Medical Writing

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Translation

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- Unleashing the power of computer-assisted translation tools
- Graphic medicine in veterinary communications
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EMWA — EUROPEAN MEDICAL WRITERS ASSOCIATION

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the European Medical
Writers Association
(EMWA). It is a quarterly
journal that publishes
articles on topics
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Medical Writing

Translation

"Translating highly technical and scientific concepts into a language that a non-specialised audience understands helps make information accessible and closes knowledge gaps."

Ana Sofia Correia, Claire Harmer

Cover: Cirsten Verleger/EMWA Creative Team.

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EMWA EUROPEAN MEDICAL WRITERS ASSOCIATION

Medical translation: A driving force behind equitable access to healthcare

Welcome to this *Medical Writing* issue on Translation, where we explore the transformative role of translation in advancing medical communications and improving access to healthcare. Represented by cogwheels in our cover visual, translation

is the intricate process of converting the written word from one language into another, enabling communication on a global scale.

But medical translation is about so much more than that, as we'll see in this issue.

Translation breaks down language barriers to enable knowledge sharing across countries and continents. In our first article, **Prado Antolino, Marina Persoglia Bell, and**

GUEST EDITOR

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Claire Harmer
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Vonessa Costa look at language access as a fundamental component of health equity.

The language we use has a big impact on how a message is received and plays a part in contributing towards health equity. Translating highly technical and scientific concepts into a language that a non-specialised audience understands helps make information accessible and closes knowledge gaps.

For this reason, among others, plain language has been a hot topic as of late, as demonstrated by the 56th EMWA conference last year. **Romina Marazzato Sparano** delineates five strategies for adapting technical content for lay audiences, offering practical guidance for writers seeking to convey complex medical concepts in a clear and engaging way. **Rachel Jenkins, Johanna Todd, and Olivia Alexander** offer a publisher's perspective on maximising patient engagement with Plain Language Summary of Publication articles (PLSPs) and strategies for enhancing the trustworthiness of medical publications among patient audiences.

One factor that contributes to building trust is the quality of the information we provide. Accuracy is paramount, and in medical translation, inaccuracies can have major implications. **Andrew Bell and Pedro Aguilar Torres** examine the use of computer-assisted translation tools and quality assurance measures specifically to translate medical reports, with a view to maximising accuracy; **Iain Matheson and Barbara Kollmer** provide insights from the language service provider (LSP) perspective, examining both human and automated approaches.

Another crucial aspect of providing quality translations is ensuring they are appropriate for their intended audience. This involves careful decisions on how to render cultural and linguistic nuances. **Karol Tapia de Moya** explores how translators navigate these aspects to adapt mental health tests beyond clinical research settings, and **Raluca Chereji** looks at the challenges of translating "medicalese" in informed consent forms.

In this issue, we also look at the role of translation in a product's path to market. **Emi Pell and Valerie Carlson** focus on the importance of translation in patient engagement, recruitment and retention in clinical trials through its ability to foster trust, ensure safety, and increase efficiency in diverse healthcare settings. **Karen M. Tkaczyk** delves into the intricacies of translating medical device documentation, taking account of the unique challenges posed by regulatory requirements, while **Ekaterina**

> Accuracy is paramount, and in medical translation, inaccuracies can have major implications.

Chashnikova tackles the challenges of localising promotional materials for pharmaceutical companies, offering insights into content creation, localisation strategies, and collaboration with medical writers.

And of course, we haven't forgotten the other hot topic and the theme of the forthcoming EMWA Symposium: artificial intelligence (AI). **Ann Marie Boulanger** examines translation technologies and the pros and cons of using neural machine translation and generative AI tools in medical translation, while **Helen Williams** reflects on the surge in AI and the challenges of integrating it into linguistic validation – a robust and highly regulated process designed to adapt Patient-Reported Outcome (PRO) measures for different cultures and languages.

> Another crucial aspect of providing quality translations is ensuring they are appropriate for their intended audience.

Should the translation workflow be 100% human or fully reliant on AI? Similarly, to the medical writing industry (and many others), the answer may lie in combining both. It comes down to the ethical use of every tool at our disposal, with "ethical" being the key word here.

Drawing from personal and institutional perspectives, **Angela Dickson**'s article navigates the complex terrain of ethical decision-making in medical translation, laying the groundwork for a code of ethics tailored to the unique challenges of the profession.

As editors of this issue, we extend our gratitude to the esteemed authors for their invaluable contributions. We also express our heartfelt thanks to the dedicated editorial team at *Medical Writing* for their efforts in making this themed issue possible, as well as regular section article authors for their contributions. We hope that this compilation serves as a testament to the power and potential of translation in propelling progress and promoting equitable access to health information to everyone, regardless of their native language and geographical location.

Ana and Claire

Author information

Ana Sofia Correia is an English to Portuguese medical translator and writer based in Portugal (www.anasofiacorreia.com). For the past 17 years, she has worked with life sciences companies, contract research organisations, language services providers, and medical communication agencies. After 12 years as an in-house translator at the Center for Social Studies of the University of Coimbra and the Nursing School of Coimbra, she became a full-time freelancer in 2019. In addition to her translation and writing services, she runs the Medical Translation Mentoring programme, a community-based mentorship program specifically designed for medical and life sciences translators.

Claire Harmer is a London-based medical translator and editor working from French and Spanish into English. She works with public health organisations, journals, medical communications agencies, and CROs to translate texts into accurate, clear and compelling English. Claire also works as a translation project manager for languages such as German, Russian, Italian, Dutch and Arabic. She has a Masters in Technical and Specialised Translation, focusing on medicine and pharmaceuticals, and is an active member of the Institute of Translation and Interpreting. Claire was EMWA Honorary Secretary from 2018–2020 and coordinates the Translation subgroup under the umbrella of the MedComms SIG.

The two most important keys on your keyboard

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 standarised 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)

EMWA NEEDS YOU

EMWA is a member-run organisation

When you volunteer to assist EMWA in any capacity, you are furthering the development of our association.

You can choose how you want to get involved: in a very limited way or as part of a larger project. The choice is yours, and everyone shares the benefits.

EMWA members can volunteer in the following areas:

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Special Interest Groups
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WHY VOLUNTEER?
- Help promote the role of medical writers and strengthen our association
- Help to raise standards in our field
- Increase your visibility and communication opportunities within the medical writing community
- Add some prestige to your CV
- Improve your knowledge of medical writing and related topics

TO FIND OUT MORE

If you are a member of EMWA and eager to support ongoing initiatives, please contact info@emwa.org.

From the Editor

On multilingualism and medical writing

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I arrived in Europe in September 1991 and was completely unprepared for the multilingualism of this continent. My first European home was the bilingual city of Brussels in the trilingual country of Belgium. Not quite the Tower of Babel but still overwhelming. Since then, I have lived in three more European countries and have observed how the EU grew and evolved. With growth came more diversity and yes – more languages.

27 member states and 24 official languages

The EU currently has 27 member states and 24 official ("*de jure*" = from the law)[1] languages. Why don't the numbers match?

Several national languages (Dutch, English, French, German, Greek, and Swedish) are shared by two or more countries in the EU. On the other hand, many member states have national and regional languages that are not included in the official EU 24.[2,3] The rules on EU languages are laid down in Regulation 1.[4]

Of the 24, only 3 (English, German, and French) are considered working languages. German is especially widely spoken across the union. It is an official *de jure* language in four countries (Austria, Belgium, Germany, and Luxembourg) and used as a *de facto* ("from the fact")[1] language in Denmark, Italy, and Poland. It is spoken by approximately 20% of the EU population.[3]

French ranks second, used officially in Belgium, France, and Luxembourg, and is a first language to about 14% of EU citizens.[3]

Only 2 of the 27 EU members claim English as their official tongue – Ireland and Malta – accounting for only 1% of the EU population.[3] Yet, the large majority of medical writing and communications activities in Europe are performed in English. Do you ever wonder why?

EMA policy on translations of medicines information

EMA Policy 0084 provides some insights on how the EMA deals with EU multilingualism with respect to dissemination of information on human and veterinary medicines.

The policy document clearly states that English is the EMA's primary working language. All technical information on the EMA website is in English. This is due to the fact that English is "*the language in which the pharmaceutical industry operates globally; as well as the only language in which a large part of the pharmaceutical-related terminology of the World Health Organization and the European Directorate for the Quality of Medicines of the Council of Europe is made available.*"[5]

EMA does not translate all technical information (i.e., those included in the Common Technical Document [CTD] modules). This "*reduces the genuine risks for misunderstandings and mistakes that could arise if highly technical information (and information subject to regular changes and revisions) were to be made available in all official EU languages.*"[5]

In this aspect, EMA rightly puts the promotion and protection of human and animal health in the EU over pure multilingualism.

EMA does translate documents for the patients and lay audience and all external communications with the public and the media. Certain key information relating to medicines is made available in all EU languages (plus Norwegian and Icelandic!*)[5] including:

- Product information and package leaflets for centrally authorised products
- Overviews in lay language of what these medicines are and why they are approved
- Q&As in lay language about refusals and withdrawals of applications
- Information about major reviews of human medicines, with EMA recommendations on issues such as safety concerns

> Only 2 of the 27 EU members claim English as their official tongue – Ireland and Malta – accounting for only 1% of the EU population.

Language requirements for medical and in vitro diagnostic devices

The European Commission released in January 2024 a guidance on languages corollary to the above EMA policy document to cover medical and in vitro diagnostic devices.[6] As in pharma, technical documentations are provided in English; all patient and public facing documents (e.g., IFU, implant cards) are translated into the EU 24, plus Norwegian, Icelandic – and even Turkish.*

Languages the world over

There are supposedly several hundreds of recognised languages globally. Many countries have more than one official language. India supposedly has 16, and South Africa, 11.[6]

Between 50 to 60 countries consider English as one of their *de jure* official languages.

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* Even though Iceland and Norway are not EU members, they are part of the European Economic Area (together with Lichtenstein) and follow the European medicines and medical devices regulatory framework. Turkey is fully recognised under the MDR and IVDR since 2022.

Interestingly, the US and Australia are not among them. In these countries, English is the *de facto* (not *de jure*) language.

Multilingualism is complex, yet beautiful. It comes with challenges and opportunities. This issue of *Medical Writing* spotlights multilingualism and the important role that medical translators play, not only in Europe but throughout the world.

Thank you to Claire Harmer and Ana Sofia Correia for putting this edition together. *Merci. Danke. Gracias. Grazie. Salamat.* I wish I could say it in many more ways!

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Valencia

2024 European Green Capital

This award recognises the city's achievements working toward inclusive sustainability for residents and visitors; including sustainable tourism and food production, climate neutrality, and ecosystem restoration.

and the host city of...

EMWA Spring **2024** 57th Conference 7th-11th May 2024

President's Message

See you in Valencia ...

Maria Kołtowska-Häggström
EMWA President 2023-'24
president@emwa.org

Dear EMWA Members, Friends, and Colleagues,

Time is flying and we just left the autumn conference and now are approaching our main EMWA event – the spring conference, to take place May 7– 11, 2024. This time we go to Valencia, and I am sure that no one needs to be encouraged to travel to this fantastic Spanish city. It is not just the destination that is attractive, but also a superb programme that both the conference and the EMWA Professional Development Programme (EPDP) Teams are working on. I do not want to disclose too much, as it is a work in progress, so just two headlines.

The first one I would like to mention is Expert Discussion Groups (EDG), the initiative that started last spring during the conference in Prague. It was created in 2023 by Jules Kovacevic, Laura Collada Ali, and the EPDP Team to address experienced medical writers and provide a platform for expert discussions on specific, advanced topics. The meetings of rather small groups (8-10 participants) are planned for 1.5 to 2 hours and the discussions are led by a carefully chosen moderator. The participants need to be professional medical writers for more than 10 years and have a special interest and experience in the current topic for discussion. The pilot EDG sessions were very much appreciated and attended. The 3 sessions were on wide ranging subjects from an initial discussion on artificial intelligence (AI) in medical writing, patient voice in medical publications, and authorisation pathways. This year, there will be up to 5 EDGs run on varied topics from the nuances of writing for rare diseases, and including master protocols lessons learned. Finally, I would like to underline that the EDG formula requires from all attendees preparation and their active contribution; a few thought-provoking questions to facilitate it are provided before the meeting and there are experience requirements set by the moderator to ensure the discussion is at a very high level.

The second headline is about the Expert Seminar Series (ESS), started by Sam Hamilton during her EMWA presidency in 2016. The idea was to provide experienced and senior medical writers with in-depth knowledge on key topics of importance. Over the years a number of very interesting seminars were presented and now an exciting selection is being prepared by the ESS Organizing Committee members – Tiziana von Bruchhausen, Eva-Maria Damsgaard-Nielsen, and Bente Riis – for the upcoming conference. This year for the first time, EMWA's Creative Team, led by Carola Krause, is organising an ESS on visual healthcare communications to explore the growing significance of visual aids in the medical field. We will also have a dedicated ESS session to address a truly hot topic, AI in medical writing. I am also going to mention one more ESS organised by a new Regulatory Special Interest Group (Reg SIG). It is devoted to non-clinical writing, quite a niche area of regulatory writing, and for sure will attract many experienced medical writers.

Speaking of the Reg SIG, you may remember that I planned to write about EMWA's new baby in the previous *Medical Writing* issue but my message became too long, so I had to skip it. Now, I am very happy to update you on this very active group, created just a few months ago as a continuation of the Regulatory Public Disclosure SIG. We at the Executive Committee felt that EMWA should have a SIG that covers much broader scope of regulatory aspects than just public disclosure; regulatory writing is such an important part of our professional engagements! Therefore, a general regulatory SIG was created with Sarah Hopwood and Jules Kovacevic, who are co-chairs. Not only does the SIG meet regularly to discuss different topics of interest, but also a LinkedIn group has been created with the following subgroups:

1. Transparency and Disclosure led by Zuoyen Lee
2. Clinical Regulatory Writing led by Sarah Hopwood
3. Non-Clinical Writing led by Sally Hill

I am sure more subgroups will be created as the SIG grows and many more regulatory topics will be covered, such as drug applications, advanced therapy medicinal products, or documentation for paediatric studies.

Finally, during the next Meet & Share, the group will access the AI programs that are out there in the regulatory space. The Reg SIG is looking into:

- AI shared experiences
- Protocol redaction/Statistical Analysis Plan anonymised documents
- Clinical Trials Information System after Q4 2024

Now, getting back to Valencia. Apart from the EMWA conference programme, including new initiatives such as EDGs, and very exciting ESS topics, there are "must-see" sites, such as the City of Arts and Sciences, the Cathedral, La Lonja, Barrio del Carmen, and Central Market. I suggest you spend some extra time there beyond the conference. On top on that, be aware that the 2022 Expat City Ranking named Valencia the world's top destination for expatriates, because of its unbeatable "happiness level" offered at affordable costs[1] Sound inviting?

See you all in Valencia!

Maria

Reference

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A new EMWA section

The introduction of a specialised AI section in the EMWA journal aims to address the distinctive challenges and opportunities in the field of medical writing in the "AI century". This section seeks to empower both regulatory medical writing professionals and those in medical communications by aiding in the navigation of AI-based tools. It will explore regulatory frameworks, guidelines, and best practices, covering crucial topics such as risk assessment, validation, data privacy, and transparency.

Aligned with the objectives of the EMWA AI working group, integration of AI into the journal is intended to streamline the communication of accurate information about AI-driven healthcare technologies. Medical writers are encouraged to delve into discussions on AI applications, detailing their benefits, risks, and limitations to bridge knowledge gaps. Furthermore, inclusion of an AI section in EMWA is designed to promote collaboration and knowledge sharing among our readers.

Our dedicated AI section strives to equip medical writers with the knowledge and guidance necessary to responsibly navigate AI complexities, advancing the integration of AI into the medical writing field.

Artificial Intelligence

Please forward topic suggestions to Daniela Kamir at Daniela.kamir@bioforumgroup.com.

INTRODUCTION

EMWA News

SECTION EDITOR

Somsuvro Basu
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"Getting into Medical Writing" in Valencia

Exciting news for all our new and aspiring medical writers!

At this spring's EMWA conference, EMWA's **Getting into Medical Writing (GIMW) Group** is organising a day-long programme dedicated to those interested in medical writing, considering it as a career option, or taking their first steps on this career path. We know how important it is to understand the field, network with other professionals, and have the right resources to get your foot in the door.

After the success of the **New Career Guide for Medical Writers** (https://www.emwa.org/ about-us/getting-into-medical-writing/career-guide-for-new-medical-writers/), the GIMW group created an entire day for newbies to learn from experienced medical writers and network with them. Who knows when your first opportunity will show up? Come and join us on this day full of educational and networking opportunities. So, if you are a new medical writer or interested in the field, or you know someone else who is, do not miss this opportunity and spread the word.

The **GIMW Day** will take place on Wednesday, May 8th. Register for the conference at https://www.emwa.org/ conferences/conferences/valencia/

EMWA Ambassador Programme news

On October 16, 2023, **Sarah Choudhury** and **Arunon Sivananthan** represented EMWA at the Kings College Career and Employability Event in London held at the Francis Crick Institute, London, UK.

On November 15, 2023, **Raquel Billiones**, MEW editor-in-chief, was invited to give a talk at the West Visayas State University (Philippines) with the title "Bridging Medicine and Communications: How Science and Healthcare Professionals Fill the Gaps through Medical Writing." The talk was given within the framework of the 2nd Research Café, spearheaded by the university's College of Medicine.

On November 24, 2023, **Nicole Bezuidenhout**, **Francesca Cappellini**, and **Catherine Heddle** represented EMWA at the well-attended Aula Medica Chase Career Conference in Stockholm, Sweden.

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

DID YOU KNOW?

Existing EMWA members can receive a 10% discount off their next year's EMWA subscription for referring a new member to EMWA. For more information, please contact Head Office at info@emwa.org

Check out the back issues of EMWA's journal *Medical Writing* at https://journal.emwa.org!

Valencia EMWA Conference News

EMWA's 57th Conference is fast approaching!

This spring, medical writers from all over the world will gather in vibrant Valencia, Spain, from May 7–11, to network, learn, and have fun. There will be workshops, seminars, a day-long session on getting into medical writing, social events, and much more. Watch emwa.org for more details.

Valencia was recently awarded the title "2024 European Green Capital". This honour recognises Valencia's achievements in inclusive green transition (97% of its citizens live within 300 metres of urban green spaces), sustainable tourism, climate neutrality, ecosystem restoration, and sustainable and inclusive food production. Yet another reason to attend EMWA's Spring Conference!

EMWA Webinars Programme

EMWA webinars help members develop skills and keep up to date in new or rapidly developing areas.

Most of our webinars are live, online seminars allowing participants to ask questions. For live webinars, you only need to register – you will need your EMWA membership details.

Upcoming webinars: https://www.emwa.org/education/emwa-webinars-programme-2024/#webinars2023

Freelance Business Group news

The Freelance Business Group's 2023 Autumn Virtual Forum had over 110 registered participants and was run by Johanna Chester.

This year, the virtual conference included rooms with assigned discussion themes run by expert freelancers from various backgrounds.

A heartfelt thank you goes out to all the volunteers who generously dedicated their time and shared their wisdom, including **Arianna Ferrini**, **Lucia Massi**, **Beate Walter**, **Satyen Shenoy**, **Namrata Singh**, and **Johanna Chester**.

We look forward to creating contemporary discussions for the face-to-face forum during the 2024 Spring EMWA Conference in Valencia. If you have any suggestions or topics you would like to promote, please let us know via the dedicated LinkedIn group: https://www.linkedin.com/groups/12769131/
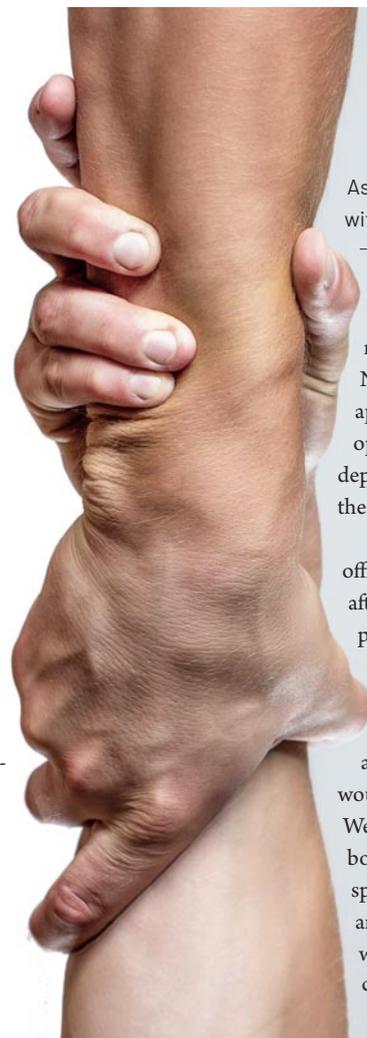
EMWA sponsorship officers

As you may know, all roles within EMWA are voluntary.

We take great pride in being an association run by members for members. Nonetheless, some roles are appointed, and others are open to members' votes, depending on the nature of the role.

Last year, the sponsorship officers' official term ended after a 2-year cycle. Based on a positive review, the Executive Committee asked the current sponsorship officers, **Ricardo Milho** and **Abe Shevack**, if they would like to keep their roles. We are happy to announce that both decided to remain as sponsorship officers for another two years, and we wish them many fruitful connections.

Advancing health equity through language access – a global imperative

Prado Antolino[1], Marina Persoglia Bell[2],
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Abstract

In this article, the authors outline the universal right to health, healthcare, and language access in healthcare, with a focus on policies and practices in the European Union and the United States. The authors spotlight contrasting views on whether language access should be considered a social determinant of health or an independent factor and assert that health equity is not achievable if language barriers are not systematically addressed in healthcare organisations and in the context of the individual care plan. Drawing from personal and professional experiences, and from a well-established body of medical research, the authors underscore what happens when language access infrastructure is not present in healthcare – with impacts to access and adherence, quality of care, and patient outcomes. The authors propose a language access framework to move healthcare organisations and the communities they serve towards health equity.

Introduction

The universal right to health is clearly articulated in the 1946 Constitution of the World Health Organization, which defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" and posits that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition."[1]

This universal right carries freedoms and entitlements. Its freedoms include the right to be free from non-consensual medical treatment, such as experiments and research or forced sterilisation. The entitlements include the right to a system of health protection providing equality of opportunity for everyone to enjoy the highest attainable level of health, which includes the equitable provision of health-related information and the participation of the population in health-related decision-making.[2]

While all member states have recognised the aspirational right to health written into the foundational document establishing the United Nations in 1948, just 38 percent constitutionally guarantee their citizens the right to healthcare services and 14 percent guarantee the right to public health.[3] Some countries have stated before human rights bodies or in national legislation that they cannot or do not wish to provide the same level of protection to migrants as to their own citizens. Many have defined their health obligations towards non-citizens in terms of "essential care" or "emergency care". Because these concepts mean different things in different countries, and sometimes in different regions of a country, their interpretation is often left to healthcare organisations or to individual healthcare practitioners.[2]

Addressing this variability in recognising and upholding the right to health and healthcare, a 2022 report by the British Medical Association asserts, "Health is such a fundamental human good that it is meaningful both to talk of it as a universal right, and to ensure that all governments are held accountable to their obligations to protect, respect, and fulfil it. Whatever the underlying economic system, where a state has ratified relevant human rights treaties, it has accepted a set of standards against which its progress in realising those rights – and any violation of them – can be called to account."[4]

The EU places a strong emphasis on an individual's right to healthcare, both within a member state's borders and in the context of cross-border migration. The legal framework and directives seek to ensure that individuals can receive healthcare services and are protected against discrimination based on nationality.[5-7] However, EU directives on the provision of healthcare do not affect laws and regulations in member states on the use of languages, effectively leaving it up to each country to decide whether to deliver information in languages other than those which are its official languages.[8-10]

The US has no formally codified right to health,[11] and while federal law guarantees a patient's right to language access in healthcare,[12] not all states have implemented or enforced these provisions equally.[13] States with strong public support for immigrant and minority rights may be more likely to implement and enforce language access provisions, while those with more restrictive immigration policies may be less inclined to do so. For example, the Florida Patient Bill of Rights reads, "A patient in a health care facility who does not speak English has the right to be provided with an interpreter when receiving medical services if the facility has a person readily available who can interpret on behalf of the patient", ostensibly leaving it up to healthcare facilities to decide whether to build language access infrastructure.[14] Florida is also the only US state to mandate that hospitals ask patients about their citizenship status.[15]

It's important to note that individuals on both sides of the pond have the right to seek redress at the national level if they believe their language rights have been violated.[16,17] However, in practice, the extent to which these overarching protections are realised may vary depending on the state in which the individual resides and the prevailing state-level policies.[10,13,18] Regardless of whether language rights are locally protected, language access and a person's experience of health and healthcare are inextricably linked. For all of us, the only way to meaningfully access

healthcare is through clear bidirectional communication with healthcare professionals and receipt of health information in a preferred language.[19]

Social determinants of health, language barriers, and health equity

In individualistic societies, free choice and personal autonomy are widely valued. Personal autonomy also appears to play a role in achieving health. In simple terms, we can make personal choices to achieve better health outcomes. Yet the idea that health equity can be attained through personal choice discounts a wide variety of social, physical, economic, and linguistic factors that contribute to achieving or failing to achieve this goal.[20] In public health, non-medical factors that influence health outcomes are called social determinants of health (SDOH), and it is broadly accepted that they directly impact a person's quality of life, their access to healthcare, their access to social services, and their risk for disease.

The US Department of Health and Human Services, in its *Healthy People 2030* initiative, categorises SDOH into economic stability, education access and quality, healthcare access and quality, and neighbourhood and built environment.[21] SDOH are directly linked to lack of health equity, which the American Public Health Association defines as "everyone having the opportunity to attain their highest level of health". The US and the EU have proposed strategies to combat health inequities, and at the core of that fight are SDOH.

Language barriers have not traditionally been classified as SDOH, although some proponents suggest they should be. A December 2019 American Academy of Applied Linguistics public affairs engagement brief calls for attention to language in healthcare "not merely as a demographic marker, but arguably as one of the most significant (and yet under-explored) social determinants of health in underserved linguistic minority communities." The authors make the case that applied linguists can play an impactful role in advancing the cause for reducing such disparities.[22]

Analyses of SDOH and patient safety in healthcare reveal that linguistic minorities are more likely to experience worse health outcomes overall because of language barriers.[23,24] Facing unattended language barriers in healthcare, minority language speakers are unable to engage in meaningful informed consent processes and their autonomous decision-making is compromised if they cannot fully grasp the nuances of the local majority language; overall, they are less satisfied patients and they experience greater emotional distress due to lack of control over their health. In other words, if social determinants undermine a patient's autonomy, so do language barriers.

While maintaining that language is an "independent determinant of health outcomes", in an article published in the AMA *Journal of Ethics*, Dr Jason Espinoza and Dr Sabrina Derrington argue for linguistic redress, highlighting that limited proficiency in the majority language is an "unchosen disadvantage" and urging healthcare providers and organisations to take responsibility for overcoming language barriers at the individual and institutional levels.[25]

Whether language should be considered a SDOH or whether it is an independent factor, the

> *Language access and a person's experience of health and healthcare are inextricably linked.*

> *Linguistic minorities are more likely to experience worse health outcomes overall because of language barriers.*

consensus is that language barriers place minority language speakers at a significant disadvantage compared to majority language speakers in any life context. Health equity, therefore, is not achievable if language barriers are not considered at the outset of caring for a patient. Moreover, it can be argued that building robust language access infrastructure in healthcare organisations and in linguistically diverse communities is foundational to any sustainable progress on the health equity front.

Inadequate language access and a lack of culturally appropriate healthcare services have profound and far-reaching consequences for patients, healthcare providers, institutions, and the healthcare system. These issues, well-documented in the medical research literature, adversely impact quality of care and ultimately health equity. For the purpose of this article, we will bundle the impact in three groups: access and adherence, quality of care, and patient outcomes. For each, we will share a small vignette from our frontline experience as language access administrators in US hospitals.

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Access and adherence

Language barriers result in decreased access to care[26,27] and reduced adherence to treatment plans.[28] Patients who cannot effectively communicate their symptoms or understand medical instructions may not receive the appropriate care they need, and this, in turn, can lead to higher mortality rates (Patient story 1).[29]

Quality of care

One of the pillars of a therapeutic relationship is effective communication. Where language access infrastructure is weak or non-existent, the overall quality of healthcare delivery is negatively impacted (Patient story 2). The resulting patient dissatisfaction[30] leads to a lower likelihood of returning or recommending a healthcare facility. Clinician satisfaction is also at stake. The inability to communicate with their patients, in the absence of language concordance or language services, contributes to moral distress and burnout, as clinicians feel unable to fulfil their commitment and vocation to provide the best possible care. How can a provider "do no harm" and establish effective communication with their patient when unattended language barriers are in the way?

Patient outcomes

Numerous studies have demonstrated that patients who are unable to communicate in the majority language are at a greater risk of experiencing suboptimal healthcare outcomes. For instance, language barriers have been associated with an increased risk of patient harm,[31–34] longer hospital stays,[34–36] a higher likelihood of hospital readmissions,[36] compromised patient well-being, and higher healthcare costs.[30,37,38] These consequences undermine the fundamental Hippocratic principle of "First, do no harm."

It is essential for the healthcare workforce, institutions, and policymakers to recognise the critical importance of building language access infrastructure, regardless of what the current local legislative landscape may be. By doing so, we not only enhance the quality of care provided to minority language populations but also make strides in the pursuit of health equity (Patient story 3).

Addressing the language access imperative in healthcare

To provide equitable, safe, and effective care for all patients, it is essential to address language access. In language concordant environments, where patients and providers share a common language, patients receive more information and are asked more questions,[23] which aids in achieving an accurate diagnosis sooner. In the highly litigious US healthcare system, physicians treating patients with whom they share a language fear malpractice much less[23] and report higher professional satisfaction than when confronted with language barriers. Language concordance, undoubtedly, is a first-line health equity strategy. Yet language concordance is not always possible, and the engagement of qualified healthcare interpreters and translators becomes the next best just strategy in linguistically diverse populations.

Successful language equity interventions are multipronged. To build a culture of language justice in a healthcare system requires infrastructure, sustained effort and commitment from institution leaders, consistent messaging and education, as well as expectation-setting through policy and enforcement. This work is reminiscent of the revolutionary focus required to instil a culture of hand hygiene in hospitals.[39]

An observational study published in *JAMA Pediatrics* reported on mortality rates among Latino children in a US paediatric intensive care unit (PICU) before and after linguistic and cultural intervention.[29] Before intervention, Latino children's mortality rate was 3.7 x higher than the mortality rate for White and African American children, when adjusted by severity of illness. After implementing a multilevel linguistic and cultural intervention, this inequity was eliminated. Interventions included cultural sensitivity training for clinicians, hiring additional bilingual staff, expanding the availability of trained interpreters in the

Patient story 1: Follow-up

Patient treated for breast cancer in community hospital with no language assistance services. Patient achieves cancer-free status, and is subsequently lost in the system, receiving no follow-up care. Patient presents two years later at a major cancer centre with symptoms; cancer has metastasised and is untreatable. Patient reports that, due to language barriers and lack of language assistance, she never understood that there was a five-year treatment plan that needed to be followed.

Patient story 2: "I like my doctor"

Patient note, written in Portuguese on post-visit hospital survey: "I like my doctor. He thinks he speaks Portuguese. Sometimes I understand him."

emergency department and PICU, making consent forms and educational materials available in multiple languages, and expanding outreach to Latino communities.[29] While it may be tempting to oversimplify the solution to the language access challenge by establishing a contract and outsourcing language services entirely, the hospital rejected a quick-fix fallacy, opting instead to address several nuanced variables. In the 3-year post intervention period, PICU mortality for Latino children dropped to a level comparable to the levels of White and African American children.[29]

The health equity imperative inspires us to propose a language access infrastructure model grounded in the global legal framework, existing medical literature on language access and health equity, and lessons from the field (Figure 1). As advocates, we seek to present building blocks that can be integrated in the structure of any organisation, if not already there, and to offer concrete action steps at all levels of a health system.

