. The additional information included about target audience and objectives for risk minimisation tools, and the expansion of consideration for effectiveness measurements should help teams design focused and relevant risk minimisation. Moving forward, it would be helpful to have more guidance on digital intervention and dissemination to acknowledge the important role these platforms now play in society. Overall, it is appreciated that the accumulation of knowledge and experience is being included in national guidelines for risk minimisation with the ultimate goal to protect patients and the public health.

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Disclaimers

Samuel Ramsden is an employee of Boehringer Ingelheim. The views and opinions represented in this article are solely those of the author and are not endorsed by or necessarily representative of those of Boehringer Ingelheim or EMWA.

Conflicts of interest

The author declares no conflicts of interest.

Data availability statement

For inquiries about data and other supplemental information, please contact the corresponding author.

References

1. The European Medicines Agency. Guideline on good pharmacovigilance practices (GVP). Module XVI – Risk minimisation

measures: selection of tools and effectiveness indicators (Rev 2). 2017. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-module-xvi-risk-minimisation-measures-selection-tools_en-3.pdf

2. The European Medicines Agency. Guideline on good pharmacovigilance practices (GVP). Module V – Risk management systems (Rev 2). 2017. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-module-v-risk-management-systems-rev-2_en.pdf
3. The European Medicines Agency. Guideline on good pharmacovigilance practices (GVP). Module VII – Periodic safety update report (Rev 1). 2013. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-module-vii-periodic-safety-update-report_en.pdf
4. The European Medicines Agency. Guideline on good pharmacovigilance practices (GVP). Module XVI – Risk minimisation measures: selection of tools and effectiveness indicators (Rev 3). Draft for public consultation. 2021. Available from: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-good-pharmacovigilance-practices-gvp-module-xvi-risk-minimisation-measures-selection-tools_en.pdf
5. The European Medicines Agency. Guideline on good pharmacovigilance practices (GVP). Module XVI Addendum II – Methods for effectiveness evaluation. Draft for public consultation. 2021. Available from: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-good-pharmacovigilance-practices-gvp-module-xvi-addendum-ii-methods-effectiveness_en.pdf
6. The European Medicines Agency. Guideline on good pharmacovigilance practices (GVP). Module VIII – Post-authorisation safety studies (Rev 3). 2017. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-module-viii-post-authorisation-safety-studies-rev-3_en.pdf

Good Writing Practice

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Grammatical disagreement in function:

Modifier to modifée



Introduction

Knowledge of the grammatical function of a modifying syntactic unit facilitates understanding a misfunctional distraction and, in turn, its revision option.

Experimental sections

Part 1 – Materials and Methods section: Method

Example: Propositional phrase

Increased mandibular growth was determined for the animal with the protrusion appliance.

Revision

Increased mandibular growth was determined

*for the animal **treated** with the protrusion appliance.*

Notes

In the Example, it is not clear whether *with the protrusion appliance* is an adjectival modifying *animal* or an adverbial modifying *was determined* as in *Increased mandibular growth for the animal was determined **by using** the protrusion appliance*. The underlining cause is the ambiguity of the preposition *with*. In the Revision, replacement by the adjectival past participle *treated* explicitly marks *animal* as the modifée of *with the protrusion appliance*.

Likewise, the adverbial modification can become explicit by usage of a syntactic unit with

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a decidedly adverbial function (such as the preposition-gerund phrase *by using the protrusion appliance*) and by transposing *for the animal* so that the verb phrase *was determined* is contiguous to *by using*. Although this adverbial alternative is syntactically plausible, the meaning is erroneous.

The preposition-gerund phrase is so frequent in research writing that its consideration as a unique structure seems justified. This structure

primarily functions as an adverbial, e.g., *Ascorbic acid was determined by using alpha, alpha-dipyridyl.*

Part 2– Results section: results statement and preliminary interpretation

Example: Preposition-gerund phrase

Mutated PTEN that has lost only lipid phosphatase activity failed in mediating repression.

Revision

*Mutated PTEN that has lost only lipid phosphatase activity failed **to mediate** repression.*

Notes

Which is more effectively matched as the direct object of the transitive verb *failed*: a preposition-gerund phrase or infinitive phrase? The infinitive phrase *to mediate* sounds better, probably because it can function as a nominal, whereas *in mediating* cannot. In this example, the preposition-gerund phrase could be functioning as a modifier of the transitive verb *failed*, but the intent is *failed something*; thus, a nominal is needed as a complement (direct object).

Contextual Sections

Part 2 – Title

Example: Preposition-gerund phrase

The Ability for Synthesising Proline in Streptozotocin-Induced Diabetic Rats

Revision 1

*The Ability **to Synthesise** Proline in Streptozotocin-Induced Diabetic Rats*

Revision 2

*The **Proline-Synthesising** Ability in Streptozotocin-Induced Diabetic Rats*

Revision 3

***Proline Synthesis** in Streptozotocin-Induced Diabetic Rats*

Notes

Many descriptive nature-of-study titles, in contrast to message titles, are noun and prepositional phrase rich and formal. In contrast, the preposition-gerund phrase (Example) and infinitive phrase (Revision 1) are more animated, but are less familiar than the noun + participle also functioning as an adjectival (Revision 2). The advantage of this structure is its highly thematic focus *proline-synthesising ability*. However, Revision 2 could be further revised to Revision 3 by deletion of the self-evident *ability*.

Part 2 – Introduction section: research problem background

Example: Adjective

Raf-1 is a common messenger in mitogenic stimulated signal transduction pathways.

Revision 1

*Raf-1 is a common messenger in **mitogenically** stimulated signal transduction pathways.*

Revision 2

*Raf-1 is a common messenger in **mitogen-stimulated** signal transduction pathways.*

Notes

In the Example, what word class is required to modify *stimulated*? An adjective such as *mitogenic* traditionally modifies a noun, but not an adjectival participle such as *stimulated*. In Revision 1, usage of the adverb *mitogenically* is grammatically correct (adverbs modify an adjective or an adjectival) but seems a hypercorrection (i.e., unfamiliar and stilted). In Revision 2, *mitogen-stimulated*, a noun-participle compound adjectival, is a familiar type of modifier (see Part 1). The compound nature,

common for a noun followed by a participle modifier, is reinforced by hyphenation.

Part 3 – Introduction section: research importance

Example: Adverb

Lymphedema results in chronic inflammation, fibrosis, infection, and frequently loss of joint function (motion, muscle strength).

Revision

*Lymphedema results in chronic inflammation, fibrosis, infection, and **frequent** loss of joint function (motion, muscle strength).*

Notes

Usage of the adverb *frequently* is dissonant. Modification of the noun *loss* requires the adjective *frequent* not the adverb *frequently*. However, if commas segregate *frequently*, then *frequently* could back-modify the phrasal verb *results in*.

Summary

The following are examples of modifier-to-modifiee misfunction:

Experimental sections

1. Prepositional phrase ambiguous function either adjectival *animal with the protrusion appliance* or possibly adverbial *determined with the protrusion appliance*.
2. The adverbial preposition-gerund phrase *in mediating* misused as a nominal direct object *failed in mediating*.

Contextual sections

1. The adverbial preposition-gerund phrase misused as an adjectival *ability for synthesising*.
2. The adjective *mitogenic* misused before another adjectival *mitogenic stimulated*.
3. The adverb *frequently* misused before a noun phrase *frequently loss of joint function*.



This is called the hash, pound, or number character. A hashtag is a keyword or set of keywords that is preceded by the # character. It is used in social media to create a thread of conversations around a specific theme or topic conveyed in short texts or microblogs. It is commonly used in Twitter, Instagram, YouTube, Pinterest, etc.

A dictionary of most common hashtags can be found at <https://www.hashtags.org/definition/~h/>. For your info, EMWA is compiling a list of standardised hashtags for our social media use.