The foundation of the proposed model is anchored on the global legal framework that health equity and language access are a human right, and the Hippocratic Oath to, "first, do no harm". Building on best practice guidelines,[40] and expanding with lessons from the field, we put forward for consideration four pillars: language services, people, processes, and technology, to eliminate linguistic and cultural barriers in healthcare and enable health equity through language access. The requirements for this "Language Justice Framework" are set out below (Figure 1).

Language services

All healthcare language access models include oral interpretation. For quality and practical purposes, it is recommended that the institution maintains qualified healthcare interpreter staff – nationally certified where applicable – in the largest minority languages, supplemented by vendor services. Staffed in this way, service is delivered in a combination of modalities (in-person, video, and telephonic) to meet communication needs at all touchpoints. For fast-paced environments such as emergency wards, intensive care units, surgical centres and birth centres, deployment of area-assigned staff interpreters or unit-based interpreters[41] serving the largest minority languages may help mitigate any absence of language services due to time pressures associated with the provision of critical care in an already fast-paced environment. Many healthcare systems deploy video remote interpreting (VRI) devices in patient care areas to facilitate on-demand language access in multiple languages. Some healthcare systems build interpreter call centres, with the goal of handling most telehealth, video, and telephonic interpretation requests internally for the largest minority languages. All healthcare systems should procure high-quality contracted services as a backup to internal systems and a fail-safe for handling emergent or unanticipated language needs.

Critical written communication is translated by qualified professionals. As part of the language needs assessment, each institution identifies specific business-critical communications and vital documents. Some vital document examples are patient history forms, consent forms, after-visit summaries, patient instructions, questionnaires, and leaflets providing information about services. Alternate media to written communication are made available to those who are unable to read, who speak languages without a written form, or who prefer to consume information via audio, video, social media, or health apps.

People

If serving a large organisation, professional interpreters enjoy career advancement within the institution and remain in the profession while achieving new levels of competency, continuously developing through milestones (professional certification, advanced academic degrees, etc.), and contributing to process improvements, education, and the community. Interpreters are valued as team members, enriching the en-

Patient story 3: Eye injection

Deaf patient who uses American Sign Language (ASL) to communicate is seen in eye clinic without an ASL interpreter. Provider applies eye injection. Mother reports patient distress. A few days later, patient is hospitalised to address comorbidities. Same eye injection treatment is required prior to discharge, but this time an ASL interpreter was present. History-informed provider states plan to perform eye treatment with patient sedated to improve compliance. ASL interpreter provides a communication consultation and recommends that the provider explains the procedure, including risks and benefits. After interpretation, the patient consents to undergo the eye injection without sedation. Patient is collaborative during the procedure and is complimented for outstanding compliance. Institution and family save costs associated with a longer hospital stay, anaesthesia, additional clinicians, and operating room time.

Health Equity
Language Access Infrastructure

Eliminating language and cultural barriers in healthcare

Improving healthcare access and outcomes for linguistically diverse communities

Providing comprehensive language services and culturally appropriate care

LANGUAGE SERVICES

- **Oral interpreting in all modalities**
  - Qualified interpreter staff
  - Unit-based interpreters
  - Appropriate modalities at all points of contact (in-person, video, telephonic)

- **Translation of written materials**
  - Business-critical communications
  - Vital documents
  - Patient Rights
  - Health App messaging
  - Wayfinding signage

- **Alternate media**

- **Qualified Bilingual Speakers (QBS) - clinical and non-clinical staff**

PEOPLE

- **Institutional language services standards council governance**

- **Professional recognition: Medical Interpreter/ Translator Certification**

- **Elevating medical interpreter/translator: Career progression rewards specialisation, education and contributions**

- **Language professionals partner with physicians in research and publication**

- **Engagement of internal and external stakeholder communities**

- **Staff onboarding education**

- **Structured cycles of in-service training throughout organisation**

PROCESSES

- **Linguistic needs assessment: Identifying language minorities, frequency of occurrence and touch-points**

- **Language services policies and procedures**

- **Annual goals aligned with health system goals**

- **Internal and external marketing, communication of language services**

- **Data-driven decision-making**

- **Continuous process improvement**

- **User-friendly interpreter/ translation request and dispatch functions**

- **QBS Competency Evaluation**

TECHNOLOGY

- **Integrated phone, video and telehealth technology solution supports staff interpreters and expands to partner for global language reach**

- **Multilingual electronic health education library**

- **Translation Management System**

- **EMR supports documentation of**
  - Preferred language: patient & caregiver/ support person
  - Language of care (oral & written)
  - Other communication needs/assistive devices

- **Request management and Dispatching system**

- **Multilingual website, health apps, appointment management**

- **Interpreters' communication device within institution**

Hippocratic Oath: First, do no harm

Global Legal Framework: Health Equity and Language Access as a Human Right

Figure 1. Language Justice Framework

The Language Justice Framework provides a comprehensive language access framework to support building a new, or improve an existing, comprehensive language access programme.

Abbreviations: EMR, electronic medical record; QBS, qualified bilingual speaker.

Health equity is a holy grail of modern healthcare.

counter by providing cultural consultation to help bridge patient and provider perspectives. Ideally, clinicians receive early education in intercultural communication, starting in medical school. Healthcare institutions implement onboarding and in-service training for faculty and staff to learn to engage language assistance services efficiently and effectively. Providers and language professionals partner with faculty to conduct research, learn from each other, share governance, and bring about improvements that authentically meet the needs of all stakeholders. At the highest level, interpreter scientists advance practice within an institution and contribute to the broader medical language access literature.

Processes

Conducting a language needs assessment is the cornerstone for establishing the scope of a language access programme.[42] It is necessary to understand the demographic ecosystem in which the healthcare organisation exists, and how, in turn, this organically determines the minority language mix: How many languages need to be served? Where and how often do the minority language populations come in contact with the organisation? From the reception desk to the operating theatre, consider implementing language access infrastructure that seamlessly supports communication at all points of contact. Whatever the reach of the organisation, it is essential to right-size language services, people, processes, and technologies to the needs of the community when creating your language access plan.[40]

Established processes provide precise guidance for accessing language services appropriately and in a timely manner. Institutions make sure that patients and visitors are informed of free language assistance services through obvious signage and clear instructions.

Standard and objective verification of language competency is required for bilingual clinicians to provide safe and effective language concordant care. A guiding rule of thumb may be to mirror availability of linguistically competent bilingual providers and staff – such as physicians, nurses, and clinical and non-clinical support staff – proportionate to the size of the community's minority language groups. Finding and developing local talent, hiring clinicians and staff from the community, can help build trust and strengthen the healthcare organisation's connection to the diverse population it serves.

Technology

When used appropriately and implemented correctly, technology streamlines access to qualified interpreters and helps support a seamless and consistent patient experience. Its utilisation should be focused on ensuring quality and the best care experience possible.[43] Electronic medical records (EMR) support language preference and "interpreter needed" fields for patient and caregiver/support person. Interpreter request and dispatch systems are integrated with the EMR and are user-friendly and intuitive. This is an efficient mechanism to track utilisation and share common information, as well as a source of data to verify compliance, support research, and inform resource advocacy. Tracking metrics allows for quick identification of successful initiatives as well as opportunities for data-driven improvements.

Conclusion

Health equity is a holy grail of modern healthcare. No one has built a perfect system, nor do we presume to believe that this model would. It is our aspirational goal that healthcare institutions everywhere engage in building cultures of language justice and take meaningful steps to advance the practice of health equity for the communities they serve.

Disclaimers

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

Disclosures and conflicts of interest

The authors declare no conflicts of interest.

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Five "translation" strategies to adapt technical content for lay audiences

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Abstract

Writing for lay audiences requires language that is understandable by readers without expertise in the subject matter at hand. This means carefully selecting, organising, wording, and supporting content, focusing on conveying relevant points in a straightforward and engaging manner. Applying the principles of plain language can help writers achieve these goals.

An important point is that plain language principles apply to all informative writing, whether readers possess specialist knowledge or not. Readers at all levels of expertise welcome and deserve clarity. The goal of this article is to present strategies for translating content originally created for specialists using the principles of plain language.

P lain language is defined as writing in which wording, structure, and design help intended readers find, understand, and use information. As such, it is not a specific way of wording, organising, or designing content. Rather, it is an approach to those processes aimed at conveying the message intended by the writer in a way that fits the needs of the target readers.

Brian Garner, former editor of Black's Law Dictionary, defines plain language as "the idiomatic and grammatical use of language that most effectively presents ideas to the reader."[1] Authors rely on grammar to convey meaning, because grammar provides the common ground necessary for weaving words together in a way that makes sense to readers of a language. Idiomaticity draws from stylistic and aesthetic preferences that help readers connect with content. Certainly, these are not new ideas: Quintilian, the father of modern schooling as far back as the 1st century of the common era, advocated for simplicity with style so that messages are conveyed with accuracy and elegance.

In June 2023, the International Organization for Standardization (ISO) published Standard 24495-1:2023 Plain language – Part 1: Governing principles and guidelines.[2] This standard has generated a lot of interest and discussion about how the outlined principles are to be implemented. As a brief disclosure, I am part of ISO Technical Committee 37 developing language and terminology standards, as a member of the mirror committee in the US for the American National Standards Institute (ANSI). Yet the ideas presented here emerge from my professional practice and differ only slightly from

> Collaborative development is referred to as co-design and requires negotiation and compromise that often leads to innovative solutions.

what is presented in the standard. In particular, I use five dimensions for intervention, which I call RAISE for relevance, accessibility, intelligibility, suitability, and efficacy.

I unpack the principle called "understandable" in the standard into intelligibility and suitability (so called in part to fit into the RAISE acronym). These two principles cover two related, but distinct, linguistic aspects technically known as textuality and adequacy. The challenges of creating and maintaining the logical flow of text differ from the challenges of choosing terms and wording that fit an audience's stylistic preferences. Of course, despite being described separately, clear writing principles are not applied sequentially or independently during the writing process but rather guide intertwined decisions during the planning, drafting, and revising of text. Let's now briefly review the principles.

RAISE principles

Plain language requires interventions in wording, structure and design to respond to the needs of the readers and the goals of the communication. To address interventions, I developed the RAISE rubric covering 5 dimensions: relevance, accessibility, intelligibility, suitability, and efficacy. While interventions in these dimensions are presented sequentially, in reality, they overlap to create an integrated whole.

Relevance of content to the intended purpose includes the selection of topics and objectives, their explicitness in the text, and the perspective and depth with which those topics are addressed. To make these decisions, the writer can rely not only on the judgment of experts (including their own) and review existing literature on the characteristics of the readers but also invite readers into the process through interviews, surveys, and sampling. Collaborative development is referred to as co-design and requires negotiation and compromise that often leads to innovative solutions.

For example, as part of the Rapid Acceleration of Diagnostics (RADx*) initiative in response to the COVID-19 pandemic, the National Institutes of Health (NIH) fostered accessibility of COVID-19 home tests by engaging various stakeholders in a collaborative project. The process included:

- Input and feedback from advocacy groups like the Alliance on Ageing and Vision Loss, the American Council of the Blind, and the World Institute on Disability
- Usability and accessibility consulting by subject matter experts
- Insight from government agencies
- User testing by Georgia Tech HomeLab.

The learnings from this initiative have been captured in a best practices document (U.S. Access Board, 2023)[3] that covers guidelines for the five principles at hand.

Accessibility of content involves where the content is published, the rhetorical structure of the message, and the physical design of the document – including the use of non-textual elements, such as images, graphics, or videos, that help capture and maintain the reader's attention, as well as process textual information. The term accessibility employed here intersects with but goes beyond digital accessibility, which focuses on access to materials and computer platforms for people with disabilities. Note that digital accessibility strategies can be used on a text that is not clearly written. (The guidelines for digital accessibility are outlined by the World Wide Web Consortium, in the Web Content Accessibility Guidelines Initiative.)

Intelligibility primarily involves textuality. Textuality, so called by linguists, is the construction of meaning attending to the grammaticality, acceptability, cohesion, and coherence. It certainly also includes adequacy – adapting the form of expression to the reader and the context to communicate with empathy – but, as mentioned, this dimension deserves independent consideration.

To achieve textuality, that is, to construct meaning, a writer uses vocabulary, grammatical constructions, and argument organisation that best suit the message. For example, to explain a process, its stages must be presented in a logical progression that leads to the expected result. If a step is out of order, the writer revises the text before publishing. This contrasts with speech, where speakers can engage in a real-time revision process, adding, clarifying, and restating on the go.

Suitability involves the adequacy of the text in terms of adapting style and register to the target audience for the text. It includes positioning the text in its cultural environment, especially as part of a socially consensual genre. The writer must adapt the content not only in terms of the selection of topics, the depth of their treatment, and the intelligibility of their wording, but also in terms of the register and style to support communication with the intended reader. Note that we understand by register the interpersonal aspect of the text as defined by Eggins.[4] Empathy plays a very important role in effective communication; for example, in healthcare, empathy improves diagnosis by fostering exchange between a professional and a patient, encourages evidence-based decision-making, and promotes adherence to treatment. This concept has been formalised in the style guidelines on respect and objectivity of the American Psychological Association (APA)[5] primarily directed at research but useful elsewhere – especially in the case of descriptors of individuals and groups.

Efficacy of the text concerning the intended use involves evaluating the document throughout its life cycle using appropriate methods for each stage, such as literature review on the audience, interviews and surveys, A/B tests, performance surveys, etc. While traditionally this has been a *post facto* task, adopting a co-design approach brings together professional expertise and insights from readers throughout the development process to help enhance the readability, understandability, and applicability of texts.

Taking into account these five dimensions, five key translation strategies to adapt content for lay audiences are discussed below.

1. Use a stepwise process

Translating technical text into text for lay audiences is more than substituting lay explanations for technical terms. In fact, it often requires a stepwise process to first ensure that RAISE principles are implemented in the technical version. Once we have a clear technical version, then we can adapt the document to readers who are not specialised in the subject matter.

In Figure 1, the bottom left corner shows an original technical text that includes redundancies and a complex message structure, presenting first the aetiology and then the symptomatology of the disease. If we use this text as the basis of our lay version, moving along the horizontal axis and

changing only the technical terminology, we do not address those issues, and may possibly introduce new ones (such as the reference chain mismatch *migraines/its*). If, instead, we streamline the technical version along the clarity axis, we can pinpoint the two main concepts easily, reorganise them to suit the needs and expectations of lay readers (more familiar with symptoms than causes of disease), and provide an easy-to-follow list for the symptoms, along with explaining the technical terms.

Clear

Migraine is an incapacitating neurovascular disorder characterised by paroxysmal attacks of unilateral throbbing headache. It is often accompanied by autonomic dysfunction symptoms including nausea, dizziness, and sensitivity to light and sound.

A migraine is a type of **headache** that:
• often appears suddenly.
• causes pounding pain, typically on one side of the head.
• can reduce your ability to function in daily life.

A migraine involves changes in the nerves and blood vessels in the brain. These changes can cause nausea, dizziness, and sensitivity to light and sound.

Technical ← → **Lay**

Migraines consist of an incapacitating disorder of neurovascular nature, typically characterised by sudden paroxysmal attacks of unilateral throbbing headache and usually accompanied by a host of autonomic dysfunction symptoms including nausea, dizziness, and sensitivity to light and sound.

Migraines are a disabling condition that affect nerves and blood vessels. Its main symptom is sudden pounding pain usually on one side of the head. Migraine causes symptoms such as nausea, dizziness, or sensitivity to light and sound.

Obscure

Figure 1. Using a stepwise process along 2 axes
Image by Romina Marazzato Sparano

2. Always mind the basics

When translating technical text into lay text, we must not forget to review the lay version to make sure the basics are right. Common issues to check for include:
• subject–verb agreement errors
• ambiguous or mistaken reference chains
• wrong or misleading punctuation
• lack of parallel structures
• unclear centre embedding
• confusing noun piling

These issues can make parsing for meaning harder or require undue inference on the part of the reader. Some emerge from cut-and-paste style editing as we adapt technical language to lay language. For example, incongruous verb agreement and a mistaken comma after the subject tend to linger after removing intervening information between subject and verb. Deviating from using parallel structure for parallel ideas or presenting ambiguous reference chains often emerge from editing or translating phrases within a larger structure. (See Figure 2 as a humorous example of such ambiguity.)

Let's look at some examples:

• **Few are the teachers who, at the age of five, can teach children to read.**
The prepositional phrase "at the age of five" does not refer to the age of the teachers, the preceding noun, but to the age of the children, a noun presented after the phrase. To avoid ambiguity, the phrase can be moved to the end of the sentence, closer to the intended antecedent, rather than relying on the reader to intuitively resolve the ambiguity.

• **The new data convinced her students have the maturity to talk about difficult subjects.**
Here "her students" is read as a unit first, because it appears to follow a frequent noun phrase structure. The reader has to then walk back this interpretation after encountering a verb that signals the necessary separation between "her" and "students" as belonging to two sentence elements: a direct object and a complement. Using the complementiser "that", often omitted in speech, where intonation signals separate elements, can introduce the complement clause, and resolve the ambiguity.

Guilt and bitterness can be destructive to you and your children. You must get rid of them. ^these feelings.

Figure 2. Example of editing an ambiguous and potentially dangerous text fragment
Image by: Romina Marazzato Sparano with OpenAI's DALL-E model

It is extremely difficult, if not impossible, to unpack all the knowledge and know-how embedded in technical terms.

3. Create project-specific glossaries

Among specialists, technical terminology serves as shortcuts carefully crafted to house layers of meaning that include both knowledge and know-how. Explaining such terms to lay audiences requires selecting and focusing on particular layers. It is extremely difficult, if not impossible, to unpack all the knowledge and know-how embedded in technical terms. The difficulty is in part formal: it would require overly lengthy rendition to spell out the meaning layered within terms. But, more importantly, it may require an educational journey beyond the scope of the document or content you are trying to share.

Glossaries must thus be project-specific to focus on the layers of meaning relevant to the communication purpose at hand. For instance, the term "cancer" may be adequately defined in a brochure that lists reasons for swollen lymph nodes as "a disease in which some of the body's cells grow uncontrollably". However, it may require a different definition in the context of distinguishing specific types of cancer, their symptoms, diagnosis, and prognosis.

Consider the following example of injection types. Intravenous, intramuscular, and subcutaneous are terms used to describe different methods of administering medication or substances into the body. Each method targets a different layer of the body's tissue. For a general description, you may choose to create the following glossary:

Technical term	Lay Explanation
Intravenous	Injected into a vein
Intramuscular	Injected into a muscle
Subcutaneous	Injected into the skin

However, if the term "intradermal" is included in a different project, you will need to modify your glossary. For example, you may choose to use the following:

Technical term	Lay Explanation
Intravenous	Injected into a vein
Intramuscular	Injected into a muscle
Intradermal	Injected into the surface layer of the skin
Subcutaneous	Injected into the fatty layer under the skin

Another example of glossary terms needing adapted explanations for different projects is arrhythmia. For one project, it was simply defined as *"irregular heartbeat"*. But the term required further details in a project about tachycardias. The lay explanation for arrythmia now had to include reference to a group of heart rate disorders in which the heart can beat too fast (tachycardia), too slow (bradycardia), or irregularly.

Existing glossaries are certainly a tool that may help you develop your own glossary. But we should not rely on existing glossaries without careful scrutiny to understand the purposes and needs they served. An existing glossary may be used as a basis to expand on. For example, expansion in the glossary about injection types may include a description of use and goals of each type of injection, such as delivering a substance directly into the bloodstream for quick action versus an administration aimed at a slower and more consistent absorption of medication. Consider, also, the possibility that an existing glossary may not serve your message purpose or your readers' needs, and that it may be easier to compile your glossary from scratch.

4. Use relevant storytelling and imagery

The use of storytelling and imagery in explaining technical concepts to lay readers can be a powerful tool for transforming complex ideas into engaging and understandable narratives. Storytelling engages empathy when processing information, so embedding a technical concept in a story can make it more relatable and easier to grasp. However, careful consideration of drawing on emotion is needed. While emotion can assist reasoning[6] – especially when risk and conflict in personal or social matters are involved – it can also "bias evaluative judgments of unrelated events or topics".[7]

Stories can embody abstract concepts through characters, plots, and settings that readers can visualise and connect with, facilitating a deeper and more intuitive understanding. Imagery can be used independently or as support for storytelling. Analogies and metaphors can draw parallels between complex concepts and items familiar to the audience, simplifying the understanding by linking the unknown to the known.

Visual illustrations that also apply plain language principles can distill complex information making it more accessible. Well-crafted images, diagrams, or infographics must include only the relevant aspects of the concept, avoid decorative elements, use meaningful colour and contrast as well as parallel structure, for instance. For example, when explaining a complicated process like venous and arterial blood flow, an annotated diagram can convey the sequence of events and interactions more effectively than text alone. This visual representation acts as a cognitive shortcut, allowing readers to grasp the essence of the concept quickly.

Combining imagery with storytelling not only breaks down barriers to comprehension but also makes the learning process more engaging and memorable, catering to the varied ways in which people access and process information.

An example of analogy in my practice includes explaining how an MRI machine works. MRI stands for Magnetic Resonance Imaging and refers to a medical imaging technique used to visualise internal structures of the body in detail. Explaining how the visualisation happens can be a daunting task. However, we focused on the distinction from invasive diagnostic techniques – which was the main issue for the patients we were trying to reach. We set out to explain the non-invasive nature with the following analogy.

Figure 3. Using analogy and metaphor can help convey a message in terms of objects and processes familiar to your lay readers.

Images by: left, Romina Marazzato Sparano with OpenAI's DALL-E model, right, MRI from cdimiami[8]

The MRI machine is like a magnetic pin cushion and hydrogen protons in the body are like pins. Hydrogen protons, like pins in a sewing project, are abundant and easy to detect with a magnet. Hydrogen protons make up the water and fat tissues of the body. The magnet in the MRI can tell apart the hydrogen proton "pins" from all the other materials in the body. The magnet momentarily aligns the protons of body tissues as if aligning pin heads and tips to take a neat picture. After the MRI is turned off, hydrogen protons return to their natural orientation without affecting the person, just like pins can be dropped back into their box after being picked up by a magnetic pin cushion (Figure 3).

This image represents the analogy of an MRI machine as similar to a magnetic pin cushion to align hydrogen protons "pins" in order to capture an image of the heart.

5. Consider second-language readers in your grammar

English is, for reasons we will not get into here, the *lingua franca* adopted as a common language between speakers of diverse languages and cultures. As such, it may be better suited to speakers of some languages than others because of lexicon, grammar, or common cultural norms. Some idiosyncratic aspects of English to consider include its use of phrasal verbs, its motion event typology, the resultative construction, and the use of idiomatic expressions.

Phrasal verbs are combinations of verbs and prepositions or adverbs, which can have meanings that are not always predictable from the individual words. For example, "give up," meaning to quit or stop trying, does not directly relate to the meanings of "give" and "up."

Event typology[9] refers to how a language expresses motion in terms of manner and direction or result. English is a *satellite frame* language that also incorporates *verb-frame* constructions due to its rich linguistic history. Verb-frame constructions, inherited from French, involve verbs that express the direction or result of action with manner being an optional element expressed in adjuncts (as in "She entered the meeting [surreptitiously]"). They are characteristic of Romance languages and typically considered higher register in English. Satellite-frame constructions involve verbs that express the manner of action with the direction or result expressed through mandatory particles or prepositions (as in "She snuck into the meeting"). They are characteristic of Germanic languages and the preferred construction in everyday English. The coexistence of these two types of constructions allows for nuanced expression and flexibility. This can help you adapt how you phrase manner and result in verb phrases when writing for second language readers.

The prevalence of satellite-frame constructions in English has an impact on what's called *resultative constructions*. Resultative constructions express an action in terms of the outcome or result they produce using a complement (a mandatory element in the predicate that qualifies the subject or the object), as in "He wiped the counter clean." Many languages cannot create such phrases because manner verbs cannot

be combined with a complement conveying result. Consider whether your focus is the manner or the result in conveying your message to non-native readers and use the verbs accordingly. If necessary, express the other aspect (result or manner) using an adjunct or an additional phrase.

Last, but certainly not least, we must consider idiomatic expressions, cultural references, and cultural context-dependent meanings. Understanding the figurative meanings of idiomatic expressions can be challenging. If an idiom or culture-related image is essential to your message, consider explaining it or rephrasing it in a literal way. This can help readers understand the intended meaning without relying on the cultural context of the idiom.

You can, however, use idiomatic expressions and cultural references to your advantage. As part of a campaign to educate different parts of a community (men, women, youth, etc.) about heart disease, a team of colleagues used American football, soccer, knitting, and using apps for custom versions of the same basic message.

Lay language as a democratising tool

The benefits of translating technical content for lay audiences include saving time and effort in understanding and thus support learning, decision-making, and inclusivity. In addition, adapting technical content for lay readers aids in knowledge dissemination, allowing important findings or information to reach a broader audience. This aspect is key for bringing knowledge to the general public, educators, policymakers, and specialists outside the field. Consider that a jury of peers is increasingly called upon for the task of weighing highly technical evidence such as chemical, financial, forensic, and AI-related. Also, a significant portion of legislation includes technical content that lawmakers need to understand and evaluate. Lastly, lay versions of specialised content can make complex academic research more accessible to researchers in related fields who might not have encountered, understood, or paid attention to the paper in its original, more specialised publication.

Translating technical text into lay language is key to democratising access to knowledge, promoting a wider understanding of complex aspects of our modern world, and fostering an inclusive environment where information is accessible to all. Applying the strategies listed above, among others, will help you tackle technical concepts, promote engagement with your material, and facilitate decision-making.

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How can we maximise patient engagement with Plain Language Summary of Publication articles (PLSPs)? A publisher's perspective

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Abstract

Plain Language Summary of Publication articles (PLSPs) are aimed at non-specialist audiences, using non-technical/jargon-free and easy to understand language to provide summaries of publications. The introduction of PLSPs has added to the growing need for medical publishers to reach and engage patient audiences. This has introduced new challenges for publishers, including raising awareness of the existence of PLSPs and making them easily discoverable for patients as well as fostering trust in medical publications within the patient community. This article discusses ways in which publishers can work towards overcoming these challenges and maximise patient engagement.

Introduction

It is widely recognised that making bio-medical research understandable to non-specialist audiences is vital for promoting patient engagement activities.[1] In the last few years, Plain Language Summary of Publication articles (PLSPs) have quickly gained popularity as a publication extender that can make biomedical research more understandable, particularly in the era of open access and the open science movement, which is making biomedical research more freely available to non-traditional audiences. Aimed at non-specialist audiences, PLSPs have built on abstract-style plain language summaries, using non-technical language to provide infographic-style, standalone summaries of published trials and research studies.[2] By increasing the understanding of scientific content, PLSPs have the potential to increase readership and downloads of an original article. Multiple publishers, including Taylor & Francis, Sage, Becaris Publishing, and Adis, now offer the option to publish different styles of PLSPs in their journal framework, providing authors with a choice of journals to submit to across a wide range of topics in healthcare. Despite the positive steps this takes towards patient-centered care, PLSPs present unique challenges for publishers. The first challenge is that the main audience for medical journals are healthcare professionals. This means that even when published, PLSPs aren't always discoverable to genera-lised, non-scientific audiences. Second, with high volumes of health information available online, it can be tricky to distinguish legitimate infor-mation from information that is misleading and inaccurate. How can people without prior medical knowledge or awareness of medical journals trust that what they are reading is accurate and complete? Third, and perhaps the most fundamental challenge, is that patient audiences need to be aware of what PLSPs are in the first place to search for them. Here, we discuss actions that can work towards establishing trust

> It is widely recognised that making biomedical research understandable to non-specialist audiences is vital for promoting patient engagement activities.

and increasing awareness and discoverability of PLSPs with the aim of maximising engagement of patient audiences.

Patient and caregiver perspectives

Patient and caregiver authorship

Including patients and caregivers as authors adds unique insights to PLSPs and establishes trust with audiences who may be encouraged to engage with a publication that includes a representative of their community. Research titled "Who are the authors of Plain Language Summaries of Publications?" presented at the 19th Annual Meeting of the International Society for Medical Publication Professionals (ISMPP) 2023 found that including a patient or caregiver author may increase the general reach and engagement of a PLSP.[3] The research compared the authoship groups and engagement of 72 PLSPs published by Future Science Group between August 5, 2020, and February 28, 2023. On average, PLSPs with a patient or caregiver author (n=10) had higher downloads and Altmetric scores.

Publishers should encourage and facilitate the ethical involve-ment of patients and caregivers in medical publications. It is essential that authorship criteria are followed during the creation of PLSPs. The Good Publication Practice (GPP) 2022 guidelines recommend following the International Committee of Medical Journal Editors (ICMJE) recommendations for authorship criteria for all authors, including patients and caregivers.[4,5] There are multiple resources available online that provide guidance and recommendations for how to include patients in publications.[4,6,7]

It is important for patient and caregiver

authors to be made aware of the implications of any personal identifying information, such as name, disease state, treatment history, etc., being perpetually available on journal websites, indexing services, and search engines. Some publishers may require consent forms to be completed by patient and caregiver authors to ensure they consent to their identifying information being used.

In addition to authorship of a PLSP, patients and caregivers may provide their own perspective on the content of the PLSP. These perspectives can enable patients and caregivers to share their experience rather than limiting the narrative to only facts and statistics. This can help foster trust in medical information and raise awareness of the patient voice. Indeed, similar to patient- or caregiver-authored PLSPs, PLSPs that include a patient perspective section have higher downloads and Altmetric scores when compared to PLSPs that do not.[3] When including perspectives, it is important to recognise that

> *Publishers should encourage and facilitate the ethical involvement of patients and caregivers in medical publications.*

individual patient and caregiver experiences and outcomes differ. PLSPs are tools that can help empower people to draw their own conclusions about their own or someone else's care plan. Therefore, perspective sections should aim to empower readers to learn about the condition and treatment options instead of providing individual conclusions about treatment outcomes.

Patient peer review

As with patient authorship, peer review of PLSPs by patients provides insights into what is relevant and is of importance to the patient community, whilst ensuring the content is clear and the language is aimed at a non-specialist audience. Involving patients in the review process for PLSPs is a vital step for establishing trust in the content and showcases a publisher's commitment to patient-centred publications.

Some patient reviewers may not have worked on a PLSP before or had experience with the peer review process. Publishers may offer guidance to patient reviewers on the purpose and process of peer review, including practical advice on how to submit their review via electronic submission systems, and recognition for the review e.g. via Publons.[8]

> *There are multiple challenges when translating plain language into a different language.*

An ethical question faced by publishers is whether to provide renumeration to patient reviewers for their review. There is debate surrounding paying traditional peer reviewers as it can introduce a conflict of interest; however, it is important to consider that patients are often not part of the research publication pipeline and take time out of their day-to-day lives to review PLSPs.[9] Thus, providing payment to patients for peer reviewing PLSPs supports a larger, more diverse pool of reviewers by removing cost as a limiting factor.

Translations

For PLSPs to have a global reach and be accessible to patient audiences from different countries and cultures, they need to be translated into local languages. Clearly communicating a PLSP in different languages can help readers to fully understand the content, building trust and ensuring people are accurately receiving the information. Currently, there is a lack of research looking at the impact of translations on PLSPs specifically, but previous research has shown that language is a key barrier for engagement across the healthcare pipeline.[10]

There are multiple challenges when translating plain language into different languages. Generally, there are different ways that the same complex sentence can be written in plain language. Sentences from one writer may have a completely different structure and wording compared to another. This also applies when translating plain language into different languages. In addition, the same words and phrases may be considered culturally appropriate or inappropriate across different cultures so would need adapting depending on the target audience. Therefore, the multilingual translation of plain language text may not be a literal translation, but instead nuanced to what makes the most sense in that language and what is most accurate and clear.

Considering these nuances when creating and publishing multilingual PLSPs, it is important to use a systematic approach with multiple rounds

of checks to minimise errors and maximise quality.[11,12] A growing number of qualified professionals specialise in plain language translation of medical publications, as well as publishers who offer these as third-party or in-house services. Using a professional service can help to maximise quality as these services often have inbuilt quality control systems. This quality control may include a review of the initial translation by a second translator, final proofing checks ensuring consistency, accuracy, and completeness throughout the translated PLSP, back translations, localised patient reviews, and mono-linguistic reviews against a plain language brief.

Once published, it is important to consider where the translations will be hosted so that they are discoverable for patients who may not be confident using a journal website. Many publishers have now moved on from hosting content in the supplementary material and instead use better signposting to the translations on the article page and host on platforms such as Figshare.[13] These platforms increase discoverability of supplementary content but are not optimised for audiences with no experience in the publishing world.

Search engine optimisation

When exploring how people discover PLSPs, survey research presented at the 19th Annual Meeting of the ISMPP 2023 showed that out of 17 patients who responded, 41% discovered PLSPs through Google.[14] This may be because patients with no previous publication experience do not use PubMed or publisher websites as a means of finding PLSPs, which tend to be the main routes of discovering traditional journal articles. The same survey discovered that out of 32 healthcare professionals, 41% found PLSPs via PubMed, compared to 12% of patients.[14] Therefore, if publishers can apply best practices for search engine optimisation (SEO) on each PLSP, then it can improve a PLSP's chances of being discovered on Google, making them more findable for patients. This includes optimising the meta data by using key words, for example including the term "plain language summary" in the title of each PLSP. Using SEO brings some challenges as it relies on a person typing these keywords into their search engine, and it is possible that many patients will not be aware of the term "plain language summary".

Patient advocacy groups

Potentially the best way to increase discoverability and awareness of and trust in PLSPs is to share them with patient advocacy groups (PAGs), which represent and support patients and their caregivers living with a specific condition.[15] Patients often rely on these groups as sources of credible information and support, for example, plain language resources about their condition and treatment options. Publishers should be encouraged to share PLSPs with PAGs as they are in a position to disseminate the material directly to patients and on their social media channels, whereas pharmaceutical companies are unable to do this without it being considered promotional. In the 19th Annual Meeting of the ISMPP 2023 survey, alongside 41% of PLSPs being discovered via Google, 18% were discovered through individual recommendations and 12% through social media.[14] Other research has found that the most popular reason that patients used social media for health-related reasons was for social support, such as sharing resources and that social media is an important method for patient organisations to discover research.[16,17] This suggests the power of sharing PLSPs with patients who have relevant networks and are more likely to recommend material to others.

Conclusion

The advancement of patient-centred communication, such as PLSPs, has introduced nuanced challenges for medical publishers, who are now looking to actively reach and engage patient audiences. This requires a multi-stakeholder approach, including patients and their caregivers, translators, PAGs, publication professionals, and many more. To optimise engagement with patients, publishers need to focus on improving discoverability and awareness, and increasing trust in publishers, researchers, and their publications.

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Translating medical reports:
challenges and quality assurance

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Abstract

This article discusses the challenges and quality assurance measures implemented by the authors when translating medical reports. In particular, the authors discuss the challenges posed by acronyms, handwritten and scanned text, and desktop publishing, as well as their use of computer aided translation (CAT) tools, term bases, and bilingual revision in their quality assurance workflow to ensure their translations are accurate.

Introduction

As medical translators, we work with various types of medical documents, but perhaps one of the most frequent and challenging documents we come across is medical reports. We will draw on our own experiences to discuss three challenges we have come across when translating medical reports, as well as three quality assurance measures we implement in our workflow.

Challenge 1: Acronyms

Acronyms are extremely common in medical reports, however despite how frequently they are used, we believe they are perhaps one of the most difficult elements to translate. Unlike journal articles where standard practice is to include the full form of the term when the acronym is first used, this is very seldom the case in medical reports. Medical translators must therefore be familiar with medical terminology in both the source language (the original language) and the target language (the language the text is being translated into) in order to be able to translate medical acronyms effectively, in addition to being able to implement research and technological skills to identify uncommon acronyms.

Unidentifiable acronyms: our experience

We were once translating a medical report for a patient who received treatment abroad and wished to continue their follow-up in the UK. There were several acronyms in the article, some we knew from past experience, and others required some research, but this translation will always be memorable because there was one acronym that we could not identify, no matter how much research we did. For context, the medical report was originally in Spanish and was issued by a cardiologist, we were translating the text into English, and the Spanish acronym in question was "DI".

What did we do?

Usually when we come across an unknown acronym, we will look at credible resources, such as Cosnautas, discuss the issue with colleagues, or search and/or post questions in specific medical translation forums, such as the Institute of Translation and Interpreting Medical and Pharmaceutical Network's e-group. We found many possible translations, but unfortunately, they did not seem appropriate in the context of cardiology, and thus we had to try a different approach. With the patient's permission, we decided to contact the hospital who issued the report directly. The hospital informed us that there was a typo, and the acronym should have been "DL" for *dislipidemia*, or dyslipidaemia in English.

Challenge 2: Handwritten and scanned text

We all know the stereotype that doctors have infamously illegible handwriting. It turns out the stereotype is true in some cases, and despite living in a world with an abundance of technology, there are times when medical reports are written manually with a pen and paper. When the doctor's handwriting is illegible, this can add an "extra round" of translation to the task, as the handwritten text first needs to be "translated" into legible text before it can be translated into another language.

This issue of illegibility also occurs when the source text is a scanned document or a photograph of the original text, as low-quality photographs or scans can result in blurry and thus hard to read text. There is also a possibility of truncated sentences with handwritten and scanned documents due to margins being cut off during the scanning or photographing process.

> When the doctor's handwriting is illegible, this can add an "extra round" of translation to the task, as the handwritten text first needs to be "translated" into legible text before it can be translated into another language.

What can we do?

Standard translation practice is to insert [illegible text] into the translation when the source text is illegible. The translator should of course use their background knowledge and the resources available to them to try to decipher the text before implementing this strategy, because if [illegible text] is inserted too many times, the resulting translation may be incomprehensible, thus defeating the object of the translation task. We believe the translator also has the responsibility to inform the client if they believe the text is not suitable for translation due to the quality of the source text. In such cases, the translator could either refer or collaborate with a colleague who they believe may be able to decipher the text, or even advise the client on how to improve the quality of the text, for example, take photographs of individual sheets of paper without flash.

Challenge 3: Desktop publishing

Desktop publishing is not a skill necessarily associated with a translator, yet it is a useful and sometimes necessary skill to produce a faithful translation of the source document.

When a medical report contains tables or attached images, graphs, etc. this information should also be translated. The aim is to keep the format of the translation as similar as possible to the source text, thus allowing someone who does not speak the source language to look at the source text and the translation side-by-side and understand which part of the source text corresponds to the translation. However, when the formatting is difficult to reproduce, the translator may spend more time desktop publishing than translating.

What can we do?

There is no general solution to this problem. Tables tend to be the easiest element to format, although they may require some alterations as languages tend to have different space requirements. For example, "units" in English is five characters, whereas the Spanish equivalent "unidades" is eight characters, which can affect how much space is required to convey the same information across languages. Images that include text tend to pose a greater challenge. One solution is to copy the original image and super-impose a text box with the trans-lation over the source language text. When there is not much text to translate, this can be an effective solution, however the use of multiple superimposed text boxes can affect

the aesthetic quality or intelligibility of the image. In such cases, adding a legend to the image with the translation of each term can be an effective way to convey the information. If the format is too difficult to reproduce, the translator should try to be as faithful to the original format as possible and add any non-textual information in square brackets or add a translator's note, which is a footnote to explain a specific aspect of the translation.

Quality assurance

Implementing effective quality assurance meas-ures in medical translation is vital, as any mistake could have very serious conse-quences.

> This issue of illegibility also occurs when the source text is a scanned document or a photograph of the original text, as low-quality photographs or scans can result in blurry and thus hard-to-read text.

Computer-aided translation (CAT) tools

While it is beyond the scope of this article to discuss CAT tools in detail, we believe they must be mentioned as they form an important part of our quality assurance process. At the most basic level, CAT tools work by splitting the source text into more manageable chunks, usually sentences or paragraphs, and act as an interface for all the different resources and quality assurance tools used by trans-lators, such as termbases, machine translation engines, translation memories, among others. For more information on CAT tools and their

features, we would recommend reading Routledge Encyclopedia of Translation Tech-nology, and in particular Chapter 3 – Computer-aided translation: systems.[1]

CAT tools and termbases

Termbases, or glossaries, in the context of translation, are bilingual databases of terms and their translation into one or more languages. They are especially useful when translating acronyms, as once the translation of an acronym has been confirmed through research, it can be added to a termbase for future reference, both in the current translation task and in future tasks. Depending on the termbase programme used, additional information can be added to a given entry, for example, we use the termbase feature in the CAT tool Memo Q, and we are able to add images, examples of sentences where the term is used in both the source and target languages, and any additional notes, among other information.

We believe that termbases are more effective when used within a CAT tool as opposed to a stand-alone termbase, because the CAT tool will indicate when a term in the termbase appears in the source text, and it will also create a warning message if the corresponding term in the target language is not used, thus ensuring that terminology is translated consistently and accurately.

While we would recommend using CAT tools to translate medical reports, there are some document formats which are not compatible with CAT tools, particularly the aforementioned scanned documents and photographs, as the

CAT tool is unable to extract the text from the images. There are solutions to this problem, such as optical character recognition software, however it is beyond the scope of this article to discuss this in detail. If a CAT tool cannot be used, the translator can (and should) still use a termbase, but they will need to manually crosscheck the termbase with the source and target document to ensure an accurate and consistent translation.

Bilingual revision of translation

The final quality assurance step that should be carried out, regardless of whether a CAT tool is used, is a bilingual revision of the translation against the source text. This involves reading the source and target text side by side to ensure that the translation has been performed correctly. The translator should first perform a self-check of their own work to ensure the translation is correct, and whenever possible, the text should also be bilingually reviewed by another medical translator. Bilingual revision is listed as a translation workflow requirement in the ISO 17100 international translation standard,[2] and therefore we would always recommend implementing this step. When translators work with Language Service Providers, it is the responsibility of the latter to organise the bilingual revision of the file, but when working with patients or healthcare professionals directly, translators should consider collaborating with colleagues to implement this step.

Final remarks

Based on our own experiences, we have discussed some of the challenges involved in the translation of medical reports, such as the translation of acronyms and handwritten and scanned documents, as well as additional desktop publishing requirements. This list is of course not exhaustive, as translators may experience challenges inherent to their language combinations, as well as the unique challenges posed by individual texts. By using the resources available to them, and by implementing effective quality control measures, medical translators are able to facilitate the communication of information between patients and healthcare professionals across different languages and cultures.

Disclosures and conflicts of interest

The authors declare no conflicts of interest.

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The June 2024 edition

Soft Skills for Medical Writers

Medical writing is a highly specialised field that requires a unique combination of technical knowledge, writing skills, and soft skills to produce high-quality work. While technical knowledge and writing skills are undoubtedly important, it is how one interacts with people that can truly set medical writers apart and enable them to succeed in their careers. This issue will focus on how soft skills are used within the different areas of the medical writing industry, and we hope it will provide valuable insights and inspiration for medical writers at all stages of their careers.

Guest Editors: Clare Chang and Nicole Bezuidenhout

Quality assurance in medical translation

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Abstract

Quality assurance (QA) is an important part of the translation process; its ultimate aim is to ensure that a high-quality translation is produced. Traditionally, QA was very much a task undertaken by humans, but recent years have seen the advent of a variety of automated tools to facilitate the process. This article focuses on QA in relation to medical translation in the language service provider (LSP) setting and provides some examples from human and automated QA. We show that there is a place for both approaches to QA at the current time.

Quality assurance in medical translation

Quality assurance (QA) is an important part of the translation process and aims to ensure a high-quality product that meets the requirements of the party that requested the translation. This article focuses on the processes involving QA in relation to medical translation in the language service provider (LSP) setting and on aspects to consider when performing human QA and using tools for automated QA.

Why QA matters

Medical translations may be required for a variety of reasons: drug registration, adverse event reporting, documentation for patients in clinical trials, instructions for use for medical devices, and scientific research, among others. It is essential that the information is correct to ensure patient safety. Incorrect dosage instructions, for example, may lead to medication errors and poorly translated instructions for use may lead to incorrect device use. Translations of scientific research needs to ensure that the information has been correctly imparted. These examples indicate the need for a rigorous QA process to pick up any errors to avoid such issues, which could result in cost and reputation penalties for the LSP and, indeed, for the client, or compromise patient safety.

The International Standard ISO 17100 "Translation services – requirements for translation services" sets out the specifications to be followed to provide quality translations. Where ISO certification is not present, it is likely that the LSP will very often already be fulfilling many of the specifications and processes described in the standard.

To achieve a quality medical translation, suitably experienced translators and the most appropriate linguist are essential. While a medical qualification is not by any means a prerequisite, for some texts, such as discharge letters, medical reports, or descriptions of surgical procedures, which may be heavily jargon-laden or use abbreviations known only to the initiated, having a medically trained translator can be helpful. Where this is not possible, a third review step by an individual with subject-matter expertise may suffice.

Likewise, for medical devices texts, it may be advantageous to use a translator with a

technical or engineering background. Translations of product information (summaries of product information/labelling/package leaflets) intended for submission to the European Medicines Agency (EMA) require adherence to the quality review of documents (QRD) templates, the associated annexes, and reference documents (e.g., abbreviations, stylistic matters). In addition, Medical Dictionary for Regulatory Activities (MedDRA) terms for adverse reactions/undesirable effects and standard terms compiled by the European Directorate for the Quality of Medicines & HealthCare (EDQM) for dosage forms, routes, and methods of administration, must be followed for the languages in which they are available. Failure to comply with this reference material could result in delayed or denied marketing authorisation for a medicinal product if the translation is not of sufficient quality. These reference documents ensure translation consistency and quality. It is very important that dosage instructions and methods of administration are translated accurately to avoid errors that could impact patient safety. Similarly, for texts intended for study participants, it is important that the correct register is used so that the medical terms are understandable to patients or laypeople.

When the translation is complete, it then needs to be revised by a second translator, with a word-for-word check of the target text against the source text, a process also referred to as bilingual editing. The reviser therefore needs to be equally well qualified or as experienced as the translator, if not more so, depending on the approach used by the LSP. For example, some LSPs may use junior translators who are less experienced but will ensure the revision is performed by a well-established senior medical translator. For language combinations where there are few native speakers with the adequate expertise, a document may need to be translated and revised by non-native speakers of the target language. Typically, this could be the case for translations from the Baltic languages or Hungarian into English. In this case, a review by an English native speaker with subject-matter expertise is strongly recommended, to check the terminology for correctness, and polish the English so that the translation has the requisite quality.

Despite the translator's and reviser's best

> For less experienced translators, seeing the revisions made to their translations can be a useful learning process.

efforts, the translation may still contain errors or omissions and thus final QA steps are necessary to check for various aspects.

These can range from more formal checks, such as running a final spell check and ensuring that the formatting is consistent with the source, to more in-depth checks of the translation against the source text, depending on the processes applied by the LSP and the nature of the document.

In the medical field, eliminating numerical errors is of particular importance in the context of dosages and administration frequency to avoid medication errors. Checks for adherence to mandatory terminology or common errors may also be included at this stage.

A critical part of the QA process is also that any ambiguities or unclear text in the source language are resolved to the greatest possible extent, in particular where there is a potential impact on patient safety, and that remaining doubts are highlighted in the translation. This part may also necessitate further discussion with the linguists involved and/or the client.

With the priority being the delivery of a high-

quality translation to clients, returning the final quality-controlled document to less experienced translators can be a useful learning process.

Typical things to look out for during "human" QA

It is not always possible or appropriate to use automated QA tools in the translation process. When performing "human" QA, it can be useful to consider common or potential problems. The examples given here are based on our long experience of the QA process.

1. Prefixed words with opposite meanings that are easily mixed up such as hypertension/hypotension, or hyperglycaemia/hypoglycaemia.
2. Some terms may be referred to on an alternating basis within the same text and in a similar context and end up being mixed up in the translation, such as "renal and hepatic" and "kidneys and liver".
3. Sometimes, because certain concepts often appear together in a medical text, the translator automatically enters the usual concept, whereas the source might be slightly different (such as "in liver or renal impairment" as opposed to the source "in liver or respiratory tract impairment").

4. Similar concepts and related terms that may appear within the same text may give rise to copy/paste errors or to accepting a suggestion from the memory when using a CAT tool, e.g., "critically ill adults with fever" in one place and then incorrectly used elsewhere, instead of "critically ill children with fever".

5. Similar sounding words may lead to the wrong one being used (e.g. "intravascular" instead of "intramuscular", which could have serious patient safety implications if not picked up, or "pivotal study" instead of "pilot study").

6. The word "not" may be inadvertently over-looked or even added by mistake, and may have safety implications in instructions about how to administer a medicinal product or the population in which it may or may not be used.

7. When checking lists, such as adverse reactions, it is useful to count through them as it is very easy to inadvertently omit one from long lists.

8. Seemingly "insignificant" words may be missed in long sentences, e.g., "at least" in the sentence "… is indicated for the treatment of patients who have progressed after *at least* two courses of chemotherapy for advanced disease".

Where automated QA tools can help and where they can't

The vast majority of translators and revisers work with computer-assisted translation (CAT) tools nowadays. Not all scenarios lend themselves to the use of CAT tools, but where this is feasible, a number of tools are available to automate some QA features. Needless to say, fully automated QA is not sufficient in a field where it is critical to render the meaning of the source text accurately. So what can QA tools do?

- Automated QA tools are a valuable and time-efficient asset to check the final translation output for consistency, i.e., whether the same string of text (or segment) has been translated in the same way throughout the document. Where term bases are available, the QA tool can also be utilised to check for adherence to any mandatory terminology. Similarly, QA checks against translation memories confirm whether consistency with previously translated text has been maintained.

- Automated checks for matching numbers in source and target are an important "safety belt" in a medical context, in particular where dosages are provided to patients. It should be remembered, however, that any automated checks are never 100% reliable. A German case report may be referring to a patient "im 28. Lebensjahr", (in the 28th year of life), which correctly translates as the patient being "27 years of age". An automated QA tool could incorrectly flag this up as a numerical error in the translation.

- Automated QA checks can correct other aspects such as punctuation, spaces, capital letters, and length of segments, and they can be customised further to check for more specific reglularly occurring problmes.

> Needless to say, fully automated QA is not sufficient in a field where it is critical to render the meaning of the source text accurately.

Disclaimers

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

Disclosures and conflicts of interest

The authors declare no conflicts of interest.

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The September 2024 edition

Clinical trial transparency and disclosure

The clinical trial transparency and disclosure space continues to grow at pace. With the EU Clinical Trial Regulation being applicable since the 2022 launch of the Clinical Trials Information System comes increased requirements for public-facing documents. Provision of a summary of clinical trial results in lay language is also now mandatory in the EU. Challenges continue in balancing protection of personal data of trial participants with transparency, especially in the wake of the COVID-19 pandemic. All of these bring opportunities for medical writers to drive best practice in authoring clinical trial documents with disclosure in mind.

Guest Editors: Holly Hanson and Alison McIntosh
The deadline for feature articles is June 1, 2024.

The role of translators:
Adaptation of mental health tests beyond clinical research

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Abstract

This article explores the role of translation and translators within the process of test adaptation. With similarities to the linguistic validation process in clinical research, test adaptation is a complex multistep and iterative process in which linguistic and cultural nuances are an essential aspect. In the context of mental health tests, the impact on individuals can be significant, with far-reaching consequences across various life domains. In this specialised field, translators play a crucial role, contributing their unique expertise and insights on language and culture to help shape the test adaptation.

One of the most exciting fields for translators involves translating instruments, such as questionnaires, to measure mental health aspects in the context of clinical trials. However, this is not the only field where mental health testing is relevant.

This article describes the role of translators and translations in an assessment industry that extends beyond the pharmaceutical and medical device sector. Its applications span behavioural and social science research, education, clinical practice, forensics, organisational psychology, and various other domains.

When we venture outside the field of clinical research, it's impossible not to notice that the terms "clinical outcome assessments" and "linguistic validation" are replaced with the terms "tests" and "test adaptation". Knowledge tests, questionnaires, scales, and inventories are all examples of tests: tools with items, standardised procedures, and established evidence of reliability/ precision, validity, and fairness for measuring behaviour and mental attributes.[1-3] Test adaptation, in simple terms, refers to "moving a test from one language and culture to another".[2]

You might have spotted that the term "translation" is not used. This is because experts in the field prefer "test adaptation" to prioritise intent over content (adaptation) rather than content over intent (what they consider translation to be limited to).[4] For them, the aims of adaptation go beyond aesthetics (how well it reads) and readability (how easy it is to understand). While these aspects are important and desirable, the test adaptation process also evaluates appropriateness in terms of psychometric characteristics.

In general, the test adaptation process aims to produce a test in the target language and culture, measuring the same construct as the original test, maximising fairness, minimising bias, ensuring sufficient reliability/precision, and maintaining validity for the proposed uses.[5] With this in mind, the process includes everything from determining whether an adaptation is needed or even

possible, to choosing translators and conducting validation studies.

What can go wrong?

Let's pause a moment here to paint an image of how this process can fail spectacularly. The best example is seeing what happens if someone administers a test that is not adapted for a certain country/language:

Once, when I was practising as a psychologist in Colombia, my colleagues and I were instructed to administer a language test, specifically a naming test, as part of a routine neuro-psychological assessment. This particular test simply involved showing patients images they had to identify by name, and this is probably why the people in charge thought it would be acceptable to administer the test using the US English version in our Colombian context.

The result? Many patients were unable to recognise the images. "Is that a rat?" was a
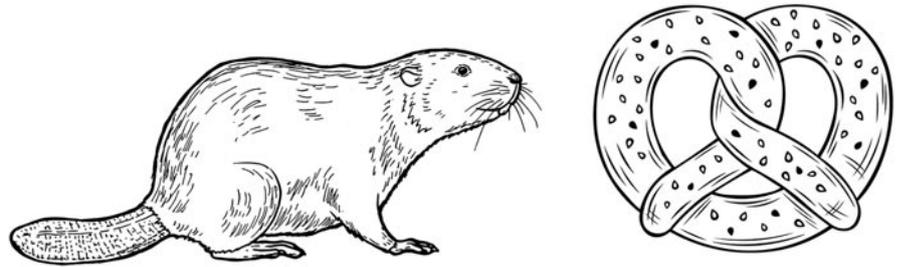
Figure 1. Images of a beaver and a pretzel similar to the ones in the naming test

common answer for the beaver and, better still, some identified the pretzel as a snake (Figure 1)! Granted, some people were able to identify the images – these were affluent patients with previous exposure to US culture. We could have mistakenly concluded that there was a widespread epidemic of

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aphasic patients in the lower-income parts of our city, but what was actually happening was that these items were not truly measuring naming ability; rather, they were reflecting other aspects like socioeconomic status. Any interpretations taken from the scores could not support any kind of diagnosis or recommendation at all.

How to prevent testing disasters

If we want to prevent a testing disaster like in the example above, there's a process that should be implemented and followed.

First, a need should be identified and defined. A test is adapted to a different language or culture because it needs to be available for an applied use (e.g., clinicians need it to assess people with a specific health condition in another country) or to support small- or large-scale research (e.g., international social/ educational research).[4] In the case of our example, it was needed as part of a routine neuro-psychological assessment.

Second, a vital step involves deciding whether an adaptation is the best way to proceed. If a test was originally validated in English for English-speaking test takers, accompanied by English instructions, and administered by English-speaking test administrators in a specific culture, its interpretations are valid only within this particular context. Acknowledging this is essential when deciding whether an adaptation is appropriate.

Continuing with our example, one alternative could have been to just create a naming test from scratch and not bother adapting it. But there are many compelling reasons to adapt a test:

1. Adaptation makes it easier to compare different cultural and language groups;
2. Adaptation can be a cost-effective and time-saving approach compared with developing an instrument from scratch);
3. Adaptation provides an invaluable option when the target country lacks psychometric expertise in the specific subject matter to develop a test locally; and
4. Adaptation expands and leverages the reputation of an established instrument created in another language.

Third, if it's decided that adaptation is the way to go, how should we go about it? What if my colleagues had just decided to search for some alternative images, "adapted" the test themselves to suit their context, and started applying it?

Unlike in research, where there's more flexibility with reliability/precision and validity criteria,[3] in an applied context, this is not an option. Simply translating the test does not automatically make it comparable to the original, and this is not something that can be left as an assumption – it needs to be proved.

Another thing to consider is the characteristics of the test we want to adapt, as all tests are not made equal. To illustrate this, let's take a look at some real examples of mental health tests.

On the one hand, the Beck Depression Inventory-II[6] is a short and straightforward self-report inventory that measures attitudes and symptoms of depression, so would fit with what

If we want to prevent testing disasters, there's a process that should be implemented and followed.

people generally consider to be a mental health test. On the other hand, the NEPSY-II[7] is a lengthy test made up of six domains, each assessing the neuropsychological status in children through diverse tasks, such as imitating hand positions, constructing models with blocks, and looking at faces in photographs. On a completely different dimension, the KIDSCREEN questionnaire[8] measures health-related quality of life in children (like psychological well-being, moods and emotions, and bullying) as part of a European large-scale research project.

These examples paint a good picture of the diversity of the mental health testing landscape: a short questionnaire that a clinician will use as a

Table 1. Linguistic/cultural components of test content

Linguistic/cultural components	Examples of interventions
Currencies	Changing the currency, changing the amount itself, changing denominations (e.g., understanding of dimes, cents, or pennies is heavily influenced by culture and a straightforward currency conversion will not always work).
Measures	Changing measurement system (imperial, metric, US customary system), converting measures, rounding figures up/down (e.g., replacing teaspoons with millilitres or grams in a recipe-related item).
Sport	Referencing sports that are familiar to the test takers (e.g., asking about sumo rules might not be appropriate for European test takers).
Geography	Changing geographical references to more culturally relevant ones (e.g., the number of continents varies depending on the culture and might range from 4 to 7).
Numbers	Considering how numbers are written, how they are verbalised, and their complexity in different languages (e.g., using commas or periods to separate numbers: 20.000 could be a twenty with three decimal zeroes or could be read as twenty thousand).
Art	Using artistic references relevant to the specific culture (e.g., Fernando Botero is a renowned Colombian painter who might not be as well-known in other countries).
History	Changing historical references to more culturally relevant ones (e.g., asking about the Mexican Revolution is an easier question for students in Mexico compared with students in Nigeria).
Daily life	Many items might require significant adaptation or complete replacement as they reference specific education systems, food, animals, activities, etc. (e.g., with regard to opening hours for businesses and shops – in Colombia they typically open at 7 am, whereas in Spain they tend to open at 9 am).

Adapted from Iliescu D. Adapting Tests in Linguistic and Cultural Situations (Educational and Psychological Testing in a Global Context). Cambridge: Cambridge University Press; 2017.

brief screening tool in their practice is not the same as a test with a clear diagnostic aim or a test that is going to be used for international public health research. Aside from the inherent characteristics of the test, there are other variables that play a crucial role in shaping our approach to the adaptation process, especially from a translator's perspective. These include the target population (e.g., children, young adults with intellectual disability, adults looking for a job), the construct being measured, the geographical context of its application, and the mode of administration (e.g., computer-based or paper and pencil).

Fourth, at this point, you might be wondering who determines the correct approach or if there are objective criteria for overseeing this process. The answer is; there are several sets of standards designed for this purpose:

- The *Standards for Educational and Psychological Testing*[1] are considered the gold standard, and they provide definitions for essential concepts such as validity, fairness, reliability/precision, and ethical aspects. This framework also holds relevance in the clinical research context, as evidenced by the *Food and Drug Administration Draft Guidance for Clinical Outcome Assessments*,[10] which references the standards as one of its foundations.
- The International Test Commission (ITC) has established a series of guidelines and checklists for the test adaptation process.[2] In collaboration with the Association of Test Publishers, the ITC has also produced translation/adaptation guidelines for technology-based assessments.[5]
- The *Guidelines for Best Practice in Cross-Cultural Surveys*[11] provide guidance on the questionnaire design and translation/adaptation process for multinational, multicultural, and multiregional surveys. Additionally, Dept, Ferrari, and Halleux[12] explore the various methodologies employed in the translation of large-scale assessments, such as Programme for International Student Assessment (PISA) surveys.

Finally, to check whether the translation ticks the boxes and meets the objectives of the test adaptation process, there are quality control procedures. Outside the clinical trial context, the

> Tests that are not equivalent across languages and cultures can lead to incorrect conclusions and interpretations, with far-reaching consequences on the individual lives of test takers.

approaches implemented go beyond the widely used back-translation: the designs tend to have a more hybrid approach and involve multiple iterations with various steps and checks. This marks the end of the translation phase, but the adaptation process continues with various other activities such as statistical analysis, norming, and publishing, which fall outside the translator's scope.

The role of translators in test adaptation

Test adaptation is susceptible to three distinct sources of error or invalidity:

1. cultural/language differences,
2. technical issues, designs, and methods, and
3. interpretation of results.[9] In terms of their hands-on work, translators are instrumental in mitigating these errors, especially those that pertain to the second category. Within this category, three aspects are of special importance to translators: the test content, the translators, and the process of translation.

The first aspect – test content – refers to the themes, wording, and format of the items, tasks, and questions, and also encompasses administrating and scoring.[1] Our initial example with the beaver and the pretzel is a good illustration of content (stimuli) that needs to be adapted to the target culture and language. Table 1 shows other cultural and linguistic components that might require attention.

The other two aspects – translators and the translation process – pertain to the potential sources of bias and errors that could be introduced by translators. To mitigate this risk, translators must possess expert knowledge of their source and target language and culture, as well as a deep understanding of the content of the test and the principles of testing,[2] as seemingly straightforward decisions can be more complex than they appear at first glance.

For example, the simple act of translating an item that says "tree" can have unforeseen consequences because using the

same word in another language does not guarantee equivalent familiarity, frequency, difficulty (e.g., tree goes from a one-syllable word in English to a two-syllable word in Spanish), or even location of the item in the target language.

Whether "small" details like this are relevant or not depends on the intent behind the item, the underlying construct, and the instructions given to translators. The process of test translation requires numerous nuanced decisions like these. Translators should recognise, address, and communicate these sometimes small but significant details, rather than assuming they are insignificant, failing to document any changes implemented, or making unilateral decisions without consulting the team.

The real impact: Who bears the consequences?

Now that we've looked at tests, test adaptations, and how translators fit into this process, there's one final yet crucial aspect to consider – the context. In research settings, such as clinical trials, a poor-quality translation of a questionnaire can affect the study's ability to assess the efficacy of an intervention or the differences between control and intervention groups, but the results are typically analysed at an aggregate level, not an individual level. Conversely, in the applied mental health field, it's important to consider that poorly adapted tests can significantly affect individuals who are often in vulnerable positions, making the impact all the more real and personal for them.

> Many life-altering decisions, such as those granting access to accommodations, benefits, diagnoses, treatment, economic aid, employment, scholarships, and adoption, often depend on the results of a test.