This is called the “at” sign or symbol. The @ sign is part of email addresses and social media user names (“handles”). Our EMWA handles are as follows: @Official_EMWA (Twitter), @EMWA (LinkedIn), and @europeanmedicalwritersassociation (Facebook)

The two most important keys on your keyboard

The Crofter: Sustainable Communications

Editorial

Greetings from the croft! In this special issue on medical journalism, we have two contributions that discuss topics that have enjoyed attention in the press: 1. the emerging environmental problem because of the growing drug market for pets, and 2. vaccine inequality. Louisa Marcombes provides

an overview of veterinary environmental risk assessments (ERAs) and upcoming changes when Directive 2001/82/EC will be repealed and replaced by Regulation (EU) 2019/06 in 2022. Jen Bell discusses how distributed manufacturing and other considerations can help make the vaccine industry more sustainable. I hope you enjoy

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reading about these two emerging areas where medical writers and communicators can have an impact.

Kimi

Paradigm shift, same old, or something in-between? What does the new EU veterinary medicines directive mean for the environmental risk assessment of veterinary medicinal products?

The emission of veterinary pharmaceuticals into the environment is an emerging problem,^{1,2} not least because of significant growth in the pet drug market.³ A 2014 report by CHEM Trust has identified the presence of pharmaceuticals in the environment as not only a threat to ecosystems but also to human health with the potential for contamination of drinking water and crops.² Behind the stories that have reached the mainstream media, such as mass death in India of vultures that have fed on carcasses of cattle that had been treated with the non-steroidal anti-inflammatory agent diclofenac,⁴ there is a mounting body of evidence of the damage caused by veterinary medicinal products (VMPs) in the environment.⁴ Despite this, extensive knowledge gaps remain about how and to what extent pharmaceutical emissions impact the environment.²

The environmental risk assessment (ERA), an “analysis of the potential risk that the use of a medicine poses to the environment”,⁵ has been, in one form or another, a legal requirement for the EMA’s marketing authorisation (MA) process for VMPs since the mid-1990s.¹ ERAs are the regulatory framework designed to mitigate the impact of VMPs on the environment. It has been proposed by Casa-Resino et al.⁶ that such legislation should satisfy three basic



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requirements: 1. that the environmental risk for every marketed VMP is known, 2. that the technical requirements to measure this risk do not result in excessive regulatory burden, and 3. that the conclusions of ERAs are consistent and reliable across all VMPs.

The legal basis of ERAs of VMPs authorised by the EMA are currently determined by Directive 2001/82/EC. On January 28, 2022, this directive will be repealed, and its replacement, Regulation (EU) 2019/06, comes into force. Here, the current format of veterinary

ERAs is reviewed, followed by a preview of what changes can be expected with the new legislation. The regulatory change is then discussed in the context of the recent controversy surrounding the use of the antiparasitic treatment, fipronil, in pets and, finally, what this means for medical writers with interest in the environment and sustainability.

The environmental risk assessment (ERA) process

Under the current EU Directive, 2001/82/EC, the ERA framework is a two-phase procedure (Figure 1).¹ Phase I screens the candidate VMP for the risk of significant exposure of the environment to the active substance in the context of its intended licensed use. Guidelines by the Veterinary International Conference on Harmonisation (VICH), VICH GL 6,⁷ have facilitated a much-needed consistency in the standard of Phase I ERAs since its publication in 2000. VICH GL 6 is an algorithm composed of 19 polar questions. There are two possible outcomes: low risk or elevated risk. An outcome that indicates a low risk of

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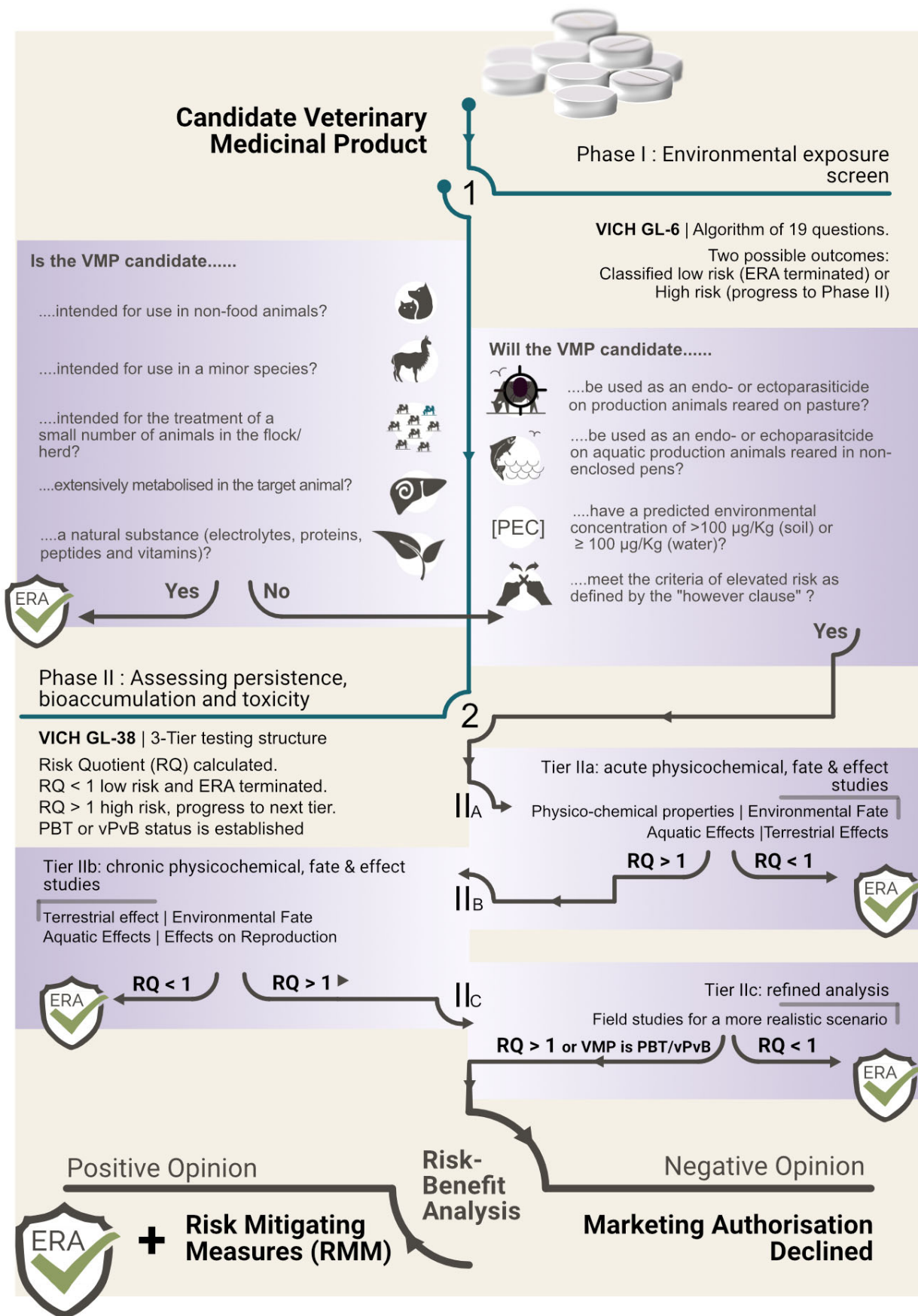


Figure 1. Schematic representation of the environmental risk assessment procedure (ERA) framework for the Authorisation of Veterinary Medicinal Products by the European Medicines Agency (based on Directive 2001/82/EC)

Abbreviations: ERA, environmental risk assessment; VMP, veterinary medicinal product; VICH GL, Veterinary International Conference on Harmonisation Guideline; RQ, risk quotient; PBT, persistent, bioaccumulative, toxic; vPvB, very persistent, very bioaccumulative; RMM, risk mitigating measures.



Photo: Unsplash.com / Flash Dantz

environmental exposure is sufficient to terminate the ERA. This is systematically the case for VMPs where the target species is a non-food producing animal, a minor species, or intended for limited treatment of individuals in the flock or herd (Figure 1).