Tests that are not equivalent across languages and cultures can lead to incorrect conclusions and interpretations, with far-reaching consequences on the individual lives of test takers. Many life-altering decisions, such as those granting access to accommodations, benefits, diagnoses, treatment, economic aid, employment, scholarships, and adoption, often depend on the results of a test.

For translators, we should never lose sight of this as we work.

Conclusion

Tests are highly specialised tools, and mental health tests in particular have a wide range of significant, real-world applications. For this reason, when adapting a test, it's imperative to have a robust procedure in place

and to comply with established guidelines.

Translators represent just one part of test adaptation, but it's an integral part. Our expertise enables us to pinpoint critical language and cultural issues that can decisively inform certain aspects of the process.

The pursuit of validity, reliability/precision, and fairness is an ongoing endeavour, and even after implementing all measures and linguistic quality control procedures, there's no guarantee that equivalence will be achieved. For translators, our primary contribution to the adaptation process lies in minimising the introduction of errors, thoroughly documenting our decisions, and reporting potential issues to other professionals, including subject matter experts and psychometricians, to aid them in their decision-making.

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The author declares no conflicts of interest.

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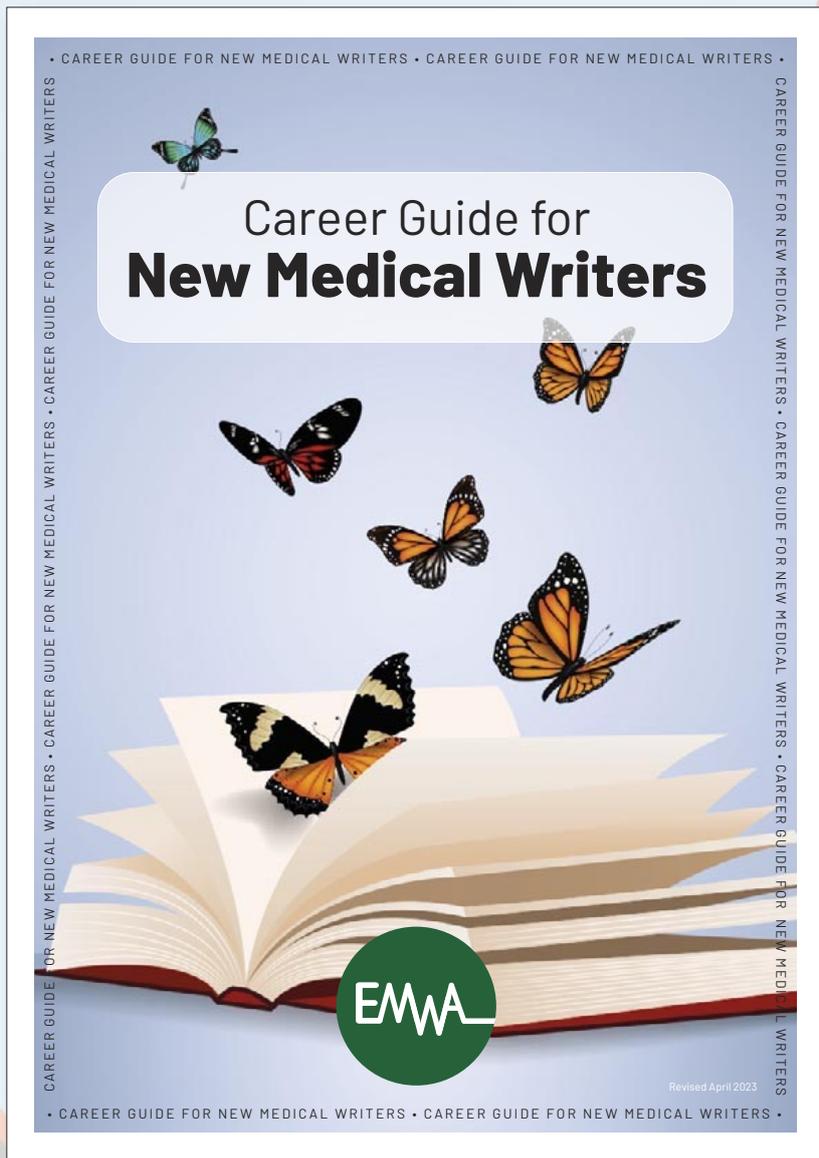
Career Guide for
New Medical Writers

EMWA's Getting into Medical Writing group has created an updated *Career Guide for New Medical Writers*, which is available on the EMWA website. If you're new to medical writing, it's a useful resource that will help you take your first steps on this rewarding career path. You can email us at gettingintoMW@emwa.org with comments.

Translating "medicalese":
The case of informed consent forms

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Abstract

Informed consent forms (ICFs) are documents used in clinical research to inform prospective participants about – and obtain their consent for – partaking in a clinical trial. Evidence suggests that ICFs may not be fit for purpose because their linguistic and textual features exceed the comprehensibility needs of their non-expert target audience. These issues also affect medical translators who translate ICFs for prospective participants of international trials. This article discusses some of the main challenges of translating ICFs, such as specialised terminology and jargon, lexico-syntactic complexity, and text length, and argues for increased training and collaboration to mitigate these difficulties in medical translation.

Introduction

In recent years, demand for medical translation services has risen exponentially, with industry reports ranking healthcare as one of the largest segments of the translation market.[1] A key driver of this growth has been the proliferation of international clinical trials in the life sciences sector, spurred in part by the COVID-19 pandemic, which generated considerable volumes of documents for translation. These texts range in nature and content from highly specialised materials for clinical trial professionals (e.g., clinical study protocols and investigator's brochures) to those concerning patients (e.g., patient questionnaires and informed consent forms [ICFs]). Of these, the latter are essential to clinical trial development as the principal mechanism for obtaining individuals' consent to participate in a trial. Yet, there is evidence that ICFs are not fit for purpose,[2–4] an issue which can be exacerbated when these texts are translated into other languages.

What are informed consent forms?

ICFs are documents used in a variety of healthcare contexts, most notably in hospital settings and clinical research studies, to record a subject's agreement to undergo a particular treatment or care regimen. They are predicated on the principle of informed consent, which in clinical research refers to the "written, dated and signed" decision to "take part in a clinical trial, taken freely after being informed of its nature, significance, implications and risks".[5] They form part of a larger dossier alongside expert-facing texts such as the study protocol, but unlike these documents which are aimed at clinical trial professionals, ICFs address non-experts or lay persons. Since they are based on complex information from the study protocol and other related materials, it is essential that ICFs are adapted and recontextualised for a new target audience.

ICFs serve a dual function: to inform prospective participants about important aspects concerning the trial and to obtain their consent to participate. This two-fold purpose is reflected in the typical structure of an ICF, which commonly includes:

- An **information sheet** outlining aspects such as study purpose, proposed treatment and administration schedule, eligibility and exclusion criteria, risks and benefits, and data protection provisions;
- A **declaration of consent** to be signed by the participant or their legal representative.

The above functions, together with the legal and ethical validity of the consent process, rest on an individual's ability to understand the information they are given and make voluntary and informed decisions about their participation.

However, there is a growing body of research showing that ICFs often exceed the comprehensibility needs of their non-expert audience.[2,3] While several factors contribute to this incompatibility between text and reader, from document length to a lack of visual aids, studies claim that the complexity of the text itself is the main obstacle to patient comprehension. Issues such as specialised terminology and jargon, sentence length and structure, and volume of information all play a role in limiting how well target readers process the information ICFs contain; this, in turn, reduces their effectiveness as vehicles for informed decision-making.

The complex nature of ICFs becomes even more challenging in translation. A considerable proportion of clinical trials are international, multinational, and/or multicentric, requiring that their documents be translated into local languages to facilitate recruiting local participants and running the trial. Yet translating information from one language into another can be complicated when dealing with patient-facing medical texts. There may be asymmetries in the doctor-patient relationship in the local context, as well as differences in the nature of this relationship between the source and target cultures. Medical translators, thus, need to be aware of how medical information is conveyed to patients in the target context and of the norms and expectations governing a doctor-patient exchange, particularly in a context that requires the patient's active, explicit consent.

Challenges of translating informed consent forms

Medical translation has become an increasingly popular specialism, ranking second after the legal

> Medical translators need to be aware of how medical information is conveyed to patients … particularly when a patient's active, explicit consent is required.

specialism among language professionals, according to a 2023 industry survey.[1] This trend is reflected in the rising availability of academic- and professional training programmes in medical translation, which offer instruction in handling a range of medical text genres, including ICFs. This type of training is essential. Not only is this a high-risk, zero-error domain, but it also entails particular challenges that medical translators need to be aware of to successfully mitigate them. We explore the most pressing of these issues below.

Specialised terminology and medical jargon

One of the main challenges of translating ICFs, and patient-facing medical texts in general, is the presence and use of specialised medical terms and jargon instead of more common, lay-friendly alternatives. This encompasses a variety of terminological choices: from medical terms of Greek and Latin origin (e.g., *ecchymosis* instead of *bruise*; *cephalalgia* instead of *headache*) to references to procedures, devices, or processes where lay alternatives might not exist (e.g., *screening, randomisation, interventional trial*). There are also differences concerning how specialised medical terminology is presented, whether it is introduced without being adequately defined or contextualised, or whether the authors used explicitation strategies alongside these concepts.

In these scenarios, medical translators are potentially faced with sourcing lay-friendly alternatives for expert terms, deciding whether to include any additional explanations in the translation which might not be present in the source, and if so, which approach to apply in each situation. This changes the nature of the translation brief and sees medical translators taking an active role in enhancing comprehensibility for patients. Doing so, however, can have a knock-on effect on the translation workflow, as translators may need to conduct additional terminology research, which can impact delivery times and project rates. Medical translators may also need to consult with their clients or project managers as to whether – and which of – these textual interventions would be allowable for their projects and educate their stakeholders about what constitutes an appropriate text for a lay target readership.

Lexico-syntactic complexity

Another characteristic of ICFs that impacts both comprehensibility and the translation process is their complex sentence structure. These texts tend to include excessively long sentences,[6] with multiple subordinate clauses nestled in equally long paragraphs. While these are typical hallmarks of expert-facing text genres, they are not appropriate for lay readers who may struggle to follow the information they contain. Sentences are not only long, but they also can be incoherent and/or inconsistent in order and structure,

requiring medical translators to "untangle" them and streamline the flow of their translations. This, too, can impact agreed-upon budgets and turnaround times, as these editing tasks may fall outside the scope of their translation briefs.

ICFs also pose lexical challenges to translators. Not to be confused with technical jargon, lexical complexity refers to other wording and phrasing that makes these texts difficult to understand. This includes a host of issues:

- Nominalisations and disproportionately using nouns over verbs, often in combination with the passive voice (e.g., *the investigation will be conducted* instead of *we will investigate*)
- Compound nominal and adjectival phrases (e.g., *phase IV, multicentre, open-label, double-blind, randomised clinical trial; recurrent major depressive episodes*)
- Phrasal verbs (e.g., *follow up, fill out, slow down, rule out*), among others.

Lexico-syntactic calque is another major challenge in medical translation. Characterised as a "borrowing" or interference from another language (the source), calque can occur at the word level, producing word-for-word literal translations, or at the sentence level, whereby the translation follows the sentence structure of the source language, rendering the output stylistically unnatural and awkward. Gallego Borghini (2012) provides a comprehensive overview of these risks as well as suggested strategies to

mitigate them in his work on translating English-to-Spanish ICFs for clinical trials and notes that these issues help explain why Ethical Review Boards complain about poor readability and comprehensibility in ICFs and their translations.[7]

Amount of information

Related to lexical and syntactic complexity is the issue of how long ICFs are or should be. Given their legal and ethical functions and the health risks to which prospective participants need to consent to partake in a clinical trial, ICFs contain a substantial amount of information ranging from medical processes and procedures to legal provisions on an individual's rights and data protection. This leads to the "wall of text" problem: Authors of ICFs include too much technical detail, partly to comply with established ICF text conventions and partly to avoid any potential liability by covering all possible bases. Yet, this can have the opposite effect, in that readers might struggle to process and retain essential trial information. Repetitions are also common, whether verbatim or by rephrasing the same content in different ways, which may be confusing to readers. This reinforces the need for medical translators to communicate with their clients and advise them about what may or may not be appropriate for a lay audience.

Lack of standardised international guidelines

A driving factor behind ICF length is the lack of standardised guidelines governing what they should look like. Although the principle of informed consent is recognised in international agreements and legislation,[8,9] there is no overarching legal framework at the European or international level codifying exactly what information ICFs should contain and how they should be written in terms of content, style, and layout. Some international bodies, such as the WHO, provide their own ICF templates,[10] but there is no legal obligation to use them. Most pharmaceutical companies and contract research organisations conducting clinical trials have their own – usually not publicly available – templates and conventions used in compliance with regulatory authority requirements. These templates generally include similar types of in-

> The absence of standardised guidelines for ICF writing makes it difficult for translators to uphold and implement comprehension-enhancing measures for lay readers.

formation but vary from one company to another or across countries or regions. They are also not standardised in the style of the EMA Centralised Procedure Package Leaflets which,[11] while imperfect from a readability standpoint, help ensure uniformity across documents prepared by different pharmaceutical companies, manage expectations about what these documents contain and look like, and provide a tool against which to check whether these expectations are met and, if they are not, hold those responsible for running the trial accountable. In the absence of such guidelines, authors of ICFs and their translators must grapple with both uncertainty and variation, which makes it all the more difficult to uphold and implement comprehension-enhancing measures for lay readers.

The rise of machine translation

A final challenge for medical translators comes from inside the proverbial house: the rise and increasing use of machine translation (MT) in the healthcare domain. Defined as the automatic translation of text from one natural language to another using a computer application,[12] MT has not yet permeated medical translation to the same extent as other specialisms. However, more and more language service providers are integrating custom MT engines trained on existing human translations into their workflows and requiring medical translators to post-edit the output. While this quality training data is likely to help produce better raw translations, MT results tend to be poorer and require more post-editing effort for expert-facing texts or those which are syntactically complex and dense from a thematic and terminological standpoint (author's own translation).[6] With ICFs, MT engines may fail to adequately handle the other challenges inherent in this text genre, adding to the issues medical translators must already contend with when translating patient-facing medical texts. The extent to which MT will be incorporated into medical translation remains to

> For easier-to-understand translated texts for patients, medical translators should combine domain-specific training with pertinent collaborations.

be seen, as is the case for generative artificial intelligence (GenAI) technology, which, nonetheless, shows promise for simplifying complex information and, thus, may find applications in streamlining medical texts for patients, including ICFs.

Looking to the future

To overcome these challenges and work towards producing better, easier-to-understand texts and translations for patients, medical translators should seek to combine domain-specific training with collaborations with colleagues and industry stakeholders.

Training for medical translators

It goes without saying that medical translators require excellent knowledge of medical or health-related terminology and concepts in addition to linguistic skills. Research shows most medical translators are either medical experts with knowledge of other languages or trained linguists without formal medical education but who have specialised in medicine through professional practice and training.[13] Supplementing this existing knowledge with training and continuous professional development is paramount to keeping up with the latest developments in a fast-paced, rapidly changing, and highly technical field such as medicine.

Medical translators could also benefit from training on plain and inclusive language to begin considering the health literacy needs of their target audience and adapt their translation choices accordingly. Knowing what is appropriate for a lay target readership in terms of lexis, syntax, style, and visual layout can empower translators to improve the comprehensibility of their translations and advocate for more readable and lay-friendly source texts to their clients and project managers. Technology training would also help medical translators become attuned to the types of errors MT engines are susceptible to, and thus improve their post-editing performance, raise awareness of responsible MT use in the medical domain, and experiment with tools such as AI or speech recognition which may help improve the comprehensibility of their translations.

> Knowing what is appropriate for a lay target readership in terms of lexis, syntax, style, and visual layout can empower translators to improve the comprehensibility of their translations.

Fostering collaboration

Of course, these efforts need to be supported by joint initiatives and collaborations between all parties involved in writing and translating clinical trial documentation: from trial sponsors and clinical research organisations to national and international health regulators, such as the EMA, and medical translators and patients themselves. Understanding patients' needs and establishing robust legal frameworks and best practice guidelines to ensure these needs are met are essential for upholding the legal and ethical validity of the informed consent process and delivering a healthcare service that better serves its patients. Effective medical writing and translation take this goal further by providing additional safeguards in support of a patient's right to be given accessible information they can easily understand, ensuring that the consent these patients give is indeed voluntary, free, and informed.

Disclosures and conflicts of interest

The author declares no conflicts of interest.

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Google Scholar: https://scholar.google.com/citations?user=XC8jXyMAAAAJ&hl=en

Speaking your patients' language – Is it really worth it?

The impact of translation on multilingual patient education materials

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Abstract

This article discusses the role of translation and its impact on the success of patient education materials, particularly in the context of patient recruitment and retention for clinical trials. We examine how translation and localisation help foster trust, ensure safety, and increase efficiency, improving recruitment, retention, and regulatory compliance in trials which are becoming increasingly diverse. We also discuss inherent challenges and considerations and look into the future.

Introduction

Clear, accurate, and informative patient education materials are foundational to a well-run clinical trial. Ethically, patients need to fully understand what they are signing up for – the potential benefits, risks, and burdens. From a practical perspective, building trust with participants early on and throughout will also benefit the study as a whole. Good patient education materials improve comprehension and compliance and save time on duplicated explanations, questions, and answers, not to mention increasing the likelihood of enrolment.[1]

So where does translation come into it? Well, in a global trial, language is a major consideration for communication with patients – arguably just as important as the drafting of the original materials, a phase generally given much more time, resources, and weight.

"Patients' stories are the living testimonies of how well-translated materials transformed clinical trials into journeys of understanding, trust, and hope," according to one patient recruitment manager.

Why so important? Try reading the first paragraph above again. If we can agree these statements are true for English-speaking participants, why would they be any less true for speakers of other languages? And how can you hope to produce clear material that helps to engage and build trust, without producing it in the participant's native language? The results of one study evaluating this area seem categorical: 49.1% of adverse events affecting patients with limited English involved some physical harm (the corresponding figure for English speakers was 29.5%), with 52.4% of the former deemed to be the result of communication errors (compared to 35.9% for proficient English speakers).[2]

And this is before touching on the impact of better engagement on other tangible metrics like Return on Engagement (ROE).

"Recent return on engagement (ROE) research from Gallup reveals that brands who successfully engage their customers go on to see 63 percent lower customer attrition, 55 percent higher share of wallet, and 50 percent higher productivity," according to Global Chief Executive Barbara Lopez Kunz, of the Drug Information Association (DIA). "Our experience and collected data point toward ROE benefits as being significant in healthcare product development as well."[3]

The diversity of people taking part in clinical trials is a growing topic of discussion within the sector, particularly following examples such as that of Clopidogrel in the UK.[4] Gone are the days (woefully recent though they are) when it was acceptable to run trials based on homogenous groups of men only.[5] It is now generally accepted that, to effectively test the potential efficacy of a drug, participation should be reflective of real-world populations and especially include those most likely to use and/or benefit from the drug in practice. Different populations react differently to the same drug – both in terms of safety and efficacy – not to mention that equitable access is an important goal in and of itself. Although the numbers relating to diverse participation remain relatively uninspiring for now,[6] new legislation on both sides of the pond is likely to positively impact these figures in the near term,[7,8] meaning diversity is on the increase (hopefully rapidly). Diversity of participants begets diversity of

> Communication is at the cornerstone of clinical trials.

language and communication. And language and communication barriers can have a significant impact on the recruitment process. By translating these materials, we facilitate broadening the scope of potential participants and foster a more inclusive environment.

"[Language barriers] translate into a possible decrease in trial recruiting and trial screening," says medical oncologist Mohana Roy at Stanford University's School of Medicine. "Communication is at the cornerstone of clinical trials."

And so – for all the reasons above and others – a clear translation strategy, well-embedded into your larger processes (and not as an afterthought) becomes key to creating impactful patient education materials and, ultimately, running a successful clinical trial.

"Translation isn't just about words; it's about including bridges of understanding, opening doors to engagement, and welcoming diverse voices that strengthen the foundation of recruitment," says Conversis CEO Craig Harrison.

Going beyond translation

Translation itself – while a step in the right direction – really only scratches the surface in terms of catering to specific audiences. To achieve meaningful impact, you will need to *localise* your materials, i.e., take into account participants' geographic location, lived experience, cultural context, and other factors that will influence how they receive and process information. For example, think about the health literacy of your target populations: the US National Assessment of Adult Literacy (NAAL) has found that 53% of US adults have "intermediate" health literacy, with over 35% at basic or below-basic levels.[10] What about general literacy? Based on a 2015 OECD survey, 1 in 6 UK adults have literacy skills below Level 1 – equivalent to an 11-year-old at most![11] There is little point creating content – in the first instance *or* via translation – full of medical jargon and complex imagery, if a significant proportion of the people reading that material are left with a partial understanding at best! And it's important to bear in mind that the chasm between literacy rates in the US and UK
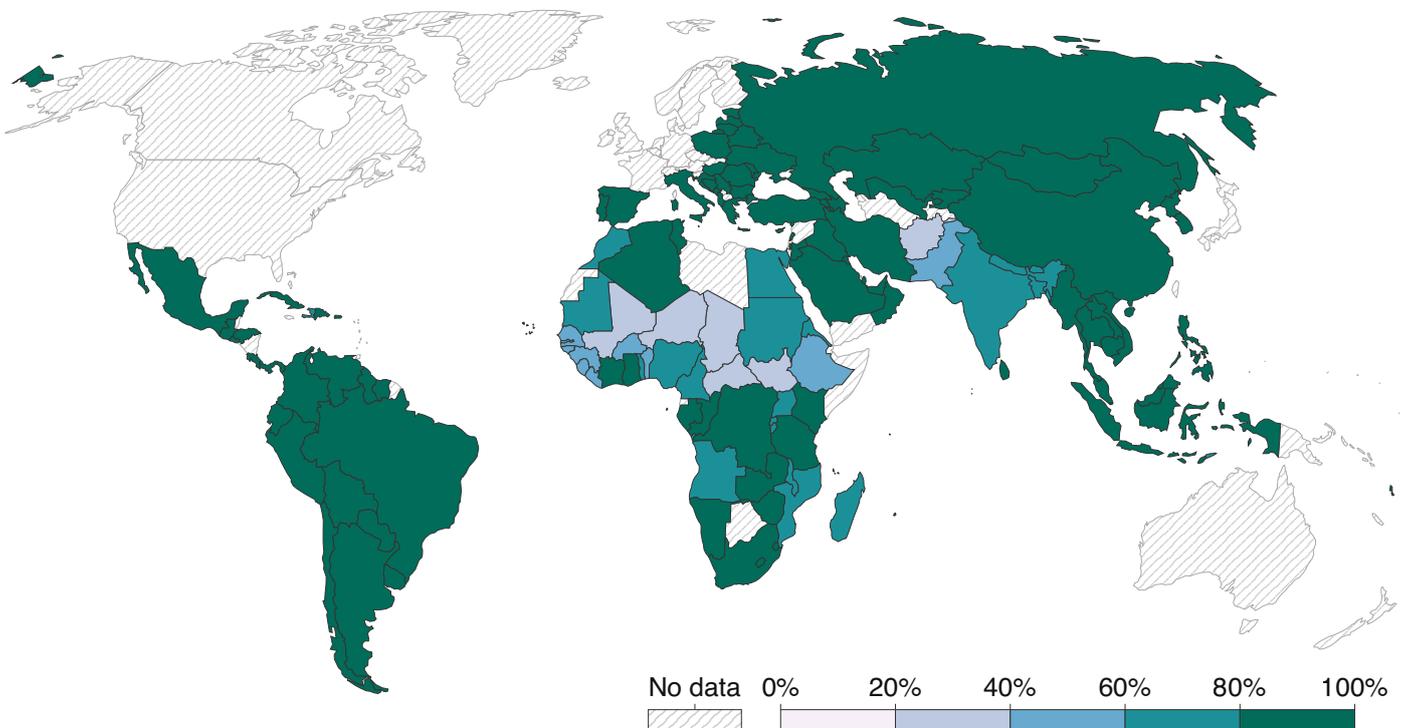
Figure 1. 2015 figures for global literacy rates among adults

The share of adults aged 15 and older who can both read and write

Data source: UNESCO Institute for Statistics via World Bank (2023) https://uis.unesco.org/en/terms-and-conditions?wbdisable=true

Note: UNESCO defines literacy as reading and writing brief daily life statements. However, criteria vary by country, and North American and Western European data uses more detailed assessment so isn't globally comparable.

Table 1. Forecast of population changes in the US
The non-Hispanic White population is projected to shrink by nearly 19 million people by 2060

	2016		2030		2060		Change from 2016 to 2060	
	Number	%	Number	%	Number	%	Number	%
Total population (in thousands)	**323,128**	**100.0**	**355,101**	**100.0**	**404,483**	**100.0**	**81,355**	**25.2**
One race								
White	248,503	76.9	263,453	74.2	275,014	68.0	26,511	10.7
Non-Hispanic White	197,970	61.3	197,992	55.8	179,162	44.3	-18,808	-9.5
Black or African American	43,001	13.3	49,009	13.8	60,690	15.0	17,689	41.1
American Indian and Alaska Native	4,055	1.3	4,663	1.3	5,583	1.4	1,528	37.7
Asian	18,319	5.7	24.394	6.9	36.815	9.1	18,496	101.0
Native Hawaiian and Other Pacific Islander	771	0.2	913	0.3	1,125	0.3	354	45.9
Two or more races	8.480	2.6	12,669	3.6	25,255	6.2	16,775	197.8
Hispanic	57,470	17.8	74,807	21.1	111,216	27.5	53,746	93.5
Native-born population	**279,283**	**100.0**	**301,318**	**100.0**	**335,150**	**100.0**	**55,867**	**20.0**
One race								
White	222,942	79.8	232,638	77.2	236,955	70.7	14,013	6.3
Non-Hispanic White	189.896	68.0	188.169	62.5	165.964	49.5	-23.932	-12.6
Black or African American	38,345	13.7	43,013	14.3	51,195	15.3	12,850	33.5
American Indian and Alaska Native	3,465	1.2	4,036	1.3	4,975	1.5	1,510	43.6
Asian	6,377	2.3	9.373	3.1	17,289	5.2	10,912	171.1
Native Hawaiian and Other Pacific Islander	576	0.2	686	0.2	866	0.3	290	50.3
Two or more races	7,578	2.7	11.572	3.8	23,869	7.1	16,291	215.0
Hispanic	37,819	13.5	51,466	17.1	83,971	25.1	46,152	122.0
Foreign-born population	**43,845**	**100.0**	**53,783**	**100.0**	**69,333**	**100.0**	**25,488**	**58.1**
One race								
White	25,560	58.3	30,815	57.3	38,059	54.9	12,499	49.9
Non-Hispanic White	8,073	18.4	9,823	18.3	13,198	19.0	5,125	63.5
Black or African American	4,656	10.6	5,996	11.1	9,494	13.7	4,838	103.9
American Indian and Alaska Native	590	1.3	627	1.2	609	0.9	19	3.2
Asian	11,942	27.2	15,021	27.9	19,525	28.2	7,583	63.5
Native Hawaiian and Other Pacific Islander	195	0.4	227	0.4	259	0.4	64	32.8
Two or more races	902	2.1	1,097	2.0	1,386	2.0	484	53.7
Hispanic	19,652	44.8	23,341	43.4	27,242	39.3	7,594	38.6

Note: The official population estimates for the United States are shown for 2016; the projection uses the Vintage 2016, population estimate for July 1, 2016 as the base population for projecting from 2017 to 2060. Percentages will not add to 100 because Hispanics may be any race.
Source: U.S. Census Bureau. 2017 National Population Projections.

versus countries predominantly speaking other languages can be vast! These are by no means among the worst-case scenarios![12]

Another thing to consider may be the historical context of clinical research within a community: for instance, the shameful example of the Tuskegee Syphilis Experiment.[13] Such examples might go some way to explaining the continuing reluctance of certain communities to participate in clinical trials at all! The importance of this kind of context is why we always recommend translation and localisation is completed by an expert from within the relevant community – for instance, content for the Mexican diaspora in the US should be translated by a Mexican Spanish native speaker living in the US. These experts can advise meaningfully on tone, cultural context and appropriateness, localise accordingly and avoid specific pitfalls, to ensure content has maximum appeal and effect.

Beyond initial recruitment, quality translation can also be a major factor in retention, curbing dropout rates by keeping patients engaged and well-informed throughout the study. The generally accepted statistic is that 30% of patients recruited to a clinical trial drop out,[14] with about 40% of those dropouts being avoidable. It also

costs nearly 3 times as much to replace a dropout as it does to recruit an individual in the first place.[15] In one survey, 35% of dropouts cited difficulty in understanding as their primary reason for leaving a trial, while some of the main motivations for continuing participation were that expectations had been set clearly and importance explained.[16] It seems obvious here that clear communication from the start and throughout is among the simplest and best ways to recruit and, crucially, *retain* participants (with everything that implies diversity, language, and translation).

From a more prosaic perspective – though no less important in terms of overall success, as some will know to their detriment – translation can facilitate

> Translation serves as the compass guiding patient education materials through the complex terrain of international regulations, ensuring that compliance paves the way to safer and more inclusive clinical trials.

compliance with the international regulations that apply to patient education materials. Take, for instance, the COVID-19 vaccine trials. For just one of the many COVID-19 trials Conversis worked on, we translated English into six South African languages and four Philippines dialects! The sheer scale of the pandemic necessitated wide-ranging expertise in international regulation. Deadlines for various national and transnational bodies had to be met; there was certainly no time to spare for rejected submissions! Translation serves as the compass guiding patient education materials through the complex terrain of international regulations, ensuring that compliance paves the way to safer and more inclusive clinical trials.

Where the challenges lie

So far, the positive impact of translation on multilingual patient education materials seems obvious. But the translation of medical content is not without its challenges. Here follow just a handful of the very many, varied challenges we have encountered over the last 20 years.

- Handling highly specific terminology is tricky on many levels. Some especially tricky instances include: where the terminology just does not exist in a given language, as a certain condition has never been discussed in that community before (happens more often than you might think); or translating said terminology for a layperson or patient, and having to bear in mind both technical accuracy and basic understandability.
- Guaranteeing accuracy – This is diifficult to do wherever humans are involved, and even more essential *because* humans are involved! We have quality management systems, independently audited processes, key

performance indicators, a dedicated QA function, and work with experts only.

- Adhering to varying in-country regulations – This is particularly tricky when translating for the 27 countries of the EU. We handle this in a variety of ways, including the creation of country-specific source texts – for example, removing all mention of reimbursement for South Africa or any language which may be seen to actively encourage people to take part in a clinical trial in Turkey.
- Tight timelines – We all know how it goes. Source content is tweaked, refined, updated, and amended right up to – and beyond – the timeline in which in-country recruitment is due to start. Then translation is commissioned, when already late, and the recruitment window grows smaller and smaller until said country is abandoned as no longer viable. We work with our clients to incorporate translation into all their workflows, so it becomes a part of the process, rather than an add-on. This means timelines are anticipated up-front, and those mad dashes at the end are – more often than not – avoided.
- File and submission conventions – The format requirements of ethics committees and various authorities can be tedious and labour-intensive. Think footer formats, file

naming requirements, and bookmarking. We have created custom tools to automate these manual processes – saving billable time and avoiding the human error that can be caused by rote work of this type.

Clearly, challenges exist. But we've seen above the far greater value of the end goal, and that none of these obstacles are insurmountable – with experience and the will to innovate. If it were easy, everyone would be doing it. If it were of less value, far fewer of us would bother!

Future outlook

We've illustrated some of the difficulties we have faced and found solutions for in the past. But what about the challenges of the future? What is the outlook going forward for medical translation in patient education?

AI and machine translation will almost certainly improve and become a more viable option for facilitating medical translation. And Conversis, and others like us, will continue to develop tools to solve recurring problems. But most important will be the shifting demographics of patient populations, influenced by globalisation, decentralised trials, changes to regulation, and gradual population change.[17] For us, this will mostly mean an increasing need to

keep abreast of local changes, new regulations, and shifting demands for specific language pairs within specialities. It will mean making sure we have the people we need, with the experience, expertise, and context to hit the ground running as soon as we feel the next shift coming.

The greatest tool available to the life sciences sector as we move into this changing future will be collaboration! We're hearing it again and again from clients and at conferences. The sector as a whole needs to collaborate more and better. We need to streamline the systems of approval and work more smoothly cross-functionally. This is as true of language and translation as it is of any clinical trial function. Collaborative efforts between medical professionals, healthcare providers, language experts and patient advocates are crucial to the success of us all and to our collective role in crafting multilingual patient education materials.

One thing that is not likely to change anytime soon is the importance of producing targeted, multilingual patient education materials that work. As we've seen, these materials, when done well, can improve recruitment and retention rates, boost comprehension, keep people safe, and lead to greater engagement throughout the clinical trial lifecycle. There are many challenges to getting it right; challenges which are likely to grow more complex and varied as we move into a future of constant change. And so, we must strive for perpetual improvement and expansion of our offerings and solutions in the space; we must continue innovating and embracing these challenges head-on. The benefits so heavily outweigh the difficulties, there is no question – certainly in our minds – as to whether that effort is worthwhile.

Disclosures and conflicts of interest

The authors declare no conflicts of interest.

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Translating medical devices:
A rule-driven game

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Abstract

Translation for medical devices often presents a unique set of challenges arising from the products' complex natures and associated regulatory requirements. Beyond medical expertise, linguists – from translators and editors to bilingual quality assessors – may require strong software localisation skills and knowledge of intricate engineering topics. Supply chain audits related to medical devices can, in many cases, demand more extensive compliance measures for language service providers than those required by most other clients.

What is our playing field?

We use medical devices every day. From contact lenses to blood glucose monitors and X-ray machines to defibrillators – these devices are all around us, revolutionising how we manage our health and improving our quality of life. The global market for medical devices was projected to reach US$471.80 billion in 2023.[1]

The European Union's Medical Device Regulation 2017/745 (EU MDR)[2] defines medical devices as "any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for… medical purposes." A comprehensive list of purposes follows.

Some teams in language services perceive the life sciences industry as a single entity. They group together pharmaceuticals, biotechnology, healthcare, and medical devices. However, it is crucial to recognise and differentiate between the various areas within this domain.

In the world of translation, our medical devices playing field includes software tools, packaging, user manuals, marketing materials, technical specifications, engineering drawings, labels, instructions for use, distributor information, legal matters, clinical trial-related texts, training materials (both e-learning and instructor lead), implementation information, websites, phone application content, and more. That means a broad authorship and readership and a wide variety of writing styles.

What are the rules?

Importing and distributing medical devices to countries around the world is subject to strict approval processes and compliance measures. Compliance is how medical device companies insulate their patients and business from risk. While internationally recognised systems are helpful in meeting many compliance needs for manufacturers, it is important to note that no single system is universally applicable. Due to varying regulatory requirements between countries, parties cannot rely on generic guidelines being suitable for a specific market. This contrasts with the situation for pharmaceuticals, where standard templates and the structured Common Technical Document[3] apply for major global markets and simplify the translation process.

The rules keep on changing

From market to market, change is the only constant. The past year or so has been dominated by changes resulting from EU MDR, and indeed, implementation delays. In the past, medical devices needed only to provide translations after a device earned the CE mark. This is changing in an effort to improve patient safety, and many documents required for the new approval process must now be translated into all 24 official EU languages prior to that approval process. This means that translation enters the product development process earlier, and translation partners may find it easier to involve themselves upstream. Specifics of language requirements for each country are now available.[4] That's the new EU regulation. But the EU is only one part of the large global market.

Good practices (GxP) guidelines by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)[6] and the International Medical Device Regulators Forum (IMDRF)[7] documents are broadly applicable. ISO 14155: 2020 is the standard relating to Good Clinical Practice for medical devices. FDA requirements such as 21 CFR Parts 11 and 820 apply in the United States.[8] Add to the mix privacy-related regulations such as the US HIPAA and EU GDPR. Other smaller markets have their own regulations. The UK, post-Brexit, will implement its own device regulation but has delayed implementation and is extending acceptance of CE marks at this time.[9] Harmonisation efforts have had success but will not replace each locale's regulation.

Regular referees

Most readers will be familiar with ISO 9001, a generic quality management system standard that can apply to any organisation. ISO 13485:2016, "Medical Devices, Quality Management Systems, Requirements for Regulatory Purposes," has a stronger focus on medical device safety, traceability, and risk management. Many translation buyers will audit providers to the standards of ISO 13485 as they relate to service providers. We now also see reference made to ISO 14971.[10] "Medical devices, Application of Risk Management to Medical Devices," which goes even further to help companies systematically implement best practices that reduce risk.

Who is playing?

Who are the clients? Manufacturers, distributors, and other interested parties, of course. And who is translating? From small buyers using individual freelancers to translate one language pair to global giants with multimillion annual spends in programmes handled internally or through one or more large language service providers (LSPs), there's no one answer. What is common to all, though?

Subject matter experts

How well the team understands the device, how it is used, and the regulations for the target markets the manufacturer is selling in make all the difference. That begins with the linguists and extends to encompass the entire team.

Medical expert linguists are key players and ideally have a life sciences background. However, this may not be sufficient to fulfil manufacturers' needs for a successful translation programme. Add awareness of differences between devices, small molecules, and biologics, to strong knowledge in the specific domain at hand. Add experience with software localisation processes to clinical understanding. Engineering drawings and technical specifications can also call for significant expertise beyond the basics. These linguists are players who are highly knowledgeable domain experts.

Machine translation?

Some try to add AI as a player here. While this may be useful for particular functions, any medical device manufacturer incorporating AI without expert human defenders on the field is adopting an extremely high level of risk. Human expertise is required to oversee and regulate the use of AI in medical device manufacturing for safety and efficacy reasons.

Some governments are stepping in here, mandating a human component to enhance public safety. For instance, in 2022, the US Department of Health and Human Services proposed a Rule[11] stating that a qualified human translator must review machine translation if an entity uses machine translation for text that is critical to the "rights, benefits, or meaningful access of a limited English proficient individual; when accuracy is essential; or when the source documents or materials contain complex, non-literal or technical language".

How do you score?

Let's not linger here on areas that apply generally to any translation and localisation project, such as suitability for the target audience in each locale or wise use of translation management systems and language assets. Those are basics. The work of translation providers for medical devices goes beyond that and is part of successful regulatory submissions.

Speed to market

Fluid processes can help with regulatory approval and speed to market. It helps if manufacturers' content management systems align with translation management systems so that systems integrate with the necessary regulators' databases and data flows smoothly.

Plain language

The ideal of using plain language to reach a target audience effectively is not unique to medical devices, but here, it is regulated, and the best providers will produce it every time. The EU MDR says that information given to the subject "shall be kept comprehensive, concise, clear, relevant, and understandable." The regulation also refers to the intended user: what is easily understandable for a healthcare provider and for a patient will of course often differ. Depending on how far the original content diverges from target audience expectations, this may require extensive rewriting, shortening or restructuring of the information. That means that linguists

must know what plain language is and is not in their target locale, which limits the talent pool.

Continuous improvement
Great translation providers help clients surpass a quality baseline and achieve continuous improvement. They point out inconsistencies. They are aware of the regulations and are translating with deep knowledge of the purpose of every document or software string. They help the client get to the next level.

Compliance
Providers could be audited to any of the quality management systems mentioned above, as far as they apply to service providers. Partnering with translation companies that have gone to the extent of becoming certified to a quality management system for medical devices, such as ISO 13485:2016, provides additional confidence for many manufacturers.

Who are the champions?
So who wins the matches on this playing field? Providers and manufacturers who form genuine partnerships are the true champions here. We talk about top-notch quality and effective processes for any translation, but few outside the life sciences sphere understand the extent to which these partners grow together to serve patients well with medical device and related stakeholders. That is perhaps why language service providers like the one I work for, Vistatec, have set apart their Life Sciences business units. They recognise that translating for this domain

requires special workflows, domain expertise, and linguistic talent with additional quality assurance measures.

It's inspiring to support the global medical device market. It's also a privilege to know that our work helps to improve patient care all around us – in any language, anywhere, on any device. May we enjoy that privilege through many iterations of changing regulations, covering global playing fields day in, day out.

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The author declares no conflicts of interest. All opinions are hers alone.

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The December 2024 edition

Medical Writing Around the World

Medical writing transcends geography, demography, language, and culture. To date, EMWA has over 1400 members from 48 countries on 6 continents, and we want to celebrate the diversity and global presence of the medical writing community. In this issue, we will focus on medical writing activities around the world and will delve into topics like the benefits of having geographically diverse teams, translation and language-specific challenges, the landscape of global freelance medical writing, etc. We hope that these insights will assist the medical writing community in strengthening interactions and collaboration with teams and freelancers spread across the world.

Guest Editors: Asha Liju and Evguenia Alechine
The deadline for feature articles is September 1, 2024.

Localisation of promotional materials for pharma

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Abstract

Unwarranted changes by the client, lengthy approvals, and multiple rounds of revision – localisation of promotional materials for pharmaceutical companies can become a nightmare if the localisation specialist is unaware of heavy regulations in the industry. The goal of localisation is not only to convey the meaning in the target language, but also to adapt the content for another country or region. When localising promotional materials for the pharmaceutical market, the secret to success lies in placing them in a wider context and accounting for additional factors such as content creation workflow and the intended use of the materials.

This article outlines the key features of pharmaceutical marketing content, addresses the content creation steps and where localisation fits in that process, highlights the benefits of working with an individual who is both a medical writer and translator, and offers insights into reducing the number of revisions and improving the localisation outcome.

Types of documents

Promotional materials for pharmaceutical companies are content localised to promote drug products in various markets. This article refers to all forms of promotional materials, including:

- Slide sets, including eDetailers
- Brochures and leaflets for doctors (to give out at conferences or calls) and patients (point of sale materials) and other advertisements
- Emails
- Promotional posters

- Website content (including interactive or gamified content)
- Promotional and educational videos and animations
- Press releases

As seen above, there is quite a range. What is the main common feature of all these materials that might play a crucial role in localisation? The answer is…regulatory compliance. All communication between pharmaceutical companies and healthcare professionals or patients is strictly regulated, and the regulations are market-specific, not language-specific. These regulations include laws of advertising and codes of practice developed by associations for the pharmaceutical industry. The most widely used and adapted code of practice is maintained by the Association of the British Pharmaceutical Industry.[1] Below is a list of the key requirements from this code:

- If the communication promotes a specific medicine, it should include the product's name, as well as information about its uses, risks, and benefits.
- The communication should not contain any inducements or incentives that could be seen as promoting the prescription or use of a particular medicine.
- The communication should be accurate, balanced, and not misleading.
- The communication should be up-to-date and reflect current evidence-based medicine.
- All statements and numbers should be referenced with trusted quality sources.
- The communication should not include any statements or claims that are likely to encourage inappropriate prescribing or use of medicines.
- The communication's tone should be respectful and professional, and the communication should not use language or images that could be perceived as disrespectful or offensive.
- The communication should be clearly identifiable as originating from a pharmaceutical company and should not be presented in a way that suggests it is independent or unbiased.
- The communication should be appropriate to the recipient's role, expertise, and level of responsibility.

Compliance is ensured from the very beginning of the marketing campaign. Some of the above points are more relevant to content creation, while others apply directly to the localisation phase. Since the requirements are market-specific, the global team cannot possibly know of all the nuances and create a global copy (usually in English) that can be simply translated without adjustments. The latter may include adding the locally approved doses, dosage forms, national clinical guidelines; updating the prescribing and dispensing procedures; and amending the patient

portrait or the speciality of the prescribing physician. Therefore, global content creators focus on the target audience, key messages (their meaning, not the wording), and the evidence. It is the responsibility of the local team to adapt the materials to local requirements.

Consider, as an example, the following statement: "The communication must not contain any inducements or incentives that could be seen as promoting the prescription or use of a particular medicine." Global text for localisation may read, "This study has shown that the drug is effective." While a direct translation may be used in some markets, the localised version for a highly regulated market would be revised as, "This study has shown that the drug has an acceptable efficacy profile." Note that even the verb form has been changed to make it clear that the material is simply citing past findings and not making claims about possible outcomes. Some regulators even prohibit the phrase "efficacy profile", which would be revised to something like, "Admini-stration of the drug has been associated with favourable outcomes."

Creation and localisation process

Before we look at more text examples from real-world projects, let's take a look at the main steps of the content creation process and the roles involved, as shown in Figure 1.

Can you spot the weak link? Localisation is either outsourced or takes place at the local office rather than at headquarters where global content are created. As a result, the localisation team is not aware of all the discussions and approvals that took place in the previous three phases. They should also be aware of the potential pitfalls in the upcoming local approval step (you will find examples in the next section). Local approval is more important

Planning	Content creation	Approval by global team	Localisation	Approval by local team
• Marketer • Product manager • Designer • Content creator	• Content creator • Designer	• Product manager • Marketer • Medical science liaison • Lawyer	• Localisation team	• Product manager • Marketer • Medical science liaison • Lawyer

Figure 1. Localisation process

because local requirements may differ from global ones and cultural differences may play a major role.

The benefits of training as both a medical writer and translator

I learned the shortcomings of the localisation process the hard way. My first marketing content localisation went like this: I received the global copy along with a brand book for designers that contained little information relevant to the content. I translated it accurately and fluently. However, the project manager forwarded me a set of comments from the client that seemed highly preferential. Below are some examples to illustrate this. The examples include the English source text and the back translation of the approved localised text (instead of the localised text itself) to account for the multilingual audience.

Which changes should and can be accounted for during localisation?

After reading about the regulations and compliance, you may have noticed why some of these changes were warranted. At the time, I felt a bit lost as a medical translator because I was not taught this. Fortunately, the agency I was working with was very professional. We compiled some kind of a style guide by comparing the updated versions with the original translations and gradually reduced the number of revisions.

Years later, I became a medical writer, received basic training at a medical communications agency, and remembered those pitfalls. Today, when I localise promotional materials for the pharmaceutical industry, I adapt my translations to local requirements and bring added value to the client.

Another potential obstacle is that the client may outsource translation without receiving an adequate brief on the target audience, the purpose of the content, and the desired outcomes of the marketing campaign. Sometimes the client is simply unaware that the translator can customise the content along with translation into the local language. Sometimes the client has already had an unpleasant experience with localisation and is prepared to take on extra work because some adaptation of the global copy is needed anyway due to country-specific clinical practice nuances or cultural differences. As a medical writer, I am also now used to the client sometimes changing 20% to 30% of the text and consider this part of the process, rather than due to my bad writing.

The difficulties for localisation specialists may arise when the client sends the next translation request and presents the legacy materials that were significantly revised after the initial translation. Which changes should and can be accounted for during localisation? If a writer or a translator participates in all briefings with the client and learns about the stylistic requirements directly, not via the project manager, the number of revisions may decrease significantly and the long-term cooperation would be smoother on both sides.

Here is an example of an adaptation that has nothing to do with compliance.

Example 1
Source: Treatment A provides visual and anatomic advantages over treatment B and treatment C at 1 year.
Back translation of the localised copy: Treatment A demonstrates more significant results in improvement of vision and anatomical indicators compared to treatment B and treatment C in the 1st year of therapy.

Example 2
Source: Anti-VEGFs are more effective than laser treatment.
Back translation of the localised copy: Anti-VEGF therapy has demonstrated higher efficiency rates compared to laser treatment.

Example 3
Source: Compared with treatment B and treatment C, treatment A increased the chances of gaining 3 lines by about 30% (16 studies, 4028 eyes).
Back translation of the localised copy: When using treatment A, the likelihood of improving visual acuity by 3 or more lines was approximately 30% higher compared to treatment B and treatment C (16 studies, 4028 eyes).

Source title: "World experts on efficacy"
Back translation of the final version of the localised title: "Expert opinion: corticosteroid sparing effect of the treatment and potential decrease in the number of atopic dermatitis exacerbations"

(Again, the translation was omitted from the example to account for multilingual audience. The changes implemented by the client become clear when comparing the source text and back translation.)

Obviously, the client wanted a more formal text than the source. This was not reflected in the original requirements and the references were not provided. In this particular case, the lack of an initial briefing resulted in half of the text being modified by the client after translation. The translator received a cautionary email from the translation agency asking them to clarify whether the client's changes were justified or not. The truth is that this extra work on the client's side and the subsequent communication via the translation agency could have been avoided if the translator had received a proper briefing.
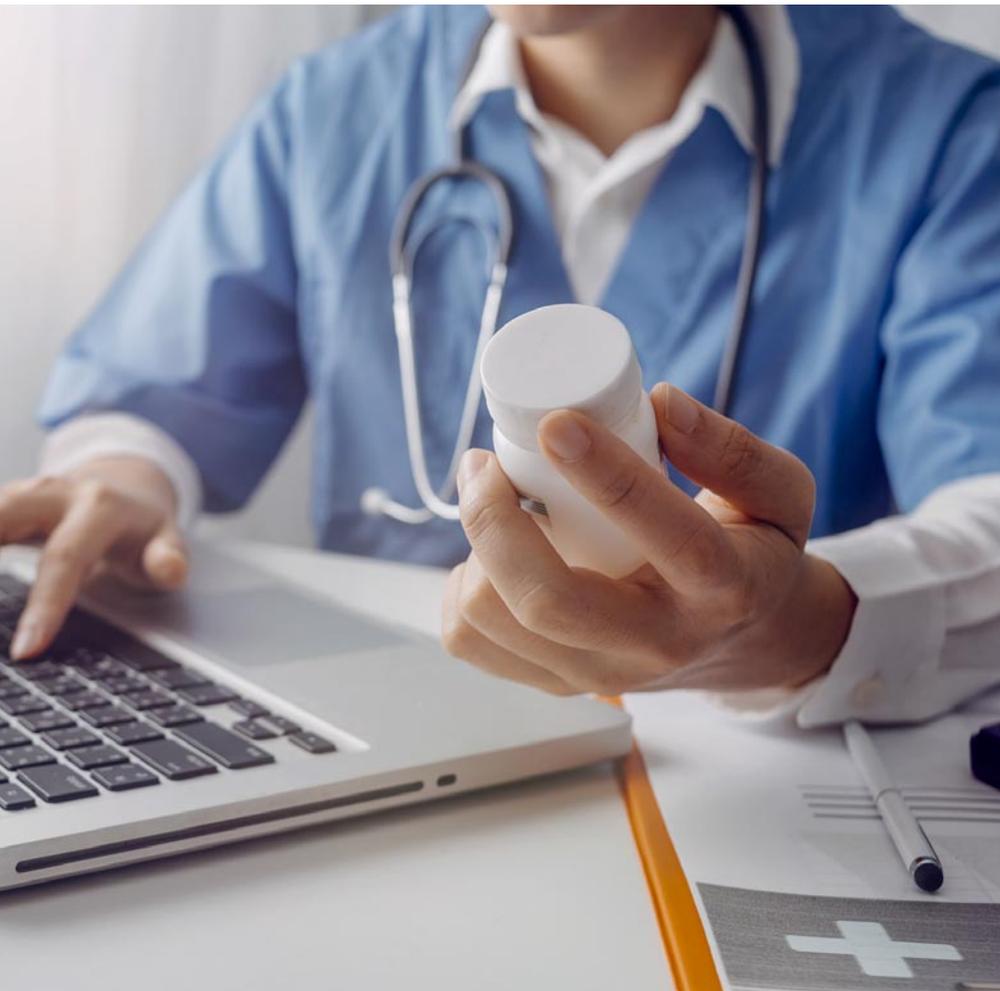
How to cut the review rounds

Here are some pointers for a localisation specialist.

- Request a briefing. Pharmaceutical companies usually allocate time for approval after localisation. This approval can take weeks and even months! Suggest cutting a slice from this time to provide you with a detailed briefing in advance.
- If a briefing is not possible, ask about the intended market, target audience, goal of the campaign, etc.
- Study local regulations to adapt the text accordingly. If the changes required are too drastic for a translation project, consult the client or leave a comment upon delivery.
- Watch out for information that has been updated since the writing stage. For example, data that were presented as new in the global copy might be about a year old when the document reaches you. When you are asked to localise the "old" global copy, this can be problematic. Leave comments for the client to show your expertise.

Conclusion

Translating marketing materials in the world of pharma can be challenging, but being well informed is the cornerstone to success as a localisation specialist. By requesting a brief and aligning translations with regulatory requirements, one can greatly increase their value in the localisation process. Clients may not have worked with an experienced localisation specialist before and may be used to extensive revisions. Localisation specialists can take a load off their shoulders and become part of the team instead of just being an outsourced vendor.

I hope this article helps you and your clients enjoy this creative process. In the reference section, you will find links to pharmaceutical advertising regulations in the UK,[2] EU[3,4], and the US.[5]

Disclosures and conflicts of interest

The author declares no conflicts of interest. The localised materials examples were taken from projects that the author was involved in as a freelancer.

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The use of machine translation and AI in medical translation: Pros and cons

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Abstract

In this article, I provide a retrospective look at the emergence of translation technologies and summarise the pros and cons of the use of neural machine translation and generative AI tools in medical translation. I will examine both the advantages and the risks for the medical translator.

When I first started studying translation at the age of nineteen, if anyone had asked me what field I was considering specialising in, medical translation would not have sprung to mind. In high school, I had a horror of the sciences. I made the grade, but every second was torture. And when I was finally given a choice in my final year between physics and 20th-century history, the World Wars won out over Newton's laws. Funnily enough, biology is the only subject I recall having a fondness for. (Foreshadowing, anyone?)

First things first: a specialisation

As fate would have it, after university, I was hired by a couple who had started their own translation business: he was an experienced certified translator and she, a registered nurse. Naturally, they focused on medical translation. With a grand total of one university course in medical and pharmaceutical translation under my belt, I took a deep breath and dived in. It was sink or swim, so I paddled for my life. And a specialisation was born.

But, as with any specialisation, it did not happen overnight. It took years of researching, reading, absorbing and processing medical texts, and learning from my mistakes to reach a level that could be qualified as "proficient". The pages of my early medical translations were more red than black, but I slowly got there, through equal measures determination and curiosity on my part, and patience and guidance on the part of my employers-slash-mentors.

The steady march of technology

While at university, I did a mandatory internship at a translation agency in downtown Montreal. At the time, Google was still a twinkle in its founders' eyes. Translation requests frequently arrived by fax or courier service, and many translators dictated their texts onto micro-cassettes for the women in the typing pool. (Typing was considered a job solely for women!) And it was not uncommon for my supervisors to trudge to the medical and engineering libraries at

nearby McGill University to track down obscure terminology.

However, by the time I'd started building the foundations of my specialisation in medical translation, technology had begun its gradual creep into the field. In the translator's toolbox, textbooks were supplanted by Google, paper dictionaries were replaced by online ones, printed glossaries gave way to computerised terminology records, and paper files were converted to electronic archives.

By now, readers have probably deduced my age. Yes, I am a member of the "old guard": a translation veteran. But unlike some of my peers, I have always kept up with, and even embraced, new technology – from early computer-assisted translation (CAT) tools to neural machine translation (NMT) engines to the latest generative artificial intelligence (genAI) platforms – as a means of doing my job better and faster. I have never viewed technology as the enemy, nor as a threat to my livelihood.

They say with age comes wisdom. Perhaps. But at the very least, my 25 years as a medical translator have given me a clear and informed perspective on the main pros and cons of the use of said technology – CAT, NMT, and genAI tools – in the medical translation field.

Pros of machine translation in the medical field

Increased speed and productivity

There is no denying that translators who use machine translation tools have seen a boost in their productivity. However, far from the 50% gain in production capacity initially touted by some translation software makers, the increase tends to be more around 20%,[1] which is not insignificant when you consider the time saved hunched over a desk, typing, researching, reading, and self-editing.

This potential gain can be magnified, however, when CAT and NMT tools are used by experienced medical translators with an expert grasp on their subject matter. To cite an example: about a year ago I was asked to translate a 6000-word informed consent form (ICF) for subjects enrolled in a clinical trial. In the pre-technology era, this would have taken me a good three days to research and translate accurately and idiomatically. By leveraging the assets in my CAT tool (translation memories, termbases, and NMT engine), it took me half a day, roughly four hours from beginning to end.

This was mainly because the quality of the NMT output was good. (Yes, it does happen!) When NMT engines are trained on corpora built from large numbers of high-quality, human-translated and -revised texts (case in point, ICFs), the resulting machine translations can be impressively accurate and, dare I say, even idiomatic. In my case, the machine translation of the ICF stood up remarkably well to a careful bilingual revision, needing only a few tweaks to the syntax and terminology.

Standardisation and consistency

When it comes to terminology, tech tools have become indispensable to medical translators as a means of ensuring the standardised and consistent use of accurate, appropriate, and up-to-date medical terms in their translations.

Take the recent pandemic. In the early stages of the global crisis, the terminology surrounding coronavirus disease 2019 (COVID-19) seemed to change as quickly as the virus itself mutated. For example, almost overnight "physical dist-ancing" replaced the more stigmatising and isolating "social distancing" as the preferred term for denoting the act of maintaining space between individuals. Medical translators in the thick of it needed to maintain meticulous termbases to stay ahead (or at least on top) of the rapidly evolving COVID-19 jargon.

The name of the disease itself also presented standardisation challenges, and strict terminology management was needed to make sure the same variant – whether "COVID," "Covid," or "COVID-19," with the preferred appellation often depending on the end client – was used consistently throughout any given text.

Recent AI tools such as ChatGPT have also risen to the fore as powerful terminology aids for medical translators. For example, they can extract keywords from a text and arrange them in a two-column table. The translator can then prompt the AI tool to insert a translation for each term in the blank column. Once carefully revised, this list can be imported to a termbase for an instant terminology boost, adding dozens or even hundreds of terms that may have taken the translator months or years to compile manually.

Multilingual support

In recent years, and especially since the pandemic, the sheer amount of information generated and disseminated internationally has exploded beyond all imaginable proportions, both in general and in the medical field. Machine translation has proven indispensable for processing these massive volumes of data, making medical texts available in multiple languages, in very short timeframes, for users around the world. Of course, this is not only a boon for the scientific community, which can quickly share its findings on a global scale, but it's also extremely valuable for patients, who can access faster than ever before the latest information about their medical conditions in their own language.

Doctors are also increasingly using AI translation technology to communicate information to patients who speak another language. Taking "translation" one step further, American company Vital recently launched its AI-powered Doctor-to-Patient Translator, "(an) innovative new (tool that) translates complex doctor's notes, radiologist reads, discharge summaries, test results and more into a 5th-grade reading level."[2] And Google is working on an AI model that can decipher doctors' difficult-to-read handwriting, with a focus on notes and prescriptions.[3]

> There is no denying that translators who use machine translation tools have seen a boost in their productivity.

Cons of machine translation in the medical field

Overconfidence

Like the now-(in)famous lawyer who humiliated himself in court by citing fake cases made up by ChatGPT,[4] medical translators who take machine translations and AI output at face value do so at their own risk. That's because merely googling – looking up the keywords or phrases generated by NMT and AI tools – is not a foolproof method of detecting errors in machine translations. As any experienced translator (medical or otherwise) knows, virtually anything can be found on Google if you look hard enough. But that doesn't make the findings correct or accurate in the given context.

The machine translation platforms operated by Big Tech companies (Google, Microsoft, etc.) are also improving at an astonishing rate. "Year after year, their BLEU scores – which measure how similar machine-translated text is to a bunch of high quality human translations – get consistently better," according to science journalist Sofia Quaglia.[5] (BLEU stands for Bilingual Evaluation Understudy.) Unlike a decade ago when machine-translated medical texts were "clunky", today's outputs sound convincingly *medical-y*, for lack of a better word.

Less experienced medical translators, who have yet to solidify their language transfer skills and/or master their specialisation, are especially vulnerable to the false sense of security created by the *medical-y* translations generated by machines. As Quaglia points out, "the errors that lead to consequential mistakes (…) tend to be random, subjective, and different for each platform and each language."[5] In other words, sneaky. When revising machine translation output, even veteran medical translators must guard against slipping into "cruise control," that lackadaisical gear where a translation sounds good, ergo it must be accurate. In short, never trust a machine translation, no matter how *medical-y* it sounds. Do your due diligence and confirm the output using credible sources.

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Pressure to reduce rates

Eavesdrop on any group of translators, and you'll quickly pick up on the perceived clear-and-present danger for the industry right now: the decreasing and even plummeting translation rates brought on by the widespread use of NMT and genAI tools. Under immense pressure from their end clients, translation agencies have made a seismic shift over the past few years to machine translation postediting (MTPE),[6] placing freelancers who previously translated "from scratch" between the proverbial rock and hard place: accept MTPE work at a fraction of their usual rate or watch the well run dry.

Many agencies apply MTPE across the board, regardless of client, subject matter, or level of difficulty of the text, believing it to be a cost-saving magic bullet. Unfortunately, medical and life sciences texts are no exception to this dangerous phenomenon. However, this has only served to alienate top-tier medical translators, who are increasingly seeking out direct clients willing to pay premium rates for accurate, high-quality human translations. Unsurprisingly, much of this less lucrative MTPE medical work falls to less experienced, less qualified translators, to potentially deleterious consequences.

The MTPE tsunami has also given rise to a new *bête noire* for medical (and indeed, all) translators, namely requests from direct clients to revise texts translated internally using an NMT engine. A typical email will read: "We used DeepL to translate this handbook for patients preparing for open-heart surgery. Could you revise it for us quickly? What is your rate for this?" Subtext: *This will be quicker and easier than translating the text from scratch, therefore we expect a discount.* This unprecedented situation forces medical translators into the uncomfortable position of then having to explain to clients that medical translation is a niche, high-stakes specialisation that deserves to be remunerated accordingly.

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What's more, the time spent by medical translators educating clients about this reality (in the form of lengthy emails, phone calls, and/or video calls) is almost never billed.

Lack of context understanding

While NMT has progressed by leaps and bounds, it's certainly not infallible, especially for specialised fields like medicine, which is characterised by complex concepts, constantly evolving terminology, and frequent neologisms. It can be tripped up by false friends, for example, rendering the French word "*intoxication*" as "intoxication" (a state of inebriation) in English, whereas the generally accepted meaning in French is "poisoning." It also struggles with the abbreviations and acronyms peppered throughout medical texts, not to mention the incomplete sentences and shorthand notations typical of progress notes. And despite Google's best efforts, doctors' handwriting is a hopeless cause! Best-case scenario, the medical translator finds themselves making heavy edits to a machine-translated text. Worst-case scenario, they throw up their hands in despair and retranslate it completely – and hope they are paid fairly for their trouble.

Confidentiality concerns

Finally, confidentiality is a major concern when it comes to using public NMT and AI interfaces to translate medical texts. Medical translators must be cognisant of the fact that free, non-subscription-based tools (Google Translate, DeepL Translate, Microsoft Bing, ChatGPT, etc.) are not secure. In fact, in their policies, these platforms openly state that any information entered may be communicated, published, reproduced, shared, and used to train their engine, or to develop future technologies or products.[7] In his article "Machine Translation and Confidentiality," Jonathan Thames even warns translators to "maybe think twice before popping that paragraph into Google Translate (…)! Better to be safe than sorry and protect your and your client's data."[7] Conversely, confidentiality is assured when using a paid, subscription-based NMT engine such as DeepL Pro.

Confidentiality is a major concern when it comes to using public NMT and AI interfaces to translate medical texts.