VMPs for which a high risk of environmental exposure is anticipated, including all endo- or ecto- parasiticide treatments intended for production animals at pasture or fish in open pens, results in progression to Phase II for higher-tier risk assessment. Likewise, for the same category of production animal target species, VMPs which exceed a set environmental threshold (predicted environmental concentration [PEC] of candidate VMPs in soil [$> 100 \mu\text{g}/\text{kg}$] or water [$> 1 \mu\text{g}/\text{L}$]) will proceed to phase II assessment (see Figure 1). A VMP that would also ordinarily stop at Phase I may also progress through a provision commonly referred to as the “however clause”, where there are known environmental risks associated with the VMP.⁸

Phase II is designed to quantify the degree of persistence and bioaccumulation in the environment, and toxicity to the ecosystem including the micro- and macro-organisms within it. Harmonisation of this complex process has been assured by guidelines detailed in VICH GL 38.⁹ Phase II

is itself divided into three increasingly complex tiers (Figure 1): Tier A (acute effects), Tier B (chronic effects & reproductive effects), and Tier C (refined analysis).

At each tier, a predicted no effect value (PNEC) and the PEC are calculated using toxicological endpoints. A risk quotient (RQ) is calculated by dividing exposure by toxicity (PEC/PNEC) for each affected ecological compartment.⁶ A value < 1 is considered low risk sufficient to terminate the ERA (Figure 1). A value > 1 results in progression to the next tier. If, after tier C, the RQ is persistently elevated, an overall benefit/risk judgement is taken by the Committee for Medicinal Products for Veterinary Use (CVMP). A positive opinion leads to a MA for the VMP, often with product-specific risk-mitigating measures (RMM). RMMs are most commonly handling and administration measures for the VMP detailed in the summary of product characteristics (SPCs).¹ A negative opinion results in the refusal of the MA. This is a provision that sets Directive 2001/82/EC apart from the equivalent directive for humans is 2001/83/EC, where a negative outcome of the ERA cannot be used as a basis to refuse a MA.¹ Phase II analysis also determines if the candidate VMP meets persistent,

bioaccumulative or toxic (PBT) or very persistent, very bioaccumulative (vPvB) criteria. Under the current regulations, this usually results in the requirement for RMM and pharmacovigilance measures.¹⁰

Limitations of the current veterinary ERA (under Directive 2001/82/EC)

Do the current regulations satisfy the three requirements for environmental regulation of VMPs, as proposed by Casa-Resino et al.²⁶ They have argued not. ERAs of VMPs have been harmonised since they were first introduced in 1998, when there was an unacceptable variation in quality and scope. As a result, there is a discrepancy between the ERAs of older VMPs and those with more recent MAs. VMPs authorised before 1998 have no ERA at all. Therefore, the environmental risk of all VMPs is unknown, and all existing ERAs are not consistent and reliable. Furthermore, the ERAs prescribed by Directive 2001/82/EC are product-based rather than active substance-based. That is to say that for every VMP undergoing an MA application, an ERA is mandated. Even if the active ingredient is a generic and the reference drug has already undergone a full ERA. This is a source of friction

and inefficiency in the regulatory framework and, it is argued, places an unnecessary regulatory burden on applicants wishing to bring a VMP to market.¹

The “referral procedure” (Article 35 of Directive 2001/82/EC) gives provision for a VMP that already has an MA to be “referred” for post authorisation review. This is a mechanism by which older VMPs can be updated by review of the risk-benefit balance. However, the legislation lacks a systematic mechanism to identify these products, relying instead on member states to take the initiative to trigger a referral.⁶ In reality, this is a seldom-used legislative route, with only 20 referral procedures triggered to date.¹

The inferior quality of older ERAs and the lack of a systematic “catch up” mechanism for updating them is a recognized weakness of the current legislation.⁶ Another perceived weakness includes the absence of legally binding pharmacovigilance of the environment, although this is partially achieved indirectly through the Water Framework Directive [2008/105/EC].¹ Furthermore, the directive governing ERAs does not take into account emissions that result from the manufacturing of VMPs, which many would consider a significant omission.

Regulation (EU) 2019/06: What's new?

One of the overriding objectives of the EC regulations for VMPs (EU) 2019/06 is better alignment with the European Green Deal.^{6,11} An additional aim is to reduce the legislative burden that encumbers the MA of a new VMP to increase the market availability of VMPs, while “guaranteeing the highest level of public and animal health and environmental protection” (Recital 5). With these stated policy drivers, what changes come into effect on January 28, 2022? And will they usher in the improvements needed?

The technical aspect of undertaking an ERA for a candidate VMP changes very little with the new legislation. The 2-phase framework of the ERA is preserved, along with the criteria which determine its progression through the phases.⁶ The ERA process also remains product-based rather than pivoting to an active-substance-based framework. However, the legislation has required that the EU publish a feasibility study (Article 156) of a “monograph system” (or alternative) to establish an ERA database of active ingredients that could pave the way for such an active substance-based assessment.

Article 72 gives member states the power to request additional environmental hazard information, the “catch-up procedure” lacking in the

prior legislation. More explicitly stated than in the preceding legislature, it determines the right for the EMA or other competent authority to request an ERA for the VMP of a generic, where the reference VMP was granted before October 1, 2005. Once again, however, it relies on the initiative of the competent authority, and critics fear the essential mechanism to systematically pick up these older VMPs is lacking.

Elsewhere, Article 37.2, for the first time, gives regulatory guidance on the management of VMPs categorised as PBT/vPvB. It gives provision for the refusal of a MA because the candidate VMP is a PBT/vPvB. There are, however, a couple of caveats. The first is that this applies only for VMPs intended for use in food-producing animals, implying PBT/vPvB VMPs will be authorised in pets as before. The second is that PBT/vPvB VMPs can be authorised for production animals if it is “essential to prevent or control a serious risk to animal health”. A definition of “serious risk” has not been provided.

These are the headline changes in the legally binding aspects of ERA legislation. Additionally, Regulation EU 2019/06 contains some notable recitals, which, although not legally binding, can be interpreted as a statement of intent from the EU and may signpost the direction of travel for future legislation. The recommendation that any VMP posing a severe environmental risk be subjected to monitoring (Recital 32) could feasibly be delivered through the Water Framework Directive (2008/105/EC) by inclusion on the surface water watch list. Or the list of priority substances, which facilitates the setting of environmental standards and addresses emissions from manufacturing (Directive 2010/75/EU). Adverse event reporting is also encouraged, where elevated concentrations of the VMP in soil or water are identified (Recital 56).

Fipronil: a case study and a cautionary tale

In their review of the ERAs of centrally authorised VMPs undertaken between 2005 and October 2019 (n=109, with 200 authorised before 2005), Fabrega and Carapeto¹ found that 95% were considered sufficiently low risk to have terminated the ERA at the end of Phase I. This included the 65 that were intended for companion animal use only. Of the five VPMs that underwent Phase I and Phase II processes, two were identified potentially PBT. One

product, eprinomectin, an antiparasitic treatment in cattle, was refused MA in 2018 due to environmental concerns. A further two have had their MA withdrawn for the same reason: zinc oxide in pigs and tylosin in calves, pigs, turkeys, and chickens, after being subjects of a referral procedure. If this data from centrally authorised procedures can be extrapolated to VMPs that have received MA through other routes, then it could be surmised that the number of VMPs subjected to the higher tier environmental risk assessment is low. This may be justified, but the systematic audit of the ERA process itself is lacking, so it is difficult to tell.

Fipronil is an insecticide widely used in agriculture as a crop pesticide and VMP to treat external parasites in companion animals. Fipronil has been identified as toxic to honey bees, having been implicated as a causative agent in a mass mortality event in France in the mid-nineties.¹²

As a result, it has not been used in the agricultural sector in the UK since 2015,¹³ and the EU regulatory body revoked its authorisation for use as a plant protector in 2017 (Commission Regulation [EU] 2019/ 1792). Nevertheless, fipronil is still extensively used in cats and dogs to treat fleas and ticks. Furthermore, in the UK and elsewhere, it is available without a prescription. In 2020, there were 66 authorised products containing fipronil in the UK.¹³

Perkins et al.,¹³ using data obtained from 20 English freshwater rivers between 2016 and 2018, found fipronil residues at all 20 sites, and that 16 of these had mean concentrations exceeding the chronic toxicity limit, with a further six sites having mean concentrations that exceeded the acute toxicity limit. The calculated risk quotients indicated a high risk to aquatic ecosystems. Given that agricultural use had all but ceased, the authors claimed this was evidence of companion animal VMPs entering the waterways via household drains and called for a change in the regulations that govern the ERA of companion animal parasiticide products.

This evidence gives rise to several questions about the effectiveness of ERAs. Is the assumption embedded in VICH GL 6 that VMPs used to treat companion animals are at low risk of environmental exposure erroneous? With this derogation, pets' VMPs never undergo higher-level environmental testing and are never screened for PBT/vPvB status. The rationale for this assumption states that high-risk emission of

The inferior quality of older ERAs and the lack of a systematic “catch up” mechanism for updating them is a recognized weakness of the current legislation.

non-food animal VMPs is less likely because there is less of the “total amount of product used”.⁷ However, there are estimated to be 85.2 million dogs and 103.8 million cats in Europe, compared with 87 million bovines and 98 million small ruminants.¹⁴ The logic of this assumption is open to challenge, particularly when the VMP is accessible without a prescription, which probably increases its use substantially. Incidentally, there is a provision in Regulation (EU) 2019/06 to restrict the prescribing practice of off-licence VMPs in aquaculture (Article 114.3) for environmental reasons.

The EMA has acknowledged the emerging evidence regarding the use of parasiticides in companion animals and is in the process of preparing a reflection paper on the issue.¹⁴ Nonetheless, this demonstrates how, as knowledge gaps are closed, insufficiencies in the current veterinary ERA framework are unveiled.

Veterinary ERAs and medical writing

There is no doubt that environmental issues are front and centre in the public discourse. Ecotoxicity caused by human and animal pharmaceutical products is a subject of public interest, as evidenced by the fact that the paper by Perkins et al. has been reported in the mainstream media.¹⁵ This has resulted in a debate on social media platforms amongst both lay and professional groups. Robust communications criticising the current VMP ERA framework have been published in the veterinary press¹⁶ and documents produced in their defence.¹⁷ This ongoing controversy belies an unmet need for stakeholders to sit down and determine what protection society wants from ERAs, not just for pet flea products but all pharmaceuticals. There is also criticism of the tension between commercial confidentiality and accessibility of the information contained in ERAs, with confidentiality currently taking precedence.¹⁸ Veterinary ERAs are no longer a niche concern and will require biomedical communication services beyond the regulatory writing domain. For medical writers and communicators wishing to learn about human and veterinary ERAs, this article is the first of a series in *The Crofter* that will take an in-depth look at ERAs. A webinar on ERAs for EMWA members is also coming soon.

Disclaimers

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

Conflicts of interest

The author declares no conflicts of interest.

References

1. Fabrega J, Carapeto R. Regulatory review of the environmental risk assessment of veterinary medicinal products in the European Union, with particular focus on the centralised authorisation procedure. *Environ Sci Eur.* 2020;32(1). <https://doi.org/10.1186/s12302-020-00374-x>
2. Lyons G. Pharmaceuticals in the environment: A growing threat to our tap water and wildlife. *CHEM Trust.* 2014;December:31.
3. Domingo-Echaburu S, Lertxundi U, Boxall ABA, Orive G. Environmental contamination by pet pharmaceuticals: A hidden problem. *Sci Total Environ.* 2021;788:147827. <https://doi.org/10.1016/j.scitotenv.2021.147827>
4. Sebestyen I, Monostory K, Hirka G. Environmental risk assessment of human and veterinary medicinal products – challenges and ways of improvement. *Microchem Journal.* 2018;136:67–70. <https://doi.org/10.1016/j.microc.2017.08.012>
5. Environmental Risk Assessment. European Medicines Agency. Available from: <https://www.ema.europa.eu/en/glossary/environmental-risk-assessment>
6. de la Casa-Resino I, Haro Castuera A, Casimiro Elena R, Rubio Montejano C, Carapeto García R. European legislation for veterinary medicines: Would a monograph system improve the environmental risk assessment? *Integr Environ Assess Manag.* 2021;00(00):1–12. <https://doi.org/10.1002/ieam.4431>
7. VICH GL 6 (Ecotoxicity Phase I) Guideline on Environmental Impact Assessment for Veterinary Medicinal Products Phase I (CVMP/VICH/592/1998).EMA; 2000.
8. Schmitt H, Boucard T, Garric J, et al. Recommendations on the environmental risk assessment of pharmaceuticals: Effect characterization. *Integr Environ Assess Manag.* 2010;6(SUPPL. 1):588-602. https://doi.org/10.1897/ieam_2009-053.1
9. VICH GL 38 (ecotoxicity phase II). EMA; 2004;(October 2005):0-9.
10. Guideline on the Assessment of Persistent, Bioaccumulative and Toxic (PBT) or Very Persistent and Very Bioaccumulative Substances in Veterinary Medicinal Products (EMA/CVMP/ERA/52740/2012). EMA;2015.
11. Krause C, Uegaki K. Impact of the European Green Deal on the healthcare industry. *Med Writ.* 2021;30(2):114-120.
12. Holder PJ, Jones A, Tyler CR, Cresswell JE. Fipronil pesticide as a suspect in historical mass mortalities of honey bees. *Proc Natl Acad Sci USA.* 2018;115(51):13033–38. <https://doi.org/10.1073/pnas.1804934115>
13. Perkins R, Whitehead M, Civil W, Goulson D. Potential role of veterinary flea products in widespread pesticide contamination of English rivers. *Sci Total Environ.* 2021;755:143560. <https://doi.org/10.1016/j.scitotenv.2020.143560>
14. Concept paper for the development of a reflection paper on the environmental risk assessment for parasiticide veterinary medicinal products used in companion animals (CVMP/ERA/55512/2020); 2020.
15. Carrington D. Pet flea treatments poisoning rivers across England, scientists find. *The Guardian.* Available from: <https://www.theguardian.com/environment/2020/nov/17/pet-flea-treatments-poisoning-rivers-across-england-scientists-find>
16. Little CJL, Boxall ABA. Environmental pollution from pet parasiticides. *Vet Rec.* 2020;186(3):97. doi:10.1136/vr.m110
17. Q&A: Parasite treatment for pets; veterinary medicines and the environment. National Office for Animal Health. Available <https://www.noah.co.uk/focus-areas/anti-parasitics-for-animals/q-veterinary-medicines-environment/>
18. Oelkers K. The accessibility of data on environmental risk assessment of pharmaceuticals – are environmental risk assessments information on emissions with respect to international and European environmental information law? *Regul Toxicol Pharmacol.* 2020;111:104571. doi:10.1016/j.yrtph.2019.104571



Distributed manufacturing and other factors in building a sustainable vaccine industry

Introduction

At the Research Quality Association (RQA), 14 attendees came together to discuss distributed manufacturing on May 4, 2021. A *Trends in Biotechnology* article called “Build a Sustainable Vaccines Industry with Synthetic Biology” provided the basis of discussion. Centralised manufacturing commonly practiced by the pharmaceutical industry is challenging as it uses extensive supply chains. These supply chains are risk laden during transport of sensitive medicines in remote locations. Participants were industry quality management professionals. To raise more awareness of distributed manufacturing a similar meeting was held by the European Medical Writers Association (EMWA) Veterinary Special Interest Group (vetSIG) on July 30, 2021. The participants were medical writers and communicators. An observer report was written after the meeting. A link to the observer report is available at the EMWA vetSIG homepage @

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https://www.emwa.org/media/3936/vetsig-q3-meeting-july-30th-observer-report-with-slides-_.pdf.

The aim of this article is to further build awareness in the EMWA community of the role of distributed manufacturing and other considerations in building a sustainable vaccines industry, and opportunities for medical writers and communicators. The article integrates key points from two previously published articles, “Distributed Manufacturing of Accessible Treatments” and “Build a Sustainable Vaccines Industry with Synthetic Biology – a Summary.”^{1,2,3}

In the news

The Telegraph published an article on June 1, 2021 saying:⁴

- “Roughly 75% of the 1.8 billion vaccine doses administered worldwide have gone to just 10 countries.”
- “Nations including Madagascar, South Sudan, and Papua New Guinea have vaccinated less than 0.01% of their population.”
- “WHO chief Dr Tedros Adhanom Ghebreyesus alongside the heads of three other UN bodies, said a “two-track pan-

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Roughly 75% of the 1.8 billion vaccine doses administered worldwide have gone to just 10 countries.

demical” was developing “with richer countries having access and poorer ones being left behind”.