Conclusion

Just as medical students begin their education with gross anatomy class, medical translators must first master the basics of grammar, syntax, style, and language transfer – not to mention hone their specialisation – before incorporating technology into their process. That said, keeping tech tools out of the equation is much more difficult now than it was two-and-a-half decades ago.

So, short of translating in a cave with rock and chisel (or the late-90s equivalent of blank word processor screen and no internet connection), medical translators must instead view machine translation and AI as nothing more than aids, tools in a toolbox, as opposed to solutions designed to do the work *for* them. As with any technology, however, they must be used responsibly. An NMT engine or an AI tool will do the heavy lifting, but a *human* translator will always be needed to provide the final layer of validation on any text. In fact, in the high-stakes world of medical translation, their intervention could mean the difference between life and death.

Disclaimers

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

Disclosures and conflicts of interest

The author declares no conflicts of interest.

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Harmonising linguistic validation with AI:
Precision, efficiency, and the human touch in patient-reported outcome translation

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Abstract

The surge in artificial intelligence (AI) prompts a reassessment of linguistic validation methods for patient-reported outcome (PRO) measures. The robust linguistic process, designed to adapt PRO measures for different cultures and languages, is upheld by regulators and the outcomes research community for its value in maintaining concept equivalence across global trial data. Its methods are entrenched in human translation and review, making it more challenging to integrate AI (machine learning, deep learning, natural language processing) compared to other parts of the global localisation industry. This article provides an overview of the key challenges in integrating linguistic validation and AI. Despite these hurdles, it advocates for the industry to embrace the potential benefits through collaborative and responsible innovation.
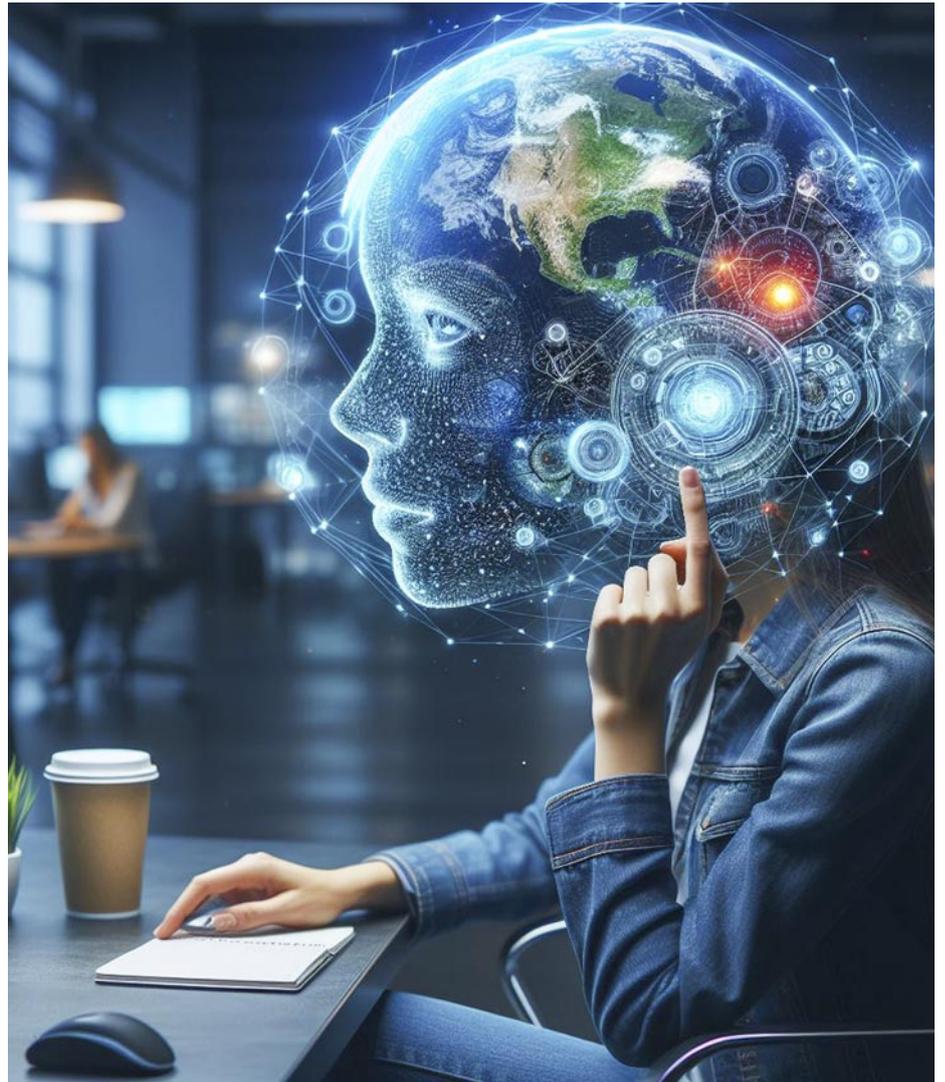
Introduction

Linguistic validation refers to the process of translating a patient-reported outcome (PRO) measure for use in a new language or culture, while ensuring that conceptual, item, semantic, and operational equivalence between instrument versions is preserved.[1] Its objective is to ensure the validity and integrity of patient-reported data gathered across different linguistic and cultural contexts and its significance extends to ethical considerations, regulatory compliance, and the overall improvement of patient-centred outcomes.

Industry standards

The EMA[2] and FDA[3] underlined the need for evidence of PRO translation and linguistic validation in 2005 and 2009 respectively, requesting details of the process used, descriptions of patient testing, language- or culture-specific concerns, rationale for decisions made to create new versions, copies of translated or adapted versions, and evidence that content validity and other measurement properties are comparable between the original and new instruments.

The International Society for Pharmaco-economics and Outcomes Research (ISPOR) Taskforce for Translation and Cultural Adaptation produced best practices for PRO measure translation in 2005.[4] In 2013, The International Society for Quality of Life Research (ISQLR) published recommended standards in a similar vein.[5] Both underscore that qualitative assess-

ment by means of cognitive debriefing interviews with patients from the target population, representing the intended PRO audience, is required for proper translation evaluation. They are now decades-old; nonetheless, these guidelines consistently yield high-quality results when correctly implemented. The methods are grounded in human intelligence, involving a range of highly qualified and trained stakeholders.

Technology in linguistic validation

The existing guidelines lack provision on the integration of translation technology into linguistic validation and it is imperative that industry thought-leaders reassess the process in light of AI advancements, ensuring that the linguistic validation discipline evolves to cope with a rising translation volume and the growing complexity of the digital

landscape. In contemporary, patient-centred outcomes research, diverse electronic platforms such as mobile devices, social media, email, SMS, video, and augmented reality solutions will play an increasingly pervasive role. Let us examine how technology currently plays into the typical linguistic validation process.

Figure 1 is an illustration of the basic flow. Variation among language service providers (LSPs) is typically confined to the execution of specific methodological steps. For instance, differences may arise in the choice between single or dual back translation, or the preference for virtual or face-to-face cognitive debriefing. Of vital importance to any project, as in the regulatory guidance, is an audit trail of every linguistic step, edit, and decision made. Of the six steps shown, none are without human input and the humans involved are highly

> *Of vital importance to any project, as in the regulatory guidance, is an audit trail of every linguistic step, edit, and decision made.*

specialised, technical experts. They include ISO-qualified linguists with medical translation experience, trained linguistic validation project managers, clinicians and patients in the target therapeutic area, and instrument developers with advanced degrees in psychology, health outcomes research, or a related discipline. The diverse and specialised nature of these roles, as well as the fundamentally complex and nuanced cultural and conceptual equivalence exercise at play in linguistic validation, underscores why it would be inadvisable to replace their collective expertise with technology, no matter how advanced.

The level of technological input in this workflow differs between LSPs but most use both computer-assisted translation (CAT) and translation management system (TMS) tools. These enhance efficiency and consistency; the former providing translation memory, terminology databases and workflow management functionality, the latter providing collaboration and automation tools to aid the coordination of

Linguistic validation

1 CONCEPT ELABORATION

2 ADAPT OR DUAL FORWARD TRANSLATE

3 RECONCILE

4 BACK TRANSLATE & REVIEW

5 COGNITIVE DEBRIEFING

6 QA

PRO measure health-related concepts explained. A roadmap for linguists.

Best of both version of the two forward translations

1-1 interviews with target population patients and report discussion between PMs and linguists

Source > target FT

Adapt when "same language, different country"

Single or double back translation options and review by LV PMs

Developer/author/ clinician review if required

Proofreading, format and quality check, final eye, certificate of translation
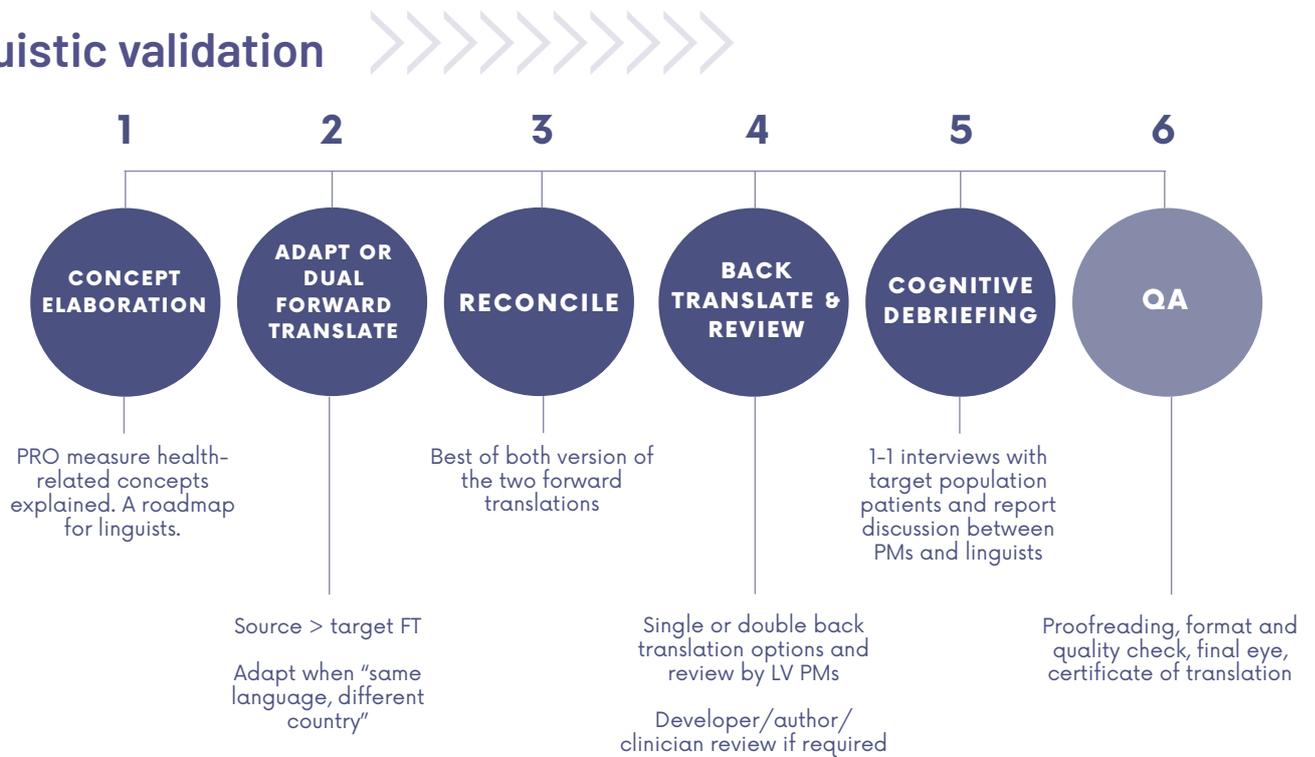
Figure 1. The Linguistic Validation process from concept elaboration to quality assurance
This figure and article do not address the linguistic validation processes related to multilingual electronic Clinical Outcome Assessment (eCOA) migration or testing and AI, as this would merit another article. Graphic by Helen Williams

Abbreviations: PRO, Patient-reported outcome; FT, Forward translation; LV PMs, Linguistic Validation project managers

tasks among multiple contributors. These aid the human translation process and ease the audit burden by accommodating trackable versioning and reporting.

Leveraging AI: challenges

There is no linguistic validation-specific industry guidance that advises replacing any or all of the six human translation, review, or test steps shown in Figure 1 with wholly automated translation. It is possible, though, that the focus could shift from humans translating the source content, to the humans correcting and augmenting machine-generated translations, or the machine and the human producing a version each for comparison. Ongoing and historic translation content of PROs could be stored to produce PRO-specific memory banks to inform AI machine translation, but this would involve considerable set-up and maintenance work, plus potentially lengthy approval processes. This logical starting point would also be complicated by the complex ownership of PRO measures and the fact that PRO measures are not naturally word-rich or lengthy. They tend to be succinct, short instruments to avoid patient burden, and AI models require vast datasets to perform well (think of the word count of a car manual, for example, in comparison to a 50-word instrument). PRO data is often proprietary and sensitive, owned by the entities conducting the clinical trial. Striking a balance between leveraging PRO translations for AI advancements and respecting ownership rights and ethical standards becomes crucial in the development of AI models in this domain. CAT tools offer access to public term banks for translators; however, in the context of linguistic validation, it is imperative to disable these features. This precaution is taken due to the potential risks associated with uncertain origins of those translations.

How can we leverage AI's capabilities to optimise the linguistic validation process? There is a growing demand to integrate AI in this field, where the predominant clinical study requirements revolve around the classic triad of quality, time, and cost-effectiveness and AI is known to help with efficiency and scalability. Understandably, questions start to mount, as stakeholders see its positive impact in other industries

> There is no linguistic validation-specific industry guidance that advises replacing any or all of the six human translation, review, or test steps with wholly automated translation.

or note that AI is lessening the burden of other life sciences translation tasks. Industries like e-commerce employ neural machine translation (MT) through deep learning models for automated text translation and they can produce a high volume of translated content at speed and relatively low cost compared to human translation. Depending on the model's depth of knowledge, neural MT can also offer contextual translations. The distinguishing factor lies in industries like e-commerce having access to substantial volumes of high-quality language data for training the models. AI including neural MT represents significant risk for the linguistic validation discipline, as it would, for example, for the legal industry, where highly sensitive content is at stake. "Good enough" simply will not do for linguistic validation; this content needs white glove treatment. It's understood that AI can help with speed and scale, but its limitations in terms of accuracy are concerning.

Human review, translation, and testing necessarily underpins linguistic validation, due to the intricate nature of health concepts, cultural subtleties and idiomatic expressions used in patient communities. AI is known to struggle with contextual or cultural understanding, compared to humans. Cultural appropriateness is key to patient understanding, comfort and engagement; if PRO language isolates and confuses the patient, they will neither be inclined nor able to participate in the assessment. They may even find the translations offensive or discriminatory. PRO translations that meet or exceed the industry-recommended minimum standards "will increase the likelihood that the evidence generated [...] reliably and validly represents the patients' perspective on health-related outcomes."[5] The stakes are high; if translations are substandard and their measurement properties are negatively affected, it can prevent evidence being used to inform clinical and health policy decision making. The robust coupling of the trusted linguistic validation methodological framework with tried-and-tested project management best practices produces reliable, auditable results. It is understandable, therefore, that the "unknown quantity" characteristics of AI may alarm industry professionals more than excite them with its potential. We can get the quality output that we need, reliably, so what does it matter if the process is a little clunky and expensive?

Several challenges impede the swift integration of AI into linguistic validation. These include ensuring compliance with regulatory standards, navigating domain-specific nuances and cultural sensitivities that pose challenges in training AI language algorithms, organisational risk aversion stemming from concerns about accuracy, biases and the nuanced understanding required for context. Additionally, issues such as data security, intellectual property, and privacy concerns arise, as AI systems often necessitate access to extensive datasets for training. Furthermore, establishing effective interdisciplinary collaboration between linguistic validation, scientific, and technology teams remains challenging due to prevalent operational silos. Methodologically, the key question revolves around striking the right balance between human expertise and artificial intelligence, aiming for efficient study execution without compromising the integrity of the final deliverables.

Responsible innovation

In the specialised realm of linguistic validation, where precision takes precedence, a discerning approach is vital, favouring judiciousness over a singular pursuit of cost and time efficiency.

> Establishing effective interdisciplinary collaboration between linguistic validation, scientific, and technology teams remains challenging due to prevalent operational silos.

Responsible innovation, guided by collaborative decision-making by qualified industry experts, should steer this transformative journey. As AI's role expands in the broader localisation market, linguistic validation experts can capitalise on AI insights from diverse fields, applying proven techniques and adapting successful strategies without starting from scratch. While embracing AI for efficiency gains and streamlined processes in PRO translation timelines, rigorous testing and integration must coexist with human review and validation. The future of linguistic validation likely involves a synergy of AI, machine translation, and human expertise, promising improved accuracy, enhanced

efficiency, and greater accessibility. Strategies, such as bespoke algorithms and early human reviews of PRO content, address potential challenges, ensuring the training of AI solutions with high-quality language data. The "translatability assurance" step, recommended when a new PRO measure is in development, could extend to assess the content for compatibility with AI. The potential of AI is huge and features such as type-ahead functions, readability highlights, detection of offensive terms, autocorrect, and the capacity to adhere to glossaries and style guides are very attractive. However, in this heavily regulated industry, challenges persist, including AI's limits in the face of contextual understanding, cultural subtleties, depth of domain knowledge, and the risk it presents with potential biases. Human oversight remains indispensable and AI solutions need to be trained within stringent quality control frameworks.

In conclusion, the integration of AI into linguistic validation should not be seen as a threat but as an opportunity for progress. When approached with caution, collaborative decision-making, and a commitment to maintaining high standards, the marriage of AI and linguistic validation holds the promise of more efficient, accurate, and accessible processes. A successful integration, alongside AI algorithms that become increasingly accurate, aware of context, and adaptive, could contribute to accelerated clinical trials, cost reduction in research, and improved data quality. All of these serve our collective goal of helping patients.

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

Disclosures and conflicts of interest
The author declares no conflicts of interest.

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The ethics of medical translation

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Abstract

Much has been written about the ethics of medical interpreting, but not so much about purely written translation. What moral principles apply (or should apply) when I translate a document for a client? Do I need to invent these principles myself, or is there help available?

In this article I explore the personal moral principles we might apply to our work, and the institutional backup that is available, for instance the Institute of Translation and Interpreting's Code of Conduct. I explore what a code of ethics for medical translators might look like.

In researching the definition of ethics, I soon found that this is a complicated and highly disputed field, which has sparked endless discussion among philosophers. Boiled down, though, the various definitions of ethics include "how one should live",[1] and "a set of concepts and principles that guide us in determining what behaviour helps or harms sentient creatures".[2] Going further back and looking at the etymology of the word, "ethics" comes from the Greek meaning "relating to character and moral nature". So using the broadest possible view, ethics is how best to develop and use one's own character and the behaviour that a person of good character will demonstrate.

It soon became apparent to me that I couldn't address the whole history and discourse around ethics in one feature article – so the key question is how we determine what ethical behaviour for a medical translator is. This is professional ethics; in other words, the behaviour expected from people working in a specific field. Of course, our personal ethics will emerge when we work; how

could they not? However, it might not be safe to assume that individuals will do the right thing at all times, and there needs to be a collective agreement on what constitutes ethical behaviour. For this reason, professional ethics are imposed from elsewhere, in the form of codes of professional conduct, either compulsory (in regulated professions) or voluntary. But there is, to my knowledge, no specific code of ethics for medical translators, so below I outline what such a code might contain. I draw upon the code of conduct of the UK's Institute of Translation and Interpretation (ITI),[3] and my own experience of working in the field.

A proposed code of ethics

The main points that are covered are as follows:

Skills to do the job

The main pillar of ethical behaviour has to be the ability to do the work. For translators, this means having the right skills in language knowledge, with degrees and certification as required (these are mandatory in some countries and not in others). In addition, translators require the right subject expertise and research skills, and the

willingness to invest in oneself to keep this skillset up to date. Of course, linguistic skills are necessary but not sufficient to be a good translator, and these specific skills relating to transporting meaning between languages should also be part of our ethical armoury. All these skills will combine to help produce accurate translations that convey meaning without loss and without misleading the reader.

Customer care

The next set of behaviours broadly covers the category of client care. We might be working for private individuals (a lot of my work is of this type), for a client company directly, or for an agency. In each case, there is a duty to provide a translation that's fit for purpose, but that is not the whole of the job. A private individual who needs medical translation may be going through a very difficult time, either because they are themselves the patient or because they are a family member who is organising the translation as part of their relative's needs, and this has to be handled with sensitivity. This individual may be liaising with doctors in two or more countries, and the translator can act (or offer to act) as a

support here, by remaining available to answer any queries that arise when the translation is used. Even when working for a client company or agency, there is still the human element and broadly we should bear in mind that our interlocutors are human, even though we might only have contact with them via brief emails. And of course, we shouldn't forget the basics, which are adherence to deadlines, asking the right questions, and not sub-contracting work without the client's knowledge.

Data protection and confidentiality
We often handle personal data, and translators should be aware of their obligations under the General Data Protection Regulation (GDPR) and make clients aware of the policies we adhere to. Data should not be kept for longer than needed, and individuals must have the right to have their data deleted should they wish. Client companies and agencies will often anonymise documents before they reach the translation stage, but if patients send their reports to us directly, they must be handled with care. Thought should be given to possible solutions and their implications – is the cloud-based provider trustworthy and secure? Where will the data be stored, and can I guarantee that it will be handled so that I meet my obligations under GDPR?

Relationships with others in the profession
The ITI's code of conduct requires members to share knowledge and experience – and the organisation facilitates this by providing subject and language networks in which members can discuss professional matters, whether tricky terminology queries or questions about client relations. The Medical and Pharmaceutical Network is an excellent, long-standing example of an ITI network and is an invaluable source of help and support for many, including me. In addition, in-person workshops with high-profile speakers are a good way to ensure that one's subject knowledge is kept up to date. These workshops also provide opportunities to get hands-on with texts, and in groups with colleagues, and a knowledge of colleagues' skill levels and ways of working is invaluable when expanding our networks and finding people to work with.

The first category in the ITI Code of Conduct is "Honesty and Integrity" and it is the last I shall tackle, though it is a key area and encompasses all the others. This covers everything from advertising services accurately and in a way that is fair to colleagues (not unfairly denigrating others' services, for instance), which is a matter of honour and correct behaviour, to formal prohibitions of bribery and corruption, which are backed up by the force of law.

Artificial intelligence and other topics
The ITI Code of Conduct is silent on the matter of artificial intelligence and on the tools of the trade. The implication is that if a good product is produced, it doesn't matter how it was produced. But if a translator enters a patient's confidential information into an online machine translation tool, or into ChatGPT, that translator is no longer in control of what happens to that data and cannot assure the client that this personal data is protected from harm. So, the use of artificial intelligence can be a matter of ethics, and perhaps our professional ethics documents should be updated to reflect this – although the AI landscape is changing so rapidly that the issues are hard to pin down at the moment. Another aspect that is not tackled in current codes of conduct, to my knowledge, is the environmental impact of translators' work. We may not travel for work as much as interpreters do, but our decisions still have an impact; for example, any data we store online requires energy just for storage. An organisation may wish to encourage members or employees to choose greener ways of travelling when they do travel, such as choosing train travel over flying.

Conclusions
The ITI has acknowledged that its Code of Professional Conduct perhaps does not meet the criteria to be a code of ethics and is, at the time of this writing, undertaking a review to consider whether a separate Code of Ethics is needed, and if it is, what it should contain.[4] The discussions that arise from this process should be an interesting examination of what ethical behaviour is in our profession, how it can be promoted, and the role a professional association can play.

Professional ethics is such a huge field that it is difficult to sum up. Current Codes of Conduct for translators (which for our purposes we can assume are also codes of ethics) are fit for purpose in some ways but could benefit from revision in areas such as environmental awareness and new developments in technology. Above all, we should take the opportunity to create codes that reflect the best of what we can do, in terms of our professional skills, the way we treat others, and how we face the future.

Disclaimers
The opinions expressed in this article are the author's own and not necessarily shared by her employer, the Institute of Translation and Interpreting, or EMWA.

Disclosures and conflicts of interest
The author is employed by University College London as a teaching fellow and is a Qualified Member and former Board member of the Institute of Translation and Interpreting in the UK.

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News from the EMA

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

First electronic product information (ePI) published for selected human medicines

November 08, 2023

The Heads of Medicines Agencies (HMA), the European Commission (EC) and EMA have published for the first-time electronic product information (ePI) for selected human medicines harmonised across the European Union (EU).

The product information of a medicine includes its summary of product characteristics, labelling, and package leaflet. These documents accompany every medicine authorised in the EU and explain how they should be prescribed and used. They can all be found, often as a PDF document, on the websites of EU regulators, with a printed package leaflet also provided in the medicine's box. Digital platforms open new possibilities to share this information electronically, keep it constantly updated and make it more accessible to end users such as healthcare professionals and patients.

The creation and testing of ePIs in real regulatory procedures is being explored through a one-year pilot initiative by HMA, EMA, and the EC to enable the transition to the electronic system for medicines evaluated both nationally and at the European level. The ePI initiative is an action under the Pharmaceutical Strategy for Europe supported by the EU funding programme EU4Health.

The published ePIs are for medicines evaluated by EMA or by national authorities in Denmark, the Netherlands, Spain, and Sweden. Companies participating in the pilot create and submit the ePI as part of their regulatory application. The pilot, which involves 25 medicines, will conclude in July 2024, and the outcomes will inform how to integrate the ePIs into common practice and expand their use across the EU.

The ePIs can be viewed at the Product Lifecycle Management Portal in English for centrally approved medicines and in the local language for nationally approved ones. Testing is ongoing to allow access to ePIs in all EU languages. In addition, ePI data can be accessed via a public application programming interface where developers can explore the potential of this new format within existing digital platforms.

These ePIs were created following the EU ePI Common Standard adopted by the European medicines regulatory network to provide a consistent structure throughout all Member States and ensure the information works across different e-health platforms. This should facilitate the use of product information to meet individual needs and access requirements. Future developments could include functionalities such as automatic update notifications, access to supportive videos or audio content, and online adverse-reaction reporting tools.

Global regulators celebrate 10 years of strategic leadership and cooperation

November 13–16, 2023

The year 2023 marked the 10th anniversary of the International Coalition of Medicines Regulatory Authorities (ICMRA). ICMRA was established in December 2013 by eight regulators to address a need for a global governance mechanism and stronger cooperation. Today, ICMRA consists of 38 members, with the World Health Organisation as an observer. ICMRA is currently chaired by the EMA with co-chairs from ANVISA Brazil and PMDA Japan.

The anniversary was celebrated during ICMRA's annual summit and Plenary in Melbourne on November 13–16, hosted by the Therapeutic Goods Administration of Australia.[1] ICMRA members exchanged views and discussed topics such as the use of artificial intelligence and machine learning in medicine regulation, evolution of clinical trials, and advanced medical products based on genes, cells, or tissue engineering.

In the past decade, ICMRA has made significant progress in a range of areas which are at the heart of the work of many regulators world-wide. Significant milestones include activities supporting the fight against antimicrobial resistance and the management of medicines shortages, but also topics such as clinical trials, pharmacovigilance, regulatory convergence and reliance, innovation, real-world evidence, and alignment in the global COVID-19 response.

ICMRA's major achievement is the leadership provided by its members working together during the COVID-19 pandemic. The coalition worked to expedite and streamline development and approval of COVID-19 vaccines and treatments and helped to increase the efficiency and effectiveness of regulatory processes and decision-making. ICMRA called for large, well-designed clinical trials to ensure regulators have solid evidence for decision-making and organised workshops on manufacturing, safety, and efficacy of COVID-19 vaccines. In June 2023, ICMRA received the Global Award for Outstanding Contribution to Health at the Drug Information Associations (DIA) Global Annual Meeting.

In the coming years, ICMRA will continue to address current and emerging human medicine regulatory and safety challenges, strengthen collaboration and communication, and enhance the quality, safety, and efficacy of medicines for the benefit of patients worldwide.

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Sustainable communications

Medical journalism

Medical decision making

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Writing for patients

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Consumption of antimicrobials in animals reaches lowest level ever in Europe

November 20, 2023

European countries have substantially reduced sales of veterinary antibiotics, which translates into a lower risk of bacteria becoming resistant in people and animals. Overall sales of veterinary antibiotics decreased by 53% between 2011 and 2022, reaching the lowest level ever reported, according to data from 25 countries. This is one of the key findings of the 13th annual report on the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC), 2009–2023.

During the same period, sales of antibiotic classes that are considered critically important in human medicine for veterinary use noticeably decreased: sales of 3rd- and 4th-generation cephalosporins dropped by 49%, polymyxins by 81%, fluoroquinolones by 25%, and sales of other quinolones dropped by 90%. While all antibiotics should be used prudently and responsibly to preserve their effectiveness, it is of particular importance for these antibiotics to mitigate the potential risk to public health, as indicated in the Antimicrobial Advice ad hoc Expert Group (AMEG) categorisation.

EMA has been monitoring sales of veterinary antimicrobials in Europe through the ESVAC project since 2009, when 9 European countries volunteered to provide data on sales of veterinary antimicrobials. The number of participating countries has increased more than three-fold since the start, and in 2022, 31 European countries were working together in this project.

ESVAC has led to the collection of reliable data on antimicrobials sold for use in animals, providing invaluable insights for participating countries on the impact of their measures to promote the prudent use and setting targets to reduce the consumption of antimicrobials in animals.

The ESVAC project is a European success story about commitment and strong collaboration. The project is coming to an end in 2023 and EMA will publish the last ESVAC report with data from 2022. The ESVAC concept has been integrated into the EU legislation, making the collection of data mandatory for all EU countries, not only for sales of veterinary antimicrobials but in the coming years also for use of antimicrobials in animals. The first report with sales and use data from 2023 will be published in 2025.

The last ESVAC report also includes information on the progress made towards the targets set in the EC's Farm to Fork Strategy to reduce the sale of antimicrobials for farmed animals and aquaculture in the EU. In 2022, the 27 EU Member States have achieved just over half of the 50% reduction target set for 2030 compared to 2018, proving that countries are on the right track of meeting the goals of the strategy.

First version of the Union list of critical medicines agreed to help avoid potential shortages in the EU

December 12, 2023

The EC, the Heads of Medicines Agencies (HMA), and EMA have published the first version of the Union list of critical medicines.[1] It contains more than 200 active substances of medicines for human use considered critical for healthcare systems across the EU/European Economic Area (EEA), for which continuity of supply is a priority and shortages should be avoided. The European Medicines Regulatory Network (EMRN) will prioritise critical medicines for EU-wide actions to strengthen their supply chain.

The list is an important tool to support the EU's efforts in ensuring supply security and preventing shortages of critical medicines. Inclusion in the list does not mean that the medicine is likely to experience a shortage in the near future. It means that the prevention of shortages is particularly important as a shortage could cause significant harm to patients and pose important challenges to health systems. A medicine is considered critical if it is used in serious diseases and cannot be easily replaced by other medicines, for example in case of a shortage. It is included in the Union list of critical medicines if it meets certain criteria, including being critical in more than one third of EU/EEA countries.

The list contains active substances covering a wide range of therapeutic areas and includes vaccines and medicines for rare diseases. It reflects the outcome of the review of 600 active substances taken from six national lists of critical medicines. The Union list will be expanded in 2024 and will then be updated every year.

The review was carried out with all EU Member States, and criticality was assigned based on an agreed methodology developed in consultation with key stakeholder groups, including patients' and healthcare professionals' organisations and industry associations.

Medicines on the list can continue to be prescribed and used as usual by patients and healthcare professionals. Additional reporting requirements for marketing authorisation holders and national

EU medicines agencies reflect on lessons learned from COVID-19

December 01, 2023

The European Medicines Regulatory Network (EMRN) has been at the forefront of the fight against COVID-19 with its crucial role in the evaluation and monitoring of medicines, including vaccines. A joint report[1] issued by the EMA and the HMA reviews the Network's response and highlights the main learnings for any future health crises.