On August 18, 2021, the WHO Director-General Dr Tedros Adhanom Ghebreyesus, explained that he asked for a “temporary moratorium on boosters to help shift supply to those countries that have not even been able to vaccinate their health workers.” In his opening statement he highlighted:⁵

- “Just 10 countries have administered 75% of all vaccine supply and low-income countries have vaccinated barely 2% of their people. I called for a temporary moratorium on boosters to help shift supply to those countries that have not even been able to vaccinate their health workers and at-risk communities and are now experiencing major spikes.”
- “Vaccine injustice is a shame on all humanity and if we don’t tackle it together, we will prolong the acute stage of this pandemic for years when it could be over in a matter of months. When G20 health ministers meet on

the 5th and 6th of September in Rome, I will call on them to consider the fragility of this historic moment and make a clear defining commitment to solidarity.”

There is pressure for a COVID-19 vaccine to be available for everyone on the planet.

The vaccine production model needs to change

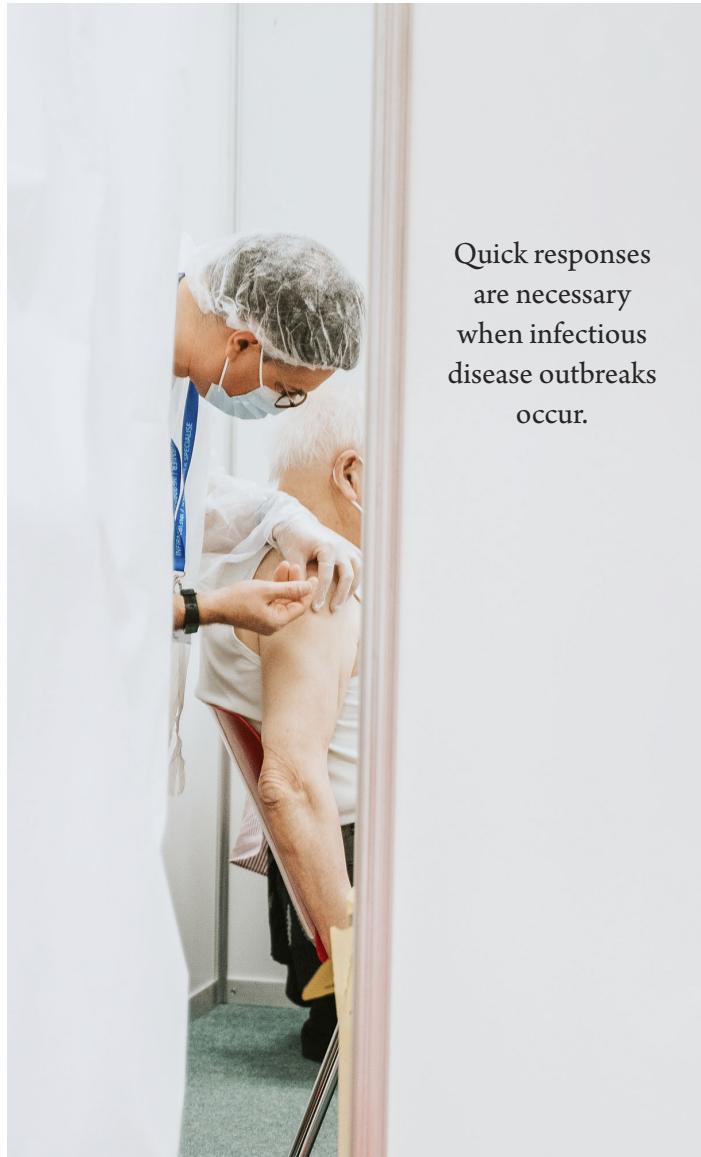
The vaccine industry has been in a difficult situation for a long time. Spending on vaccines is insignificant compared to other interventions. Five multinationals produce 80% of vaccines. There are poor financial returns to the vaccine industry and high production and R&D costs. Manufacturing facilities are capital intensive. Lower-income countries buy vaccines when they are more affordable. Before that, manufacturing costs are covered by vaccine sales in high-income countries.

Distributed manufacturing, a more sustainable vaccine model

Traditional centralised vaccine production supply chains do not have complete geographical coverage. In 2015 distributed manufacturing was in the World Economic Forum top 10 emerging technologies. Distributed manufacturing complements centralised vaccine production and would ensure vaccine production is close to the final customer. Much of the material supply chain is replaced by information.

The distributed manufacturing idea overcomes supply chain issues. All required information is electronically transmitted directly to local manufacturing sites. In theory, distributed manufacturing could enable regions to access treatments for themselves. Underserved communities are often thought of as existing in low- and middle-income countries, but they exist in high-income countries too.

The pharmaceutical industry has a wealth of knowledge and experience. It started immense efforts to manufacture and distribute medicine to over 8 billion people. This distributed manufacturing idea complements pharmaceutical



Quick responses are necessary when infectious disease outbreaks occur.

industry efforts. It is an idea that requires thought and collaboration from lots of people. Constructive, transferrable, and innovative ideas are needed as the model has its own challenges.

Pharmaceutical and medical device areas which should be considered include various operations, GxPs, and regulations. (GxP is a collective acronym for industry standards like Good Manufacturing Practice, Good Distribution Practice, Good Clinical Practice and more.) Some other considerations include angel investors, accreditation, AI, biofoundries, business ecosystems, chemicals, clinics, communication, computing, consumables, crowd funding, culture, digital biology, documents, economics, engineering biology, environment, epidemiology, equipment, ethics, franchises, information technology, law, logistics, machine learning, medicine, mobile labs, mobile manufacturing,

monitoring, policy, politics, prediction, records, reagents, regulation, revitalisation, robotics, small scale manufacturing, society, standardisation, supplies, sustainability, synthetic biology, university hospitals, and writing.

In time, community manufacturing sites could result in business ecosystems. This would bring more opportunities to those locations. A broader range of biotechnology products could be manufactured. For example, medicines for a variety of conditions or enhancement of crops for growth under difficult environmental conditions.⁶

Other considerations

Downstream of synthetic biology

Small volumes of mRNA vaccines can produce a large number of vaccine doses. A smaller facility footprint would benefit from single-use disposable culture systems. These systems reduce fixed costs dramatically and can be established more quickly than hard-pipe facilities. Many chemical engineering tools for bioprocess intensification are already available.

Robustness, standardisation, and quality

Process standardisation and robustness are essential to guarantee the safety, efficacy, quality,

and consistency of product. Environment, equipment, reagent, and operator skill variations influence robustness. Standardising and measuring influences show compliance with manufacturing limits documented in regulatory dossiers. Automation will make processes at each manufacturing site more comparable.

Safe-by-Design synthetic biology will incorporate robustness into the automated engineering cycle. Safe-by-Design is consistent with pharmaceutical industry Quality-by-Design outlined by the US FDA.

Data format standards include Synthetic Biology Open Language (SBOL)⁷ and Digital Imaging and Communications in Medicine-Synthetic Biology (DICOM-SB).^{8,9}

Responsive regulation

National regulatory authorities need to be

flexible. They need to follow the evolving science to develop regulatory requirements.

Distributed manufacturing of vaccines needs greater regulatory harmonisation between countries. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is a global standard harmonisation resource.

The “WHO Global Benchmarking Tool for Evaluation of National Regulatory System of Medical Products” helps guide countries on what to do to register medicines to treat their population.^{10,11} The global benchmarking tool points out that there are established guidelines that national regulatory authorities need to follow to approve medicines for use. They include:

- “Critical requirements need to be reviewed ... For example, label indication, mode of usage or application, storage conditions, and Good Manufacturing Practice certificates and reports.
- “Information ... should be documented and monitored. For example, location of deployment, quantities to be deployed, and identity of persons to receive and manage deployment.”

In 2017, only 30% of WHO member country national regulatory authorities could regulate their own medical products.¹² WHO has 194 member states.

Sustainability

A large number of countries could conduct final manufacturing in small facilities. This would give global coverage and bring manufacturing closer to the point of need. The United Nations Sustainable Development Goals make explicit reference to the need for affordable vaccines. There is evidence that the pharmaceutical industry is more emissions intensive than the automotive industry. Information transfer, instead of material transport, saves money and emissions, lowers risk due to cold chain failures, and speeds innovation.¹³

Vigilance

Since 2000 several human viral disease outbreaks have occurred. We have been unprepared for all of them. For each outbreak, money became available. Then money disappeared when the immediate danger subsided. Quick responses are necessary when infectious disease outbreaks occur. Electronic real-time tracking and predictive tools help public health decision making.

Challenges

Distributed manufacturing raises questions about challenges. For example:

- What is economic viability like? What happens during periods of low demand?
 - There are opportunities in biomolecules and biosystems innovation – perhaps \$500 billion to \$1.2 trillion worth of opportunities.
 - Biofoundries support in vitro and in silico toxicology testing.
- How are cyber-attacks prevented?
 - Blockchain technology is the obvious solution to enhance cyberbiosecurity.
- How can talent and education systems be developed?
 - Biologists need greater knowledge of computer science and IT systems and vice versa.

Outstanding questions

- What technical barriers exist to getting mRNA vaccines to the marketplace?
- How feasible is vaccine production in very small production plants?
- What biofoundry key attributes are needed for this model?
- Realistically, is this model economically viable?

See the answers to these questions in “Build a Sustainable Vaccines Industry with Synthetic Biology”: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7834237/>

Immediately apparent public policy issues

Distributed manufacturing of vaccines has an immature infrastructure that needs focused development. Several key technologies need to be integrated:

- Predictive epidemiology tools
- Real-time tracking of the evolution and spread of a virus in an open access platform
- Rapid detection of mutants
- Technologies like RNA printing
- Responsive regulation
- Cyberbiosecurity like Blockchain solutions
- Talent and education to create a workforce.

The University of Cambridge estimates an “optimistic loss” to the global economy due to COVID-19 of \$3.3 trillion and, in the worst case, a loss of \$ 82 trillion over 5 years.¹⁴ The World Economic Forum predicted \$1 trillion of damage

to global tourism in 2020 alone. The World Bank predicted that 150 million more people would enter extreme poverty by 2021 as a result of COVID-19.¹⁵

Spending on a solution to enable the world to respond quickly in the future will not seem expensive in comparison.

Please take this idea, make it your own and share it

Distributed manufacturing provides lots of writing opportunities. There are opportunities to share the distributed manufacturing idea with communities who might be interested in getting involved. As well as that, there are opportunities to turn documents already developed within the medical writing and communication spectrum towards distributed manufacturing, i.e., making document templates that already exist fit-for-purpose for distributed manufacturing.

“Build a Sustainable Vaccines Industry with Synthetic Biology” was published online in January 2021. Please read the paper: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7834237/>

The Global Biofoundries Alliance (GBA)¹⁶ is based at Imperial College London.¹⁷ It is a network of institutions that share knowledge, infrastructure and expertise. The GBA objectives are to:

- “Develop, promote, and support non-commercial biofoundries established around the world.”
- “Intensify collaboration and communication among biofoundries.”
- “Collectively develop responses to technological, operational, and other types of common challenges.”
- “Enhance visibility, impact and sustainability of non-commercial biofoundries.”
- “Explore globally relevant and societally impactful grand challenge collaborative projects.”

If you are interested in getting involved with biofoundries, message the GBA directly. Here is a link to their contact page:

<https://biofoundries.org/contact>

RNA technology experts are in university molecular biology departments. Look at the GBA members list and consider expanding the alliance to include your chosen university: <https://biofoundries.org/members>

The University of Cambridge estimates an “optimistic loss” to the global economy of \$ 3.3 trillion due to COVID-19, and in the worst case, a loss of \$82 trillion over 5 years.

The Research Quality Association (RQA) is dedicated to informing and advancing its members.¹⁸ They provide status and visibility for individuals concerned with the quality of research and development concerning pharmaceuticals, agrochemicals, chemicals and medical devices. Since its inception in 1977, the RQA has grown and developed to reflect regulatory changes, the impact of regulatory inspection and the changing structure and needs of industry. The RQA has set up a special interest group to work through the aforementioned challenges. There is a great depth of skills and knowledge that can take this idea forward. If you are interested in joining and participating in this group, please contact: info@therqa.com

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The author declares no conflicts of interest.

References

1. Bell J. Distributed manufacturing of accessible treatments. *Quasar*. 2021;156:12.
2. Bell J. Build a sustainable vaccines industry with synthetic biology – a summary. *Quasar*. 2021;156:28-31.
3. Kitney RI, Bell J, Philp J. Build a sustainable vaccines industry with synthetic biology. *Trends in Biotechnology*. 2021 [cited 2021 Aug 30]. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7834237/>
4. The Telegraph. Vaccinating the world: the obstacles hindering global rollout – and how to overcome them. 2021 [cited 2021 Aug 30]. Available from:

<https://www.telegraph.co.uk/global-health/science-and-disease/vaccinating-the-world/>

5. World Health Organization. WHO Director-General's opening remarks at the media briefing on COVID-19 - 18 August 2021. 2021 [cited 2021 Aug 24]. Available from: <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---18-august-2021>
6. Bell J, Philp J, Kitney RI. Addressing the post-covid era through engineering biology. *Engineering Biology*. 2021;5:21-34 [cited 2021 Aug 30]. Available from: <https://ietresearch.onlinelibrary.wiley.com/doi/full/10.1049/enb2.12008>
7. Synthetic Biology Open Language (SBOL) homepage. 2021 [cited 2021 Aug 30]. Available from: <https://sbolstandard.org/>
8. Digital Imaging and Communications in Medicine (DICOM) homepage. 2021 [cited 2021 Aug 30]. Available from: www.dicomstandard.org/
9. Sainz de Murieta I, Bultelle M, Kitney RI. Toward the first data acquisition standard in synthetic biology. *ACS Synthetic Biology*. 2016;5(8):817-826 [cited 2021 Aug 30]. Available from: <https://doi.org/10.1021/acssynbio.5b00222>
10. World Health Organization. WHO Global Benchmarking Tool (GBT) for Evaluation of National Regulatory System of Medical Products - Revision VI. 2021 [cited 2021 Aug 30]. Available from: <https://www.who.int/publications/i/item/9789240020245>
11. Broojerdi AK, Sillo HB, Dehaghi ROA, et al. The World Health Organization Global Benchmarking Tool an instrument to strengthen medical products regulation and promote universal health coverage. *Frontiers in Medicine*. 2020;7(467):1-7 [cited 2021 Aug 30]. Available from: <https://www.frontiersin.org/articles/10.3389/fmed.2020.00457/full>
12. World Health Organization. WHO Essential Medicines & Health Products Annual Report 2017 - Towards Access 2030. 2017 [cited 2021 Aug 30]. Available from: <https://apps.who.int/iris/handle/10665/272972>
13. Bell J. A black box: improving quality control risk management in biopharmaceutical transportation. *Quasar*. 2019;148:8-11. Available from: <https://www.therqa.com/>
14. World Economic Forum. \$82 trillion over 5 years? Cambridge study counts the cost of coronavirus. 2021 [cited 2021 Aug 24]. Available from: <https://www.weforum.org/agenda/2020/05/coronavirus-covid19-pandemic-economy-money-depression-recession/>
15. The World Bank. COVID-19 to add as many as 150 million extreme poor by 2021. 2020 [cited 2021 Aug 24]. Available from: <https://www.worldbank.org/en/news/press-release/2020/10/07/covid-19-to-add-as-many-as-150-million-extreme-poor-by-2021>
16. Global Biofoundries Alliance homepage. 2021 [cited 2021 Aug 30]. Available from: <https://biofoundries.org/>
17. Scheuber A. Imperial [College London] social enterprise to accelerate low-cost covid-19 vaccine. 2020 [cited 2021 Aug 30]. Available from: www.imperial.ac.uk/news/198053/imperial-social-enterprise-accelerate-low-cost-covid-19/#authorbox
18. Research Quality Association homepage. 2021 [cited 2021 Aug 30]. Available from: <https://www.therqa.com/>

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Jennifer Bell outlines Distributed Manufacturing meetings she held at the RQA and EMWA. She also summarises "Build a Sustainable Vaccines Industry with Synthetic Biology" which is located here: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7834237/>. Currently a freelance medical writer, she worked in quality management roles in medical device and pharmaceutical manufacturing and clinical trial sectors from 2010 to 2018. She holds a PhD in molecular microbiology and an MSc in pharmaceutical manufacturing technology.