This review highlights some of the unprecedented challenges related to COVID-19 that had to be addressed, the activities and areas that enabled the effective response to the COVID-19 emergency, and provides recommendations on which improvements are needed.

Accelerated procedures for the evaluation of COVID-19 vaccines and therapeutics, as well as scientific recommendations on the use of certain medicines enabled the public health response through safe and effective prevention and treatment options. Collaboration between EU and international partners was also crucial to ensure that regulators around the world adopted a coordinated approach to COVID-19 treatments and vaccines.

The Network pooled its resources to address the increased workload and new tasks like managing medicine shortages, generating evidence on COVID-19 medicines in the real-world setting, and regularly providing reliable and science-based information to the public. Additionally, the EU safety monitoring and risk management system was strengthened to collect and monitor the high volume of data from the mass vaccination campaigns. This allowed the Network to promptly identify, assess, and manage safety issues.

Throughout the COVID-19 crisis, the EMRN also ensured that medicines for other diseases affecting Europeans continued to be evaluated and supervised without delays.

The report suggests that more can be done in terms of the ability to set up large clinical studies in a rapid manner. In terms of real-world data, there is a need to gather multiple data sources that can generate useful evidence for regulatory assessments. The report also acknowledges the need to have a larger pool of experts that can be involved to carry out scientific assessments (such as accelerated reviews for promising medicines) when crisis situations arise.

The report has been adopted by EMA's Management Board. Several recommendations have already been implemented as part of EMA's extended mandate, with the Agency assuming an enhanced role on preparedness to be more proactive on public health threats. HMA and EMA also continue working closely on areas such as resourcing, process improvements and communication. In addition, the ongoing review of the EU pharmaceutical legislation will also provide a vehicle to bring about other changes to the EU regulatory toolbox. The recommendations will also be considered in future updates of EMRN's strategy.

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competent authorities will be established and become effective once the proposed pharmaceutical legislation becomes applicable.

The publication of the Union list will not impact existing or to-be-established national lists of critical medicines. However, it will support the network's efforts in drawing up national lists where these do not yet exist. In addition, it will support and expedite the EC's analysis of the supply chain of critical medicines to determine potential vulnerabilities. The EC and EMA's Medicines Shortages Steering Group (MSSG) may propose measures to address vulnerabilities in the supply of those medicines, to ultimately prevent and mitigate shortages. More information on the list, including its composition, how it was established and how it will be used, is available in a question-and-answer document on EMA website.[1]

The Union list of critical medicines complements other measures adopted by the EMA/HMA taskforce on availability of authorised medicines and by the MSSG, such as good practices for industry and for patients and healthcare professional organisations for the prevention of medicine shortages, the recently created MSSG solidarity mechanism, the MSSG toolkit, and the MSSG's recommendations for actions to avoid shortages of key antibiotics used to treat respiratory infections.

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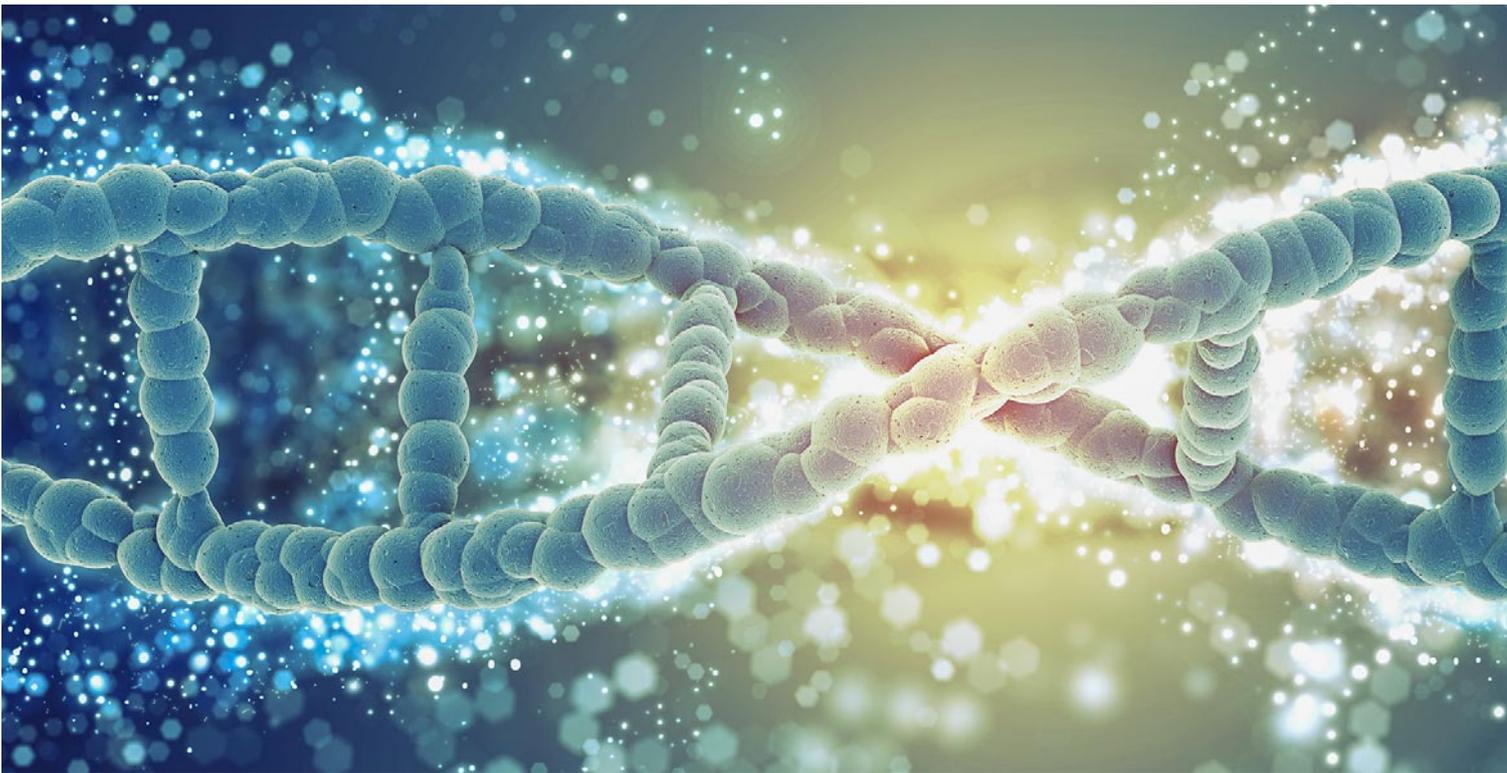
First gene–editing therapy to treat beta thalassemia and severe sickle cell disease

December 15, 2023

EMA has recommended approval of the first medicine using CRISPR/Cas9, a novel gene-editing technology. Casgevy (exagamglogene autotemcel) is indicated for the treatment of transfusion independent beta thalassemia and severe sickle cell disease in patients 12 years of age and older for whom haematopoietic stem cell transplantation is appropriate and a suitable donor is not available. This new therapy may free patients from the burden of frequent transfusions and painful vaso-occlusive crises that occur when sickled red blood cells block small blood vessels and has the potential to significantly improve their quality of life.

Beta thalassemia and sickle cell disease (SCD) are two inherited rare diseases caused by genetic mutations that affect the production or function of haemoglobin, the protein found in red blood cells that carries oxygen around the body. Both diseases are life-long debilitating and life-threatening.

Casgevy is a cell-based gene therapy medicinal product using CRISPR/Cas9 technology to edit the patient's own blood stem cells. It is a personalised one-off treatment that involves mobilising bone marrow stem cells from a patient's blood. CRISPR gene-editing finds a specific sequence of DNA inside a cell. Using "molecular scissors" to make precise cuts, it enables adding, removing, or altering genetic material at that specific location of the genome of the cells. With Casgevy, stem cells are edited at the erythroid-specific enhancer region of the BCL11A gene which usually prevents the production of foetal haemoglobin (HbF). These modified cells are then infused back into the patient, and the reduction of BCL11A gene transcription leads to increase of HbF production thus providing functioning haemoglobin.

EMA based its recommendation on two ongoing, single-arm trials in patients aged 12 to 35 years. In the first one, 42 patients, including 13 adolescents, with transfusion-dependent beta thalassemia who received a single dose, were included in the primary efficacy set. Of these 42 patients, 39 were transfusion-free for at least one year. In the second trial, 29 patients, including six adolescents, suffering from severe SCD, were included in the primary efficacy set. Of these 29 patients, 28 were free of vaso-occlusive crises (VOC) episodes for at least 12 consecutive months. Characterised by severe pain and organ damage, VOC is the leading cause of emergency department visits and hospitalisations for patients with SCD.

The safety of Casgevy was evaluated in the same two ongoing, single-arm trials and one long-term follow-up study, in which 97 adolescent and adult patients with transfusion-dependent beta thalassemia or SCD were treated with the medicine.

The most common side effects are low white blood cell counts including febrile neutropenia, low level of platelets, liver disease, nausea, vomiting, headache, and mouth sores. These events are due to the medicines required for the modified blood cells to engraft and replace the unmodified stem cells.

Casgevy was supported through EMA's PRIority MEdicines (PRIME) scheme, which provides early and enhanced scientific and regulatory support to medicines that have a particular potential to address patients' unmet medical needs. Casgevy is recommended for a conditional marketing authorisation, one of the EU's regulatory mechanisms to facilitate early access to medicines that fulfil an unmet medical need. This type of approval allows the Agency to recommend a medicine for marketing authorisation with less complete data than normally expected, if the benefit of a medicine's immediate availability to patients outweighs the risk inherent in the fact that not all the data are yet available.

In order to confirm the efficacy and safety of Casgevy, the company will have to submit the final results obtained from the currently ongoing

pivotal trials by August 2026, as well as results from the ongoing long-term follow-up study and other studies that will be conducted with the product. Patients treated with Casgevy will be followed up for 15 years, to monitor the long-term efficacy and safety of this gene therapy. To further characterise the long-term safety and efficacy of the medicine, the company will also have to conduct and submit the results of a study based on data from a patient registry.

In its overall assessment of the available data, the Committee for Advanced Therapies (CAT), EMA's expert committee for cell and gene-based medicines, found that the benefits of Casgevy outweighed the possible risks in patients with beta thalassemia and SCD. The CHMP, EMA's human medicines committee, agreed with the CAT's assessment and positive opinion, and recommended approval of this medicine.

The opinion adopted by CHMP is an intermediary step on Casgevy's path to patient access. The opinion will now be sent to the EC for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role or use of this medicine in the context of the national health system of that country.

Artificial intelligence workplan to guide use of AI in medicines regulation

December 18, 2023

EMA and the HMAs have published an artificial intelligence (AI) workplan to 2028, setting out a collaborative and coordinated strategy to maximise the benefits of AI to stakeholders while managing the risks.

The workplan will help European Medicines Regulatory Network (EMRN) to embrace the opportunities of AI for personal productivity, automating processes and systems, increasing insights into data, and supporting more robust decision-making to benefit public and animal health. The AI workplan, prepared under the joint HMA-EMA the German Federal Data Protection Act (BDSG), ensures the EMRN remains at the forefront in benefiting from AI in medicines regulation. The workplan was adopted by EMA's Management Board at its December, 2023, meeting.

The field of AI is developing swiftly. Pharmaceutical companies increasingly use AI-powered tools in research, development, and monitoring of medicines. National competent authorities are responding to the new opportunities and challenges by starting to use and develop AI tools. The workplan focuses on four key dimensions:

- **Guidance, policy, and product support:** Actions focus on continuous support to products in development as well as the development and evaluation of appropriate guidance for the use of AI in the lifecycle of a medicine. Work has already begun with the ongoing public consultation on the AI reflection paper, open until the end of December 2023. Furthermore, in 2024 preparations to support the implementation of the EU AI Act will start.
- **AI tools and technology:** The aim is to identify and provide frameworks across the network to use AI tools to increase efficiency, enhance understanding and analysis of data, and support decision-making. Full compliance with data protection legislation will be ensured.
- **Collaboration and training:** Initiatives are designed to continuously develop capacity and capability of the network, partners, and stakeholders to keep ahead of the evolving field of AI.
- **Experimentation:** The workplan acknowledges the fundamental role of experimentation in accelerating learning and gaining new insights. Several actions are proposed to ensure a structured approach to experimentation across the network.

As AI technology is fast evolving, including the ethical and policy aspects related to it, the BDSG will regularly update the workplan. Regulators, medicine developers, academics, patient organisations and other interested parties will be informed and engaged throughout the implementation of the plan.

Digital Communication

Editorial

While English is one of the most widely spoken languages globally, it cannot replace the richness of over 7,000 spoken and signed languages worldwide, each with its unique intricacies and cultural nuances. For understandable and precise medical or health information to support decision-making, translation into one's native language becomes crucial. Skilled human translators remain the cornerstone of medical translation. However, digital translation tools like Google Translate, despite imperfections in accuracy and reliability, have, without a doubt, significantly enhanced the speed and accessibility of translations globally. Where automated tools may be lacking, human experts can bridge the gap. Natasha Grande de França introduces us to computer-assisted translation tools (CAT), a type of digital translator that relies on human involvement to produce highly accurate translations quickly and consistently.

Happy reading!

Nicole

SECTION EDITOR

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Purr-fecting translation: Unleashing the power of computer-assisted translation (CAT) tools

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Medical translations are fundamental, and precision is at the core of this work. Any minimal inaccuracy can impact patients' lives and the success of a treatment, as illustrated by a case of medical mistranslation and misinterpretation that happened in Germany. German law obligated that the instructions for medical devices be provided in the German language. However, there was no specification for labelling (i.e., "display of written, printed, or graphic matter upon the immediate container…").[1] Given this gap, a US-manufactured knee prosthesis was delivered to a German hospital with the instructions in German language on the interior of the package, but with the original English label. The responsible hospital staff then wrongly translated the "non-modular cemented" (porous) information from the English label to "non-cemented" or "without cement" (smooth surface) in German.[2] This translation error contributed to the failed total knee replacement of 47 patients between 2006 and 2007 – showcasing the importance of accurate translation in medical material content.

Other medical documents include written patient information and informed consent forms, hospital information brochures, and drug leaflets, which must be precisely translated to ensure that all information is fully understood (as intended) and patients are protected.

Translating is more than the "simple" conversion of words from one language to another. It involves understanding the function of language variations, culture, and values.[1] In the case of medical translation, it is also imperative to know medical terms, jargon, and expressions, as well as applicable laws and regulations. Beyond the translation task itself, the 2023–2028 European Master's in Translation (EMT) framework stipulates "the knowledge and skills to implement translation technology" as one of the five main areas of competence of a professional translator, which involves making effective use of computer-assisted translation (CAT) tools. Interestingly, EMT centralises the human aspect of using translator technologies by saying that "human skills are differentiators in a technologised employment market".[3]

In a fast-paced world, there is an increasing demand for higher productivity without compromising quality and consistency. In addition, it is always important that medical or health content is well and equally understood across the globe and in a very standardised way.[4] In this article you can explore CAT tools in the context of medical writing – the good and the bad – to help medical translators become familiarised with this increasingly present and required translation technology.

> CAT tools are not machine translation – the human translator does the translation task with assistance from features.

What are CAT tools, and how do they work?

Firstly, it is crucial to differentiate CAT tools from machine translation (MT). Although both consist of technology created to help the translation process, CAT tools do not translate for you. The European Association of Machine Translation (EAMT) defines CAT tools as "translation software packages that are designed primarily as an aid for the human translator in the production of translation".[5] In other words, when using a CAT tool, the human translator *does* the translation task with assistance from features contained in the software, which may include MT technology.[4,6,7]

MT, on the other hand, performs automated translation without *any* human involvement, i.e., automatically converting a text into another language.[6]

MT is far more popular than CAT tools, especially among non-professional translators. Some classics include Google Translate, Babylon, Omniscien Technologies, Tauyou, and Microsoft Translator. However, despite its popularity, MT often produces translations where the language combination does not match the desired equivalence or oversimplifies the text.[6] This can result in double the work for the translator, slowing down the translation process. CAT tools can be considered an evolutionary translation technology developed for professional translators that incorporates MT as one of its many linguistic tools.[8]

How do CAT tools operate?

Once a source text is uploaded into a CAT tool, the software splits the text into smaller segments to be translated. After the translation is concluded and approved by the human translator, the software stores the translated segments (with the source text) in its database, called translation memory. When a new document is uploaded, the program scans it for the already-used words, terms, or sentences and provides an instant translation. The human translator can refuse any suggestion made by the software. The more translations are performed, the larger the memory and the faster future works will be concluded.[6,8] The detailed steps of translating with the aid of CAT tools can be found in Figure 1.

Advantages and disadvantages of using a CAT tool

Advantages

At this point, we can see that using a CAT tool in medical translation has several big advantages: [6,9]

- Increasing productivity (speeding up the translation process)
- Ensuring consistency across translations
- Promoting better quality control
- Simplifying the terminology management
- Keeping technical terminology consistent
- Reducing repetitive work
- Pricing with greater precision (word counting is done more easily)

With such extensive automated support, the medical translator can focus on the quality of the translation, delivering consistent translations in a shorter time.

Disadvantages

Some studies, mainly qualitative, have raised issues about using CAT tools in general translating.[7,9–11] Despite these studies having certain limitations (sample size, diverse methodological approach, population, etc.), they highlight important factors to consider when choosing an automated- or computerised translation tool. Additionally, identifying potential challenges to users provides software developers with critical information needed to improve CAT tools.

The International Organisation for Standardisation (ISO/IEC 25010:2011) defines structured characteristics and sub-characteristics to "measure" the quality of software and its user experience.[12] Among the key determinants of software quality

Translating with a CAT Tool

1. UPLOAD THE SOURCE TEXT
The source text can be uploaded into the software along with any pertinent reference files

2. ANALYSIS & SEGMENTATION
The software breaks the text into segments usually based on "normal" breaks in a text introduced by a period

3. TRANSLATING
The human translator translates the segment

4. EDITING & APPROVING
The human translator checks suggestions made by the software, edits, and approves the translated segment

5. TRANSLATION MEMORY
The translated segment is matched with the source segment and stored to be used in future translations

6. SAVING
The translated file is saved

7. DOWNLOAD THE TRANSLATED TEXT
The translated file is exported as needed (same or a new file format)

Figure 1. A computer-assisted translation (CAT) workflow [4,8]

CAT tools increase productivity and consistency if usability is ensured

is its usability. That is, whether the software can be understood, learned, and operated pleasingly and satisfactorily to ensure usability compliance.[12] It is fundamental that the use of the software focuses on the task with minimal distractions, such as unnecessary steps or an overload of information.[8]

If the organisation, operations, design, amount, and complexity of functions are not user-friendly, using a CAT tool can cause cognitive overload,[8] constant interruptions of the workflow, and irritability.[10] The main issues

raised by users of different CAT tools are related to:

- **Learnability:** It takes time to get familiar with the software as the supporting material (tutorials and handbooks) is not very instructive, and there is a lack of clarity of information and interface.
- **Helpfulness:** It can be difficult to obtain assistance in the face of technical problems.
- **The complexity of the user interface:** It is unintuitive and requires many mouse clicks.
- **Layout:** The visual presentation of the source and target texts on the screen is not ideal and the menu is overcrowded.

Table 1. Main features to be considered when choosing a CAT tool [6–8]

Category	Description	Why consider it?
Work system	*Desktop-based:* the software is installed on a specific device (sometimes more than one) *Cloud-based:* can be used on any device with internet	Desktop-based CAT tools don't require access to the internet and are "safer" against hacking. But they are limited in terms of cooperative work and flexibility. On the other hand, cloud-based CAT tools provide greater work flexibility, save automatically (data are not lost), and can be more rapidly updated and debugged. But they are susceptible to connection problems and being hacked.
Price	Paid version (annual subscription or perpetual license) or free version	Paid versions can be very expensive (around €300 for annual access and €650 for a perpetual license) but present more functionalities, capabilities, and safety. Free versions may be interesting to get familiar with CAT tools, but they are much more limited.
Layout and design	Amount of information visible on the screen (windows and tools), and usability	Ideally, the screen should not be overcrowded, and the operations can be executed intuitively. This prevents unnecessary interruptions of workflow and cognitive fatigue. Some CAT tools allow customising their settings.
Terminology management	Creation of a database with specific terms (termbase)	Having a glossary with specific terms (jargon, words, expressions, acronyms, brands) ensures more consistency across texts of the same client.
Project management	Collaborative functions	Allows more than one translator to work on the same project and direct communication with project stakeholders.
	Budgeting feature	Enables calculating the expenditure and revenues (assists with the financial aspect of the projects).
	Reporting and analytics tools	It generates measurable information on the translation progress, the volume of translations, and other relevant data to help in defining a budget, the deadline, and decision-making.
Supporting tools	Optical character recognition	Converts a printed or handwritten text into an editable text format, which is particularly useful when working with scanned documents, uneditable PDFs, or photos.
	Segment analyser	Assists the translator in understanding how much work the project will require.
	Machine translation engine integrated into the software or connected via plug-ins	As it automatically translates the text, can be useful in speeding up the translation when the translator starts a new project in a new domain (correcting automated translations can be faster than translating from scratch).
	Quality assurance management	In addition to spelling and grammar checking, this feature allows inspection of numerical divergences, missing tags, and format.
Upload and exportation file format	The supported file types can be diverse or limited. Some formats include SDL XLIFF, XLIFF, Microsoft Word, Microsoft PowerPoint, Microsoft Excel, RTF, HTML, and Adobe	When CAT tools are compatible with several file formats, it gives clients more possibilities, in addition to making the translators work easier and faster.

- **Segmentation:** Only a partial view of the text is available.
- **Formatting (font, tags, number):** It is immutable, not possible to highlight text, and it is difficult to delete or copy tags and quotation marks.
- **Incompatibility:** There are issues with non-Roman character sets, such as those used in Arabic and Asian languages.

Issues like the above-mentioned can impact productivity. In a study comparing two CAT tools, a more segmented layout (i.e., screen subdivided into more sectors) resulted in significantly fewer words translated in the same amount of time (194 vs. 222).[8] In addition, problems and difficulties with any of the attributes can cause irritability and anxiety and be considered a barrier to translators using CAT tools – with no specific issues particularly related to medical translating.[10]

Learning a new technology requires not only time, which we don't always have but also support, which may explain why most CAT tool users are not freelancers.[10] An additional issue frequently discussed in translator forums is how projects involving CAT tools should be billed.[11] Unfortunately, some clients don't understand the real role of the software in the translation process and may ask for a lower budget.

How to choose a CAT tool

Several CAT tools are available, some, even for free. In general, all CAT tools operate similarly: segmentation of the text, translation work, storage in the translation memory, and export of the file.[6] However, since the first models in the 1980s,[13] CAT tools have evolved and been refined, incorporating several functionalities. Table 1 details the main features to be checked before adopting a CAT tool.

To maximally avoid the issues described in the previous section, it's essential to closely examine the details of different CAT tools. Take the time to read not only the description of the software but also forums with user experiences, and test as many CAT tools as possible as most provide free trials – perhaps the one that suits your colleague best is not the best for you. It is also highly recommended to talk to colleagues and contact a few agencies to check if there are some preferable CAT tools.

No CAT tool is designed specifically for medical translation; however, some may be a better fit for this purpose. When looking for the best option, it's important to consider practical things, such as budget, flexibility (desktop-based vs. cloud-based),

> No CAT tool is designed for medical translation, but some features can better fit this purpose.

integration with other software used in your daily work (e.g., layout and page design software such as Adobe InDesign), and specific needs (does the tool support the file formats I usually use?). Some medical translators have to deal with scanned medical or laboratory reports, so having access to optical character recognition (OCR) is essential.[14] Others receive packages containing CAT projects (with termbase, translation memory, etc.), so using a compatible CAT tool is advantageous.

One of the first CAT tools launched was SDL Trados Studio, which today is one of the most well-known and comprehensive CAT tools. Therefore, it is common to come across Trados file format (SDLXLIFF) – an XML format developed for use in Trados Studio. The good thing is that nowadays many CAT tools are compatible with this format (another relevant aspect to consider).[14] Besides SDL Trados Studio, other well-reputable CAT tools include MemoQ, Wordfast, Memsource, Déjà Vu, Across, Wordbee, and XTM Cloud. All must be purchased. Free options are also available and although they have fewer functions, they can be useful when becoming more familiar with CAT tools. They include OmegaT, CafeTran Espresso, Smartcat, MateCat, and Wordfast Anywhere.[6]

Last but not least, it is essential to evaluate the privacy conditions defined by the client and the applicability of using online CAT tools. Although safe, cloud-based tools can be more susceptible to compromised privacy, when working at an agency, where collaborative work is common. In this case, agencies have several options to ensure their security and privacy, such as using private clouds or server-based CAT tools (which require access or permission to be granted).

Conclusions and perspectives

It seems inevitable and even desirable to use a CAT tool, especially when consistency is required and cooperative work is common, such as in medical translating. Although careful consideration of possible drawbacks is needed, using CAT tools provides several benefits to the medical translator, including increased productivity, improved accuracy, and a generally higher quality of the work produced. More than this, it ensures better intra- and inter-consistency of the translation. Most professionals agree with these benefits. However, some hesitation exists due to issues in the software's usability, which can irritate translators. In this sense, constant

improvements to the software are central to making the translator's work as intuitive, easy, and fast, with as few interruptions as possible.

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

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Medical Devices

Editorial

EMWA's medical device expert seminar series (ESS) brings together speakers with different expertise providing valuable insights into the medical device industry. With the Medical Device Regulation (MDR) in full force, experience and knowledge need to be shared, especially for unconventional medical devices. In 2023, the ESS at EMWA's conference focused on some niche medical devices. From medical writing under the MDR to medical device software, four speakers shared their experiences relevant to medical writers.

Payal

Medical device Expert Seminar Series: Beyond traditional medical devices

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Abstract

As with every medical device expert seminar series (ESS), we learned something new at the ESS held at the EMWA Conference last May in Prague. With the Medical Device Regulation (MDR) in full swing, the speakers not only discussed MDR-compliance challenges but also shed light on niche products, such as in vitro diagnostics (IVDs), combination products, and medical device software (MDSW). With great pleasure, we summarise the key messages of each of the four presentations for our readers.

Medical writing and the MDR

Our first speaker, Tom Melvin, a medical doctor-turned-regulator-turned-academic, opened the session with a brief discussion of the MDR changes and its effects on the current public health situation, including the impact on medical writers. Currently Associate Professor of Medical Device Regulatory Affairs at Trinity College Dublin, Tom worked for 7 years as a senior medical officer in medical devices at the Health Products Regulatory Authority.

The presentation began with a brief history of MDR developments from when the Medical Device Directive (MDD) was put in place in 1993 to the current state. With more than 33,000 medical technology companies in Europe[1], of which 95% are small- and medium-sized, it's evident who's taking the brunt of the transition hurdles. Though the EU MDR was necessary to update the outdated directive, the challenges of its implementation are affecting the cost and predictability of compliance requirements, and ultimately, the availability of the products in the EU market. But it wasn't until October 2021 when the regulators first became aware of the risk of product unavailability, especially for high-risk devices whose certificates would expire in May 2024.

So finally, the system had to grant more time, and in December 2022, a clear proposal was made to amend the transition period for medical devices to curtail the risk of impending shortages. But when the resulting amendments to the EU MDR were released under Regulation (EU) 2023/607 in March 2023, the industry was sent scrambling to understand the slew of conditions in the

> In December 2022, a clear proposal was made to amend the transition period for medical devices to curtail the risk of impending shortages.
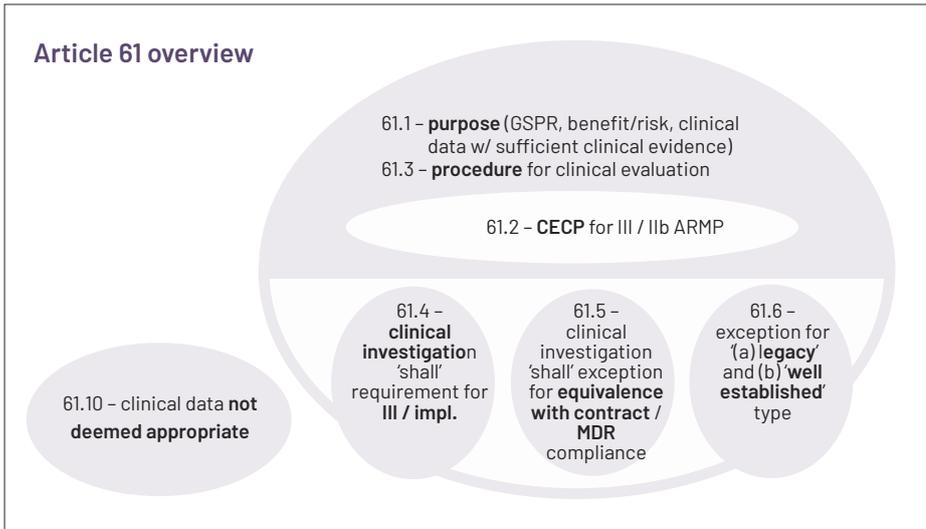
Figure 1. MDR article 61 overview

Figure by Tom Melvin, used with permission.

Abbreviations: GSPR, General Safety and Performance Requirements; CECP, Clinical Evaluation Consultation Procedure; MDR, Medical Device Regulations; ARMP, Administer and/or remove a medicinal product; impl, implantable device.

qualification of devices for the extended timelines. Many questions remain, and the situation continues to unfold before us. Despite the many factors affecting the moving timelines for compliance, medical writers are still best equipped to understand the writing implications from the regulation.

In a recap of Article 61 (see Figure 1), a graphic interpretation of the regulation illustrates different pathways applicable to different risk classes and the respective clinical investigation requirements.

Of particular importance is additional information pertaining to clinical evaluation as well as expectations for legacy devices and the limitations of declaring equivalence, found in the ISO 14155 (GCP)[2], MDCG 2021-6[3], and MDCG 2021-8[4]. And lest we forget, specific country regulations need to be considered too. But finally, a short mention of the European Database for Medical Devices (EUDAMED) objectives is a subtle reminder to stay optimistic about the efforts towards harmonisation across Europe.

Another development includes the Co-ordinating Research and Evidence for Medical Devices (CORE-MD), a work package under European Union Horizon 2020, examining the number of ISOs with clinical evidence requirements. But with all the ongoing efforts, perhaps something to look forward to most for regulatory writers are the developments toward standardising clinical evaluation through a yet-to-be-released ISO 18969.

In Vitro Diagnostic Regulation (IVDR) in the context of clinical trials

The second presentation of the hour was delivered by IVD regulatory expert and trainer Anne Paulussen for Qarad in Belgium, a consulting company specialised in regulatory affairs and quality systems for IVD and medical devices. Having worked more than 10 years in the pharmaceutical and medical industries, in both development and post-marketing activities, Anne is now involved in training and educating IVD developers in understanding the new regulations.

Like the MDR, the In Vitro Diagnostic Regulation (IVDR) was a much-needed reform to the outdated In Vitro Diagnostic Directive (IVDD, 98/79/EC) of 1998. What was once based on a "prescriptive list" of devices in the IVDD, wherein the majority of IVDs were self-certified and had easy access to the EU market, the classification under the IVDR is based on risk-based rules (Figure 2). Now under the IVDR, the majority of these "other" IVDs that did not fall under the List A or List B of Annex II of the IVDD require Notified Body (NB) approval and more complex and costly approaches to provide clinical evidence.

And just like the adjustments for the MDR timelines, under the conditions drawn out in the Regulation (EU) 2023/607 amendment, the timelines for the IVDR had to be adjusted too, to give industry more (much needed) time to comply.

Meanwhile, manufacturers must continue completing their technical documentation and ensuring the robustness of clinical evidence to support the performance claims of the IVD. But which assays are considered IVDs in clinical trials?

Typically, assays in clinical trials have different purposes and development histories. And the questions that need to be asked impact the ruling for conducting the clinical trial. In a simplified example taken from MDCG 2022-10,[5] the processes are categorised into those "with" or

> But which assays are considered IVDs in clinical trials?
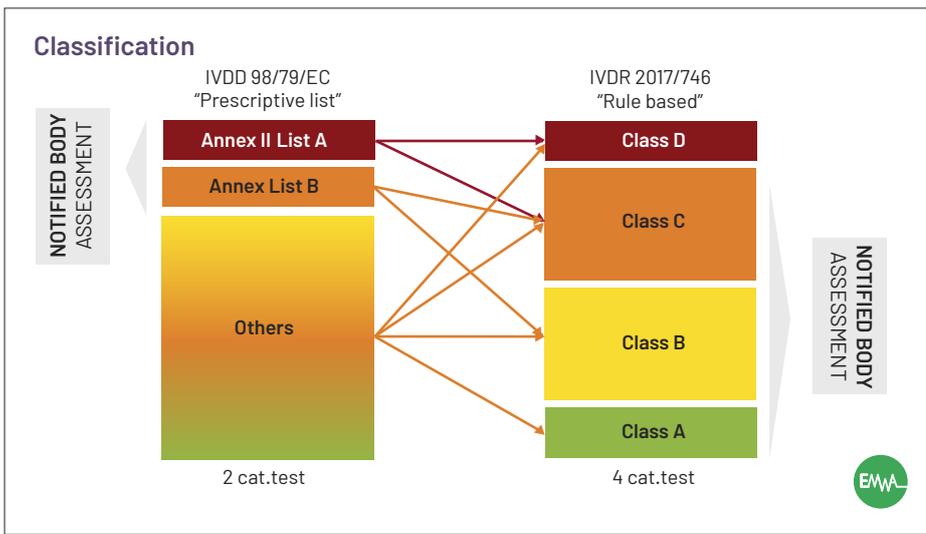
Figure 2. Classification under the IVDD and IVD6

Figure by Qbd, used with permission.

Abbreviations: IVDD, Invitro Diagnostic Directive; IVDR, In Vitro Diagnostic Regulation.

"without" impact on the patient management, thus determining whether the process must comply with the IVDR. Specifically, for processes without an impact on patient management, like those pertaining to stratification and data analysis endpoints, the IVDR does not apply. And for processes with impact on patient management, like patient selection and monitoring, the IVDR clearly applies.

However, if the answer is yes to the following speculative condition, "Is it predictable that the assay will be used with impact on patient management in future clinical trials?" then IVDR (Annex I) also applies!

In the context of clinical trials, the IVDR regulates only the development and manufacture of IVDs, not their use. Thus, if the IVD is used outside the intended purpose, the clinical trial sponsor assumes the obligations of manufacturers under Article 16(1) of the IVDR. The sponsor is also responsible for other products used in the trial and must document the competence of the testing laboratories to support the reliability of the results.

For companion diagnostic (CDx), an IVD used to identify patients and essential to qualifying them for the safe and effective use of a specific medicinal product, additional considerations must be made as additional time is required for the consultation process when the NB must seek the scientific opinion of the European Medicines Agency (EMA) during a CDx review. But with limited NB availability, it is no surprise that as of May 2023, only one CDx has been approved under the IVDR.

Not only do pharmaceutical sponsors and IVD manufacturers deal with different products, but they also function and represent two worlds apart. The timelines for developing an IVD are vastly different to that of a drug product, and so are the regulations. And where does the medical writer lie in this clash of two worlds? Perhaps speaking both regulatory languages of the pharmaceutical and IVD industries is a good place to start.

Combined products: regulation and clinical development

Another type of medical product that must take into consideration the regulations for pharmaceutical products as well as medical devices are combined products, combination products, or drug device combinations. Guest speaker Kathy Wang, the Regulatory Affairs Director, Devices and Digital Therapeutical, at AstraZeneca, discussed navigating regulatory pathways in various regions and how to bridge the gap

US combination product definitions
Combination product is formally defined and includes three types

A product where those components are either

| Medical Device | Drug/Small Molecule | Biologic/Large Molecule |

...comprised of two or more regulated components

| Physically or Chemically Combined | Co-packaged Together | Cross-labelled and Create a New Intended Use |
| US CFR 21 Part 3.2 (e)(1) | US CFR 21 Part 3.2 (e)(2) | US CFR 21 Part 3.2 (e)(3 and 4)[4] |

Figure 3. US combination product definitions
Figure by Ryan McGowan. Used with permission.
Abbreviations: US CFR, United States Code of Federal Regulations.
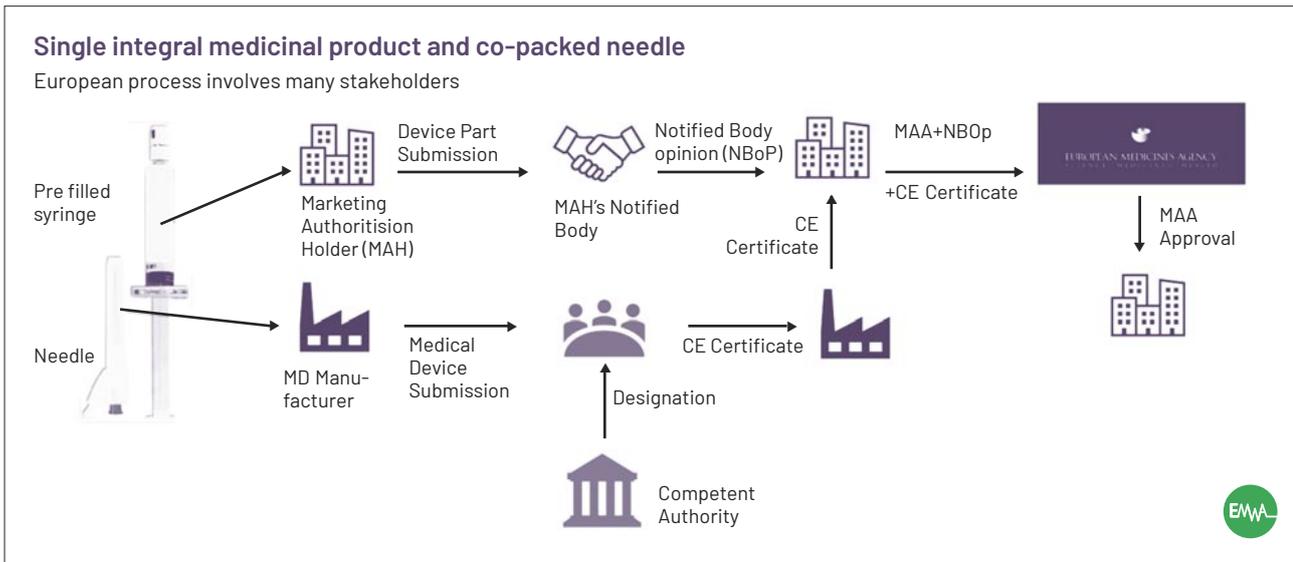
Figure 4. Complex process of MAA approval in the EU
Figure by Kathy Wang, used with permission.

between the medicinal products and the medical device frameworks.

Kathy's presentation began with an overview of these types of products and how they are regulated in the United States (US) and in the EU. Despite the development and increasing use of combination products, medical devices, and digital health technologies, there is no harmonised regulatory framework for these products globally. In the US, combination products are formally defined and categorised in the US regulations (see Figure 3), resulting in a streamlined approach to pre-market submissions

If coordinating the application is not challenging enough, manufacturers must consider the different timelines of drug (for e.g., 10 to 15 years) and device (for e.g., 2 to 5 years)

and post-market activities.

From a submission perspective, the US FDA center responsible for reviewing the entire submission is determined by the combination product's primary mode of action (PMoA). For example, the submission dossier for a combination product with a drug PMoA, like a single-integral medicinal product and co-packed needle, will be a drug submission to the Center for Drug Evaluation Research with device information integrated into Module 3 of the eCTD (Electronic Common Technical Documentation). And for combination products with a device PMoA, the drug information is included

in the pre-market notification or application to the Center for Devices and Radiological Health.

By comparison, in the EU, there is no formal recognition of the term "combination product" or the different types established in the US (see Figure 3); however, products that combine a drug with a device are referred to as drug-device combinations and involve more than just one regulatory authority. Therefore, the final market authorisation application would not only require device information but also an NB opinion or conformity declaration for the device component (see Figure 4).

And if coordinating the application is not challenging enough, manufacturers must consider the different timelines of drug (for e.g., 10 to 15 years) and device (for e.g., 2 to 5 years) development and the different types of clinical

Clinical documentation – Combined trials and the role of a medical writer

Medicinal Product Documentation	Overlap Potential	Medicinal Device Documentation
Clinical Trial Application		Clinical Investigation Application
		Clinical Evaluation Plan
Clinical Trial Protocol	◄ Protocol ►	Clinical Investigation Plan
Medicinal Product IB	◄ Investigator Brochure ►	Medical Device IB
Clinical Study Report	◄ Study Report ►	Clinical Investigation Report
Clinical Summaries (Overview as part of the CTD)		Clinical Evaluation Report (Part of technical file, updated regulatory)

Figure 5. Clinical documentation for drug-device combinations
Figure by Kathy Wang, used with permission.

evidence needed for each component.

And as Kathy emphasised in her talk, for the medical writer, being able to understand the overlap potential of the clinical documents required for a combination product or drug-device combination would be an invaluable asset (see Figure 5).

Regulating medical device software

Just like the unique challenges faced by IVDs and drug-device combinations, devices such as Medical Device Software (MDSW) or Software as Medical Devices (SaMD) must take into consideration special regulations.

Our speaker on MDSW was Dragan Jovic, a medical software consultant and certified auditor, currently the Director of Quality Assurance and IT for Re5 ApS, a medtech company based in Denmark specialising in neurological treatments.

Under the MDR, changes to the classification of software have been a leading cause for concern. The term MDSW was established in the EU within MDCG 2019-11[7] and falls under the definition of a medical device according to MDR Article 2(1). On the other hand, the term SaMD was established by the International Medical Device Regulatory Forum (IMDRF) to refer to software apart from the hardware medical device. Thus, understanding when software is a medical device is key, and this
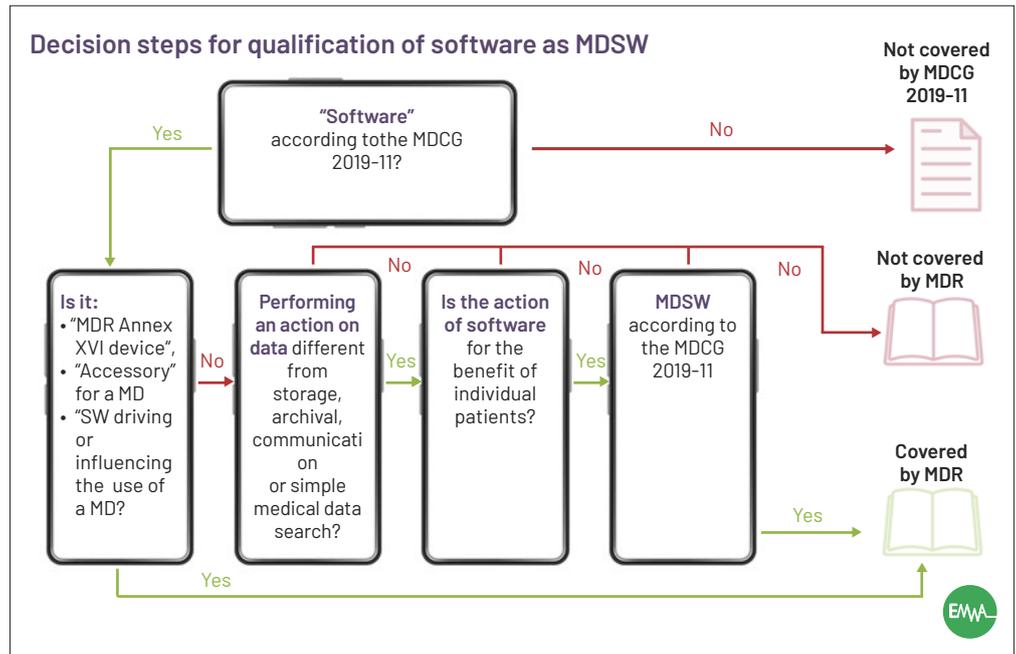
Figure 6. Decision steps for qualification of MDSW
Figure by Dragan Jovic, used with permission.
Abbreviations: MDCG, Medical Device; MDR, Medical Device Regulation; MD, Medical Device; SW, Software; MDSW, Medical Device Software.

must take into consideration the EU MDR Rule 11 of Annex VIII, or all classification and implementing rules of Annex VIII of the IVDR (see Figures 6 and 7).

In addition, manufacturers need to follow relevant standards such as IEC 623041(11), which lays out a best practices framework for software development including cybersecurity management and the corresponding docu-mentation based on the software safety classification. Moreover, the release of MDCG 2020-1 for clinical evaluation of a MDSW lays out the definition for clinical benefit and clinical evidence for SaMDs or MDSW. When the software is designed to drive or influence another medical device, the necessary compliance requirements are assessed within the intended purpose of the driven device and not the MDSW.

But as much as MDSW may further innovate the practice of healthcare, it is not unusual for manufacturers to create the MDSW before having any documentation of its development and try to avoid regulatory processes for their software. Sometimes medical application developers have little or no formal medical training and do not involve physicians in the process. Sometimes developers may even forget the medical purpose while defining the intended purpose of their device. Such communication gaps may be an opportunity for medical writers to apply their skills to provide documentation and clarity in the regulatory processes for SaMDs and MDSWs.

Conclusion

With all this knowledge shared, the panel discussion covered topics ranging from the benefit-risk assessment to the role of medical writers in this evolving regulatory landscape. Both the speakers and the audience agreed that a more transparent communication among

Figure 7. Classification of MDSW
From MDCG Guidance 2019-11
Abbreviation: IMDRF, International Medical Device Regulator's Forum.

medical writers would be needed to share best practices and experiences. The goal is the same for all: patient safety!

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Disclaimers

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

Disclosures and conflicts of interest

The author declares no conflicts of interest.

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Veterinary Medical Writing

SECTION EDITOR

Louisa Marcombes
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Editorial

In this issue of Veterinary Medical Writing, we are revisiting the concept of graphic medicine: the use of comics in healthcare communications. In the article, I give my perspective on why I believe this underused medium is an asset for medical communications. It brings medical humanities into the clinical space, in-line with the current evolution of clinical care to a patient-centred approach. Moreover, this Graphic Medicine is a powerful educational tool, as well as having the versatility to generate engaging content on social media. As a freelance medical writer with an interest in graphics and visual communications and who has loved graphic novels since I picked up an issue of the comic book series *Asterix* when I was a child, I am interested in exploring how graphic medicine can be applied to veterinary medicine to improve animal welfare. My first foray into the genre was published in this section in September 2022, and I have learned a lot since then, not least how AI can help me create graphic veterinary medicine content. If this article whets your appetite to learn more about graphic medicine, EMWA's next conference in Valencia, Spain, May 7–11, will feature Dr Monica Lalanda, co-founder of Medica Gráfica, who will speak on the subject at the inaugural Visual Medical Communications Expert Seminar Series (ESS).

Be there or be square.   **Louisa**

What's up, doc? Defining a use for graphic medicine in veterinary communications

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T his article aims to make the case for graphic medicine – comics in healthcare – and attempt to define their use in the veterinary field. Graphic medicine is underutilised in medical communications. However, a growing network of clinicians and academics has been working to change the status quo. The cognitive science that may explain why the comic style can be so engaging is explored, along with the barriers that have prevented the genre from being more widely used in healthcare communications. Drawing on the framework already established by graphic medicine, I speculate how comics in the veterinary domain – graphic veterinary medicine – might be applied to improve animal health and welfare. Finally, I provide some practical tips on how medical writers can start producing their own graphic medicine content. There is evidence that comics are superior to text alone in communicating information. Furthermore, there is an unmet need in medical communications for ways to combat harmful medical disinformation – as the recent COVID-19 infodemic demonstrated – and graphic medicine, along with graphic veterinary medicine, is a valuable tool to address this need.

What is graphic medicine?

Graphic medicine is "an interdisciplinary field within the health humanities that encompasses the creation, use and study of comics in medicine and health".[1] More succinctly, it is the "intersection between the medium of comics and the discourse of healthcare".[2] A comic is "juxtaposed pictorial and other images in deliberate sequences intended to convey information and/or produce an aesthetic response in the viewer".[3] The use of comics to communicate health information had been commonplace from the mid-eighteenth century onwards,[4] predominantly as morality tales that aimed to promote public health. In the 1950s in the US, there were even medical comic titles "M.D." and "Psychoanalysis" stacked on newsagent shelves alongside the more familiar superhero fare.[5] However, apart from a resurgence in health comic publications created during the HIV/AIDs pandemics on an awareness and social justice platform[1], the use of comics as a tool in medical communications faded into obscurity. In 2007, artist and physician Dr Ian Williams founded his website Graphic Medicine (www.graphicmedicine.org), a forum where comics in healthcare could be defined, explored, and developed. "Graphic medicine" has since been adopted as the term for comics in healthcare, and a genre was (re)born. Since then, graphic medicine communities have been established in Italy, Japan, Freie Universität Berlin, and Spain, where Dr Monica Lalanda co-founded Medicina Gráfica.

Graphic medicine has been shown to be effective in diverse areas of medical communications. Its content can be broadly separated into three overlapping categories:

- Those with an educational purpose to explain complex processes, help patients take more ownership of their care, ease anxiety about procedures, and make decisions in their treatment.[6–9]
- Personal stories ("graphic pathography") that use shared experience to provide reassurance and foster empathy. Not only are these invaluable for patients and caregivers with a specific illness, but they also help healthcare providers (HCPs) and medical students develop empathy for patients.
- Finally, as a *therapeutic bibliography*, where access to medical graphic comics can help alleviate patient anxiety, increase positivity, and safely explore the possible positive or negative outcomes they may face. Also to address clinician distress (such as burnout or moral injury); as in "Taking Turns", by MK Czierwiec. [10,11]

There are also tangible uses for comics aimed at HCPs, as well as patients and the lay public. Aside from their use in developing empathy – essential for effective patient care – the advantages of literature presented in an engaging, easy-to-read format to someone who is likely time-poor with an already high cognitive load should be

Figure 1. The use of metaphor in graphic medicine

This panel, from a graphic veterinary medicine project to raise awareness on Syringomyelia and Chiari-like malformation in Cavalier King Charles spaniels, depicts one dog with a rugby ball icon superimposed over its head and another with a football icon. The use of this imagery is fully evidenced, being based on imaging studies of affected dogs [Rusbridge, C. (2020) New considerations about Chiari-like malformation, syringomyelia, and their management, *In* Practice:42(5);252-67]. The goal is that the reader will choose a puppy with a rugby-shaped head and reduce the demand for animals with abnormally spherical craniums.

apparent.[12] "Beware of Droplets and Bubbles" by Dr Argha Manna is a standout example of a comic that would appeal to medical professionals.[13] Based on the fluid dynamics of disease transmission studies at the Bourouiba Group laboratory at MIT,[14] the comic style is used to contextualise the science to the COVID pandemic. After reading the article, the clinician will have a much better understanding of how viral particles change the physics of water droplets without needing to read a dense study report, including sections with applied mathematics. Furthermore, it can be argued that the science presented in the comic format is more engaging than if the same information was given in the traditional scientific diagram format, whatever the level of education of the reader.

How graphic medicine works: image, metaphor, & narrative

A recent meta-analysis supports the theory that the use of images in health information results in superior information, understanding, and recall.[15] Here, I speculate how the comic styles' use of image, along with metaphor and narrative,[10] not only improves understanding but prompts behaviour change.

Consider first the typical format of the comic; the text and image are presented simultaneously, giving the reader immediacy (with no need to interrupt the reading flow to hunt for a figure) along with increased engagement with the images.[16] The visual permanence of the printed (or displayed) image, as opposed to the moving one, also allows the reader to control the rate of information transfer. Moreover, the reader can skip back and forth in the reading field with more ease than it takes with text, and it also gives the reader permission to linger and process the content in their own time.[17]

Dual coding theory proposes that the learning and retention of information are optimised if that information is delivered simultaneously in verbal and image form. This theory is supported by several studies that have linked the comic format to improved information understanding and retention.[18]

The role of metaphor, a figure of speech where one thing is described in terms of something else that is very different, has been shown to have a fundamental role in how our conceptual system defines how we think, speak, and act.[19] Metaphors are used in comics to depict a concept as its metaphor visually. For example, in the large volume of graphic medicine produced during the COVID pandemic, dominating metaphors were war – depicting humanity against the enemy virus – and the superhero, where HCPs were depicted as caped heroes.[20] Figure 1 shows my attempt at the use of metaphor in a graphic veterinary medicine project I recently worked on. The subject was Chiari-like malformation and syringomyelia in the Cavalier King Charles spaniel, and the goal was to make the association in the reader's mind that a round head shape was more likely to be associated with this debilitating disease.

The importance of the role of narrative in persuading a reader (and all communication is an act of persuasion) that a fact is correct or that behaviour needs to be changed is increasingly being recognised.[21] This has been illustrated in an analysis of online anti-vaccination discourse[21] content that is almost exclusively based on unverifiable individual anecdotes and presented to appeal to the reader's emotions and invoke fear.[21] The absence of hard evidence is not a barrier to the content's credibility for a significant proportion of the audience. For this constituency, the anti-vaccine movement "told a better story"[21] than the public health scientists. A well-crafted narrative – regardless of the quality of the underlying science – can inspire the reader's imagination, stoke their passion and provide them with a sense of community, a positive relationship between exposure to a narrative and narrative-consistent beliefs: in other words, narrative persuasion.[22]

Traditional health education is based on the knowledge deficit model – the assumption that people will make positive health decisions once they understand the science.[17] This model ignores the cognitive idiosyncrasies that every-

one possesses, including cognitive dissonance, bias, and heuristics. It explains why health messages often do not translate into healthy behaviours and highlights why another approach may be needed.

Obstacles to and pitfalls of graphic medicine

The main obstacles to the widespread use and adoption of graphic medicine in healthcare communications are a lack of awareness of the format and negative perceptions of the genre.[10] One reason for this is a prevailing negative cultural perception in the US (despite being one of the leading markets for comics) that they are children's publications or superhero stories,[10] that it is low-brow and has insufficient academic rigour. Nevertheless, there have been attempts to use the format by key industry stakeholders (such as the CDC's 2011 zombie apocalypse themed "Preparedness 001")[23] or to depict contemporary health issues (the "Surgeon X" series played out in a near-future antimicrobial resistance dystopia)[24]. However, the consensus is that the graphic medicine genre is under-utilised.[10]

This is not the case everywhere. In France, the comic format (the celebrated *Bande Dessinée*) is part of the cultural mainstream. There are online French-language resources such as *SantéBD* (www.santebd.org), an online library of more than 70 free-to-access, expert-reviewed graphic medicine flyers on diverse health topics from influenza to palliative care, and *BD Medicales* (www.bdmedicales.com), a directory of graphic medicine publications.

An additional problem is that graphic medicine introduces elements to the content that are usually avoided in traditional scientific writing: individual anecdotes, politics, aesthetics, and emotion.[25] Moreover, as medical science communicators, it is worth bearing in mind that there is a constituency of social science scholars who believe that all things visual are political. "…That is, power-laden, grounded in quotidian ideology and thus also able to contribute to shaping our material and social realities".[25] Furthermore, the use of narrative and appealing to emotions – positive or negative – is something that can be done cynically. Any content that is not adequately evidence-based could be considered propaganda, and therefore graphic medicine must be subject to the same rigorous peer review as other forms of medical literature.[3]

Figure 2. In a rendering by the author, an A0-sized poster "Chiari-like Malformation and Syringomyelia in the Cavalier King Charles spaniel" is prominently displayed in a clinic waiting room.

This is a simple yet effective way to communicate health and welfare advice engagingly and entertainingly.

Application in veterinary medicine: Is there a place for "graphic veterinary medicine"?

At the time of writing, there was no substantial body of literature that reported or evaluated the use of comic style in veterinary medicine and animal healthcare communications. A search on Pubmed returned one relevant paper. Bala and collagues[26] described a study where they used comics in conjunction with virtual reality to teach young people in Portugal about the welfare issues surrounding dogs in rehoming shelters. Otherwise, very few articles on comics about veterinary or animal welfare science are searchable, including my graphic veterinary medicine article on the welfare of brachycephalic dogs, published recently in this journal.[27] This is surprising, as animals lend themselves very well to graphic representation and animal images in cartoon form enjoy a broad cultural appeal. Moreover, the use of anthropomorphic animal characters has been described in human graphic medicine to ensure a wider demographic reach[17], an artistic device used for one of the most famous graphic novels: Maus, by Art Speigelman. Considering the applications of comic narrative already applied in human medicine, we can speculate how that may translate into the veterinary field. The most important and obvious difference between the two domains is that veterinary patients are incapable of communicating their views and feelings verbally, coupled with the constant challenge of anthropomorphisism. The stakeholders most qualified to advocate for animals and their needs are veterinary and animal welfare scientists, so their input would be mandatory for any graphic veterinary medicine comic.

Furthermore, there is an educational use for graphic veterinary medicine for all types of surgical, medical, and husbandry interventions on all relevant species. Something as straight-forward as placing a comic prominently as a poster on a waiting room wall is a simple way to engage animal owners (Figure 2).

It is arguable that graphic pathography in veterinary medicine, on the other hand, does not exist. It is unlikely ever to be possible to document, with precision, nuance or credibility, a dog's feelings about living with *Diabetes Mellitus*. Nevertheless, the experience of the owner of a dog with diabetes would be an excellent subject for graphic veterinary medicine. The act of euthanasia, probably one of the most emotionally charged of the veterinarian's duties, could be documented in comic narrative pieces
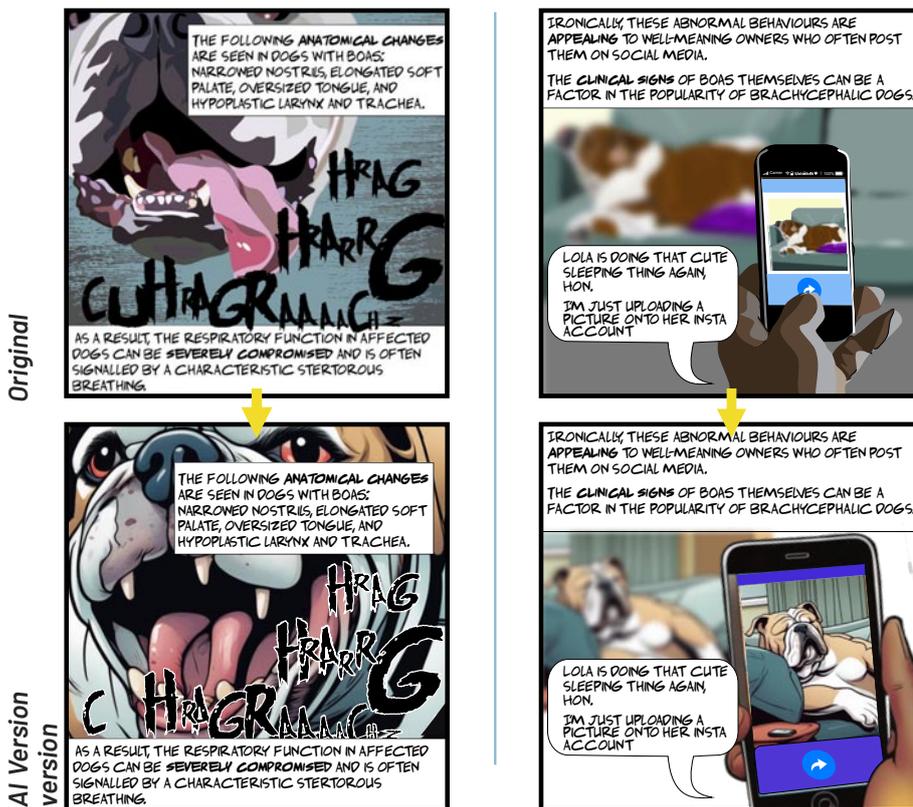
Figure 3. Demonstration of the application of AI in the production of graphic medicine content.

The panels labelled "original version" are taken from the previously published "Everything medical writers need to know about brachycephalic dogs".[27] Both panels have been recreated by generating images on aicomicfactory.com by inputting a descriptive text.

Note: Only the graphics were generated by AI; the text boxes were subsequently added by the author.

that both foster empathy for the emotional upheaval people suffer with the loss of a pet, as well as being a form of therapeutic bibliography for those who have experienced it.

One area that graphic veterinary medicine has the most potential to impact on animal health and well-being is animal welfare – specifically, animal welfare that is directly impacted on by decisions made by human beings.

A multitude of welfare issues seen in the domestic species are a direct result of how they are bred or kept by their caregivers, often unknowingly. The graphic veterinary medicine format, with its emphasis on image and narrative persuasion is ideal for communicating welfare-postiive science, such as that promoted by Human Behaviour Change for Animals (hbcforanimals.com) in a manner that can be culturally and geographically versatile.

Graphic medicine and medical writing

How can medical writers get involved in graphic medicine and graphic veterinary medicine, particularly if they have little or no experience in creating graphics? As mentioned previously, all healthcare comic-style content needs to be correctly evidence-based, fact-checked, and referenced, just as with any other science-based publication. Ideally, the same material should also undergo a target audience review to ensure cultural relevance.[28]

For those medical writers who can draw or are interested in learning how, there is a range of graphics software (Adobe Illustrator, Affinity Designer, Canva, Figma, amongst others). There is also a host of massive open online courses where one can learn how to use the software or work in various design styles. At least a basic knowledge of graphic design principles is recommended, and it will take time to get to a polished standard. Alternatively, a graphic designer or comic artist can be commissioned to provide the graphics. If the size of the project

justifies this, this can be an excellent way to collaborate with creative professionals.

Artificial intelligence (AI), as in so many other domains, promises to make comic-style content creation much more accessible. Numerous AI programs that generate comic artwork from a text description already exist online, including leonardo.ai, comicai.ai, aicomicfactory.com, and comicsmaker.ai. The latter has multiple useful features, including creating characters from sketches, a dynamic pose tool for characters and character training the AI to keep depictions of a character consistent. Figure 3 records my attempt to reproduce two panels from my graphic veterinary medicine article on brachycephalic dogs using AI-generated images. Although not glitch-free (the dog in the first panel has three upper canine teeth), I was impressed by the results. Whether they are an improvement on the original or not will be a matter of personal taste. Furthermore, the software is still limited, which can mean important nuance is lost (such as the depiction of the stenotic nostrils in the first panel). Nevertheless, there is no doubt this technology will improve rapidly and make the production of graphic medicine and graphic veterinary medicine content much more efficient.

A great advantage of the comic format is its versatility for digital publication and sharing on social media. This can be enhanced by the recent emergence of motion comics, where dynamic elements are added to an otherwise static comic image, making the content much more palatable for the moving image culture that currently prevails.[29]

Conclusion

This article has argued that comics, graphic medicine, and now graphic veterinary medicine have a legitimate place in healthcare communications. The genre introduces elements to science communications that are unfamiliar to the traditional scientific discourse, namely individual anecdote, storytelling, and emotive engagement. However, when one considers the increasing prominence of qualitative research in the health sciences and trends towards shared-decision making and patient-centred care, the integration of graphic medicine toward the mainstream is a natural evolution. There is certainly a parallel role for graphic