News and Notes from the World of Medical Writing

The 3rd Philippine Association of Medical Journal Editors Annual Convention opens with AMWA-EMWA-ISMPP Joint Position Statement on Medical Publications, Preprints, and Peer Review

The Philippine Association of Medical Journal Editors, Inc. (PAMJE) held its 3rd Annual Convention on September 20-23, 2021, with the theme, "Upholding Research Integrity in the Time of Pandemic." The virtual event was attended by 392 participants from all over the country and some participants from Singapore, Australia, USA, Canada, and Switzerland. The conference held six scientific sessions, discussing the importance of research integrity amidst the infodemic that accompanied the COVID-19 outbreak.

The plenary session opened with the AMWA-EMWA-ISMPP Joint Position Statement on Medical Publications, Pre-prints, and Peer Review discussed by Dr. Dikran Toroser, Director of Publication Planning at Takeda. He was joined by Dr Art Gertel, Principal

Consultant of MedSciCom, LLC (and an active EMWA and AMWA member); Dr Peter L Munk, Professor of Radiology, Orthopedics and Palliative Care at the University of British Columbia, and Dr Nicholas Talley, Laureate Professor and Editor-In-Chief of the Medical Journal of Australia, as panelists. Issues on the challenges of increased use of pre-prints and increased pressure to accelerate publication due to the urgency to disseminate information during the pandemic were discussed. The sudden surge of COVID data has also brought about the infodemic and its rampant misuse and misinterpretation in social media.

The convention also addressed the importance of maintaining image integrity to counter fabrication, falsification, and image manipulation in scientific publications. A review

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of the updated guideline Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2020), and the correct way of doing a systematic review were also presented. Other important topics discussed were the impact of the infodemic on healthcare in the Philippines (especially in the fight against COVID-19) and the Philippine Action Plan for Plan S Initiative for open access publishing.

The full virtual event can be viewed in PAMJE's Facebook page:
<https://www.facebook.com/PAMJE2011>.

The Oxford Climate Journalism Network

Created to support journalists interested in covering climate change and aiming to rethink how journalism and the news media approach one of the most pressing issues of our time, the Oxford Climate Journalism Network¹ is a new project from the Reuters Institute for the Study of Journalism at the University of Oxford.

The network is open to all working journalists, with the aim of helping them to develop their coverage of climate change through their offering of online courses, leadership programmes, journalist fellowships, and original academic research. Their first online course will start in January 2022, although the deadline for enrolling will already have passed by the time you are reading this. Nonetheless, there are more resources on the network's "about page",² such as links to podcast episodes, books, and online articles.

Even if you're not a journalist, I think this project may expand to other areas in the future, as climate and health continue to overlap. Besides, it is always good to know more about climate change and how to better communicate its challenges. As stated by The Lancet,³ "*climate change is the greatest global health threat facing the world in the 21st century, but it is also the greatest opportunity to redefine the social and environmental determinants of health.*"

References

1. The Oxford Climate Journalism Network. Reuters Institute for the Study of Journalism [cited 2021 Oct 30]. Available from: <https://reutersinstitute.politics.ox.ac.uk/oxford-climate-journalism-network>
2. Oxford Climate Journalism Network. Reuters Institute for the Study of Journalism

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- [cited 2021 Oct 30]. Available from:
<https://reutersinstitute.politics.ox.ac.uk/about-the-oxford-climate-journalism-network>
3. Romanello M, McGushin A, Di Napoli C, et al. The 2021 report of the Lancet Countdown on health and climate change: code red for a healthy future. The Lancet 2021 Oct;398(10311):1619-62.

A version of this text first appeared in the author's weekly newsletter, to which you can subscribe at
<https://dianaribeiro.com/newsletter/>



Out On Our Own

Editorial

We have finally reached an era where talking about our mental health is no longer a taboo, it's just taken a pandemic for us to do so! Life has dramatically changed in the last 18 months and mental stressors are even more apparent. Many of these stressors have long been affecting the self-employed and freelancers, even before the pandemic, but as more mental health campaigns are now available, people can recognise these stressors, find the essential resources that are out there, and seek help if needed.

The two authors below approached me to

write this article, and I'm so honoured they did. It summarises poignantly mental health and freelancing. Shaun Foley, a previous OOOO author, is a freelance medical writer and can relate to many of the stressors that plague the freelance. He paired up with Matthew Knight, who set up a valuable association called Leapers to offer support and mental health advice to the self-employed and freelancers. Here, Shaun talks us through the typical stressors that we come across (go through his sources of stress and see how many relate to you). If some of them tick a few boxes, then continue to follow Matthew's top 5 recommendations that he and his team

have put together to help you check in on your mental health and suggest subtle changes that can make a big difference.

Ultimately, as a freelancer, you are not alone. Reach out to other freelancers if you're feeling overwhelmed. Join networks to meet other freelancers. Follow the advice given on these valuable resource pages for mental health. As Matthew writes "You are your business' most important asset", so put yourself first.

Stay mentally and physically safe.

Laura A Kehoe, PhD

Supporting mental health for freelancers in med comms

Stress in medical communications

Agency life in medical communications is brilliant, exciting, and rewarding, although undoubtedly busy and fast-paced, and at times can be stressful. Not all stress is bad – positive stress can help us be more focused, productive, and alert, and get things done – but consistent or excessive stress is damaging, and lots of small things can easily add up to create a feeling of being overwhelmed or unable to act.

Within medical communications, causes of stress manifest from many directions. Some of the many causes of stress in medical communications include upcoming deadlines (e.g., for publications or congresses, both planned and last minute), pressure from our clients, long working hours while on-site, employee conflict and retention, business development and retaining accounts, juggling paid and non-paid (volunteer) work, or generally just being over-worked.

I searched on Google for "stress" AND "medical communications" and found very little information on how to manage stress in our industry. Recently, many medical communications agencies have identified this issue and

Given these challenges, it's important to know what you can do to manage your own mental health when self-employed.

implemented a number of excellent measures to help safeguard the mental and physical health of their employees when work becomes stressful.

But, who do the self-employed turn to when they are stressed or when they're looking for support? After all, they don't have a manager, HR department, or team to help them.

Stress and mental health as a freelance medical writer

Many medical communicators leave agency life and transition to freelance to regain greater control over their work-life balance and enjoy the flexibility that freelancing suggests. Indeed, there are many attractions to freelancing. When I first

started as a freelance medical writer I thought that, as my own boss, I can manage my own working hours, and take time out in the day to exercise and meet friends for lunch – which are all hugely positive for mental health and wellbeing. A report by The Association of Independent Professionals and the Self-Employed (IPSE) found that "almost half of freelancers (48%) stated that transitioning to self-employment had a very positive effect on their mental health with a further third (32%) stating it

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had an at least somewhat positive effect".¹

Freelancing, however, can also be emotionally demanding and is not without its challenges. In the same report by IPSE, 53% of respondents stated that finding work had a negative impact on their mental health and they struggle with the irregularity of income that comes with self-employment.¹ As a freelancer in medical communications, stress can be caused by any number of avenues (Box 1).

These stress triggers, if not carefully managed, can even lead to common mental health disorders, such as depression and anxiety. IPSE reported that "as a result of job-related stress almost half [of respondents] had felt less productive (48%), depressed or anxious (48%), or lost sleep over worry (47%). There were also 46 per cent of respondents who had experienced a lack of confidence or reduced energy levels".¹

Box 1. Sources of stress as a freelancer in medical communications

Workload

- When will I get work again?
- Why is everybody else so busy?
- How will I find time to finish all of the work that I have?
- How long can I keep up with this pace without burning out?
- How do I find time to continue to develop as a writer and deliver projects?

Finances

- Do I have enough work to cover my bills?
- How do I find the money to cover my tax bill?
- How will I afford to contribute to my pension and future?
- If I burnout, how will I cover all my financial commitments?

Work-life balance

- How do I find the time to work, exercise, and see family and friends?
- I feel unable to switch off from work
- I need a break, but if I take a holiday will the work be there when I return?
- How do I fit non-paid voluntary work into my schedule when I'm overwhelmed with paid work?

COVID-19

- How do I manage my work commitments as well as disruption to childcare/schooling?
- I feel isolated and lonely working from home as a freelancer
- My workload has changed as result of COVID-19 (e.g., cancellation of scientific congresses, shifting of planned projects)
- I worry about exposure to COVID-19 while attending meetings or meeting clients

Reliance on others

- A long-time client has moved roles and I'm worried about whether I will continue to receive work
- My client has lost an account and it has affected my workload
- I worry about not having access to statutory employment benefits (sick pay, holidays)



Leapers: the lifeline for freelancers

Given these challenges, it's important to know what you can do to manage your own mental health when self-employed. Leapers is a free and open community which supports the mental health of the self-employed. In the past 4 years, we've helped over 70,000 people who work for themselves, playing the role of a team for people without a team. Our community is a safe place to chat with fellow freelancers, make a cuppa, celebrate your little wins, ask questions to get advice, and share how you're feeling with others. We take those conversations in the community and curate them into resources and guides to support others, and signpost to valuable and effective tools we've found elsewhere, as well as working with employers to help them understand how they can support their freelancers better.

Both from our own annual research, and within the conversations in our community, we see a wide range of issues, concerns and influences that the self-employed face every day, so we've gathered our five top recommendations and resources to help. Of course, these are also available in full at <https://www.leapers.co/>, among other helpful resources for the self-employed.

1. Remember that you are your business' most important asset. If you aren't taking care of your own mental health, you're less able to do your best work. Even just taking 15 minutes a week to reflect back on what's been happening, how you've been feeling and anything which has impacted you and your work (negative or positive) will help. Keep this self-reflection in a journal, and it can really help you when you're looking back to find the common or recurring stressors, so you're more aware of your own wellbeing at work. Try setting a recurring calendar invitation for yourself, perhaps on a Friday afternoon, where you block out time to ask "How am I doing?" Use that time to also capture any consistent negative thoughts, feelings or little worries, so you can start to build up a picture of the things which you might want to tackle or change in how you work.

2. Working for yourself doesn't mean working by yourself. Find your tribe. There are dozens of fantastic communities for the self-employed and freelancers, spaces where you can chat with others, share how you're getting on, ask questions, look for advice, bounce ideas off each other, or just say good morning and make a cup of coffee. You can find sector-specific

communities (i.e., healthcare), capability-specific communities (i.e., writing) or generalised communities (i.e., freelancing). Even if you don't want to join a community, take the time to create your own support network, find fellow freelancers who understand the experience, people you turn to for specific types of questions, and even collaborators, so if you need to take a break, you've got folk who can step in to support you.

3. Rest and boundaries are really important. If there's something we've all learned over the last 18 months, it's the importance of and the difficulty in setting good boundaries between work and not work, which has been even harder if you're working from home. Establishing a time when you "switch off", routines to close down for the day, schedules of when you're not available, and consistent quality time off to rest is absolutely critical to recharge. Physical health is intertwined with mental health. That means remembering to focus on good food, good exercise, and good sleep to create a good foundation. But without rest, burnout is a risk to all of us. That said, even taking time off can cause stress, so find ways to plan time off, and clearly communicate to your clients or buddy up with a collaborator to cover whilst you're away. Even if you're not able to take the

If you're doing fine, see if you can support fellow freelancers who might need a helping hand. Helping others is another way of supporting your own mental health, as there are proven benefits in being there for others, too.

time off, which is a reality for many freelancers, try and ensure you're doing work which motivates you, so you're not burning out from work which doesn't align with your "why".

4. Communicate with your clients. From our research at Leapers, over half of the stressors come directly from working with others, whether it is dealing with late payments, poor client communication or behaviours, workload, or boundaries. Things will never get better unless we get better at communicating our needs and preference to those we're working with. Be clear on how you want to work, which times you're available, and anything else which is important to you, or you're seeing has a negative (or positive) effect on you. It's not about being difficult or demanding, but rather communicating how you and your client can do the very best work together.

5. Get proactive. Finally, but perhaps most importantly, don't wait until you're in crisis to seek support. Instead, start working on building up your support network and healthy working habits now, to try and avoid ever really needing to call upon them. However, if you are really struggling right now, mental health emergencies

are just as important as any emergency; you're not wasting anyone's time. Call emergency services if you don't feel safe or are at risk. If things are hard, but you don't feel at risk, speak to support groups confidentially and for free, 24 hours a day, or arrange a time to talk to your general physician. If you're doing fine, see if you can support fellow freelancers who might need a helping hand. Helping others is another way of supporting your own mental health, as there are proven benefits in being there for others, too. There are lots of amazing resources on general mental health provided by charities like Mind, or specific resources for the self-employed at leapers.co.

References

1. IPSE. The impact of the coronavirus crisis on freelancers' mental health. 2020 [cited DATE]. Available from: <https://www.ipse.co.uk/policy/research/the-impact-of-the-coronavirus-crisis.html>.

Disclaimers

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

Conflicts of interest

Shaun Foley is the proprietor of Biome Professionals and declares no disclosures or conflicts of interest.

Michael Knight is the proprietor of Leapers.co and declares no disclosures or conflict of interest.



Upcoming issues of **Medical Writing**



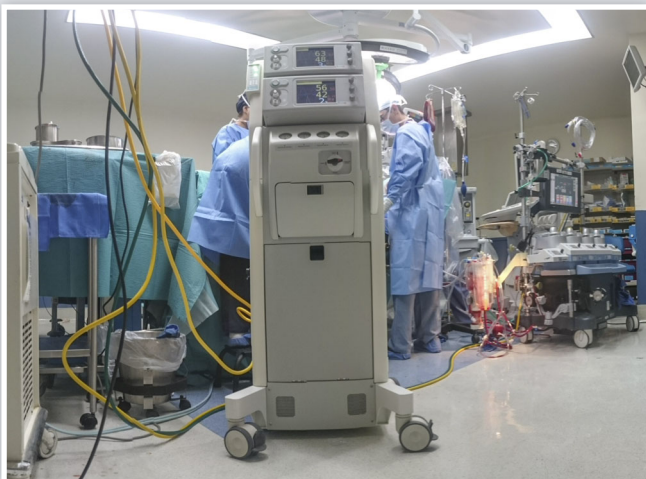
March 2022:

Sustainable communications

Sustainability is a key focus area across all economic sectors, including the pharmaceutical and healthcare industry. This issue will focus on where and how scientific and medical writing can contribute to current debates on scientific and environmental problems and their impact on human health. The issue will also cover emerging career opportunities for medical writers in this area.

Guest Editors: Surayya Taranum and Elisa Sala

The deadline for submitting feature articles has passed.



June 2022:

Medical devices

The implementation date of the EU Medical Device Regulation has arrived, marking a new era of heightened attention to medical device safety and performance. This issue will explore the experiences, challenges, and lessons learned over the last years preparing for the MDR requirements as well as potential opportunities these changes bring. Moreover, we touch base on the implementation of the EU In-Vitro Diagnostic Regulation and on other aspects of writing for medical devices.

Guest Editors: Kelly Goodwin Burri and Beatrix Doerr

The deadline for feature articles is March 1, 2022.



September 2022:

A virtual workforce

Working remotely/working from home has become the norm these days. This issue will focus on various aspects of working from home- the good, the bad, the ugly. We will have articles on the challenges of writing from home, managing teams and also, on how some of us overcome these challenges and enjoy this opportunity.

Guest Editor: Archana Nagarajan

The deadline for feature articles is June 1, 2022.

CONTACT US



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



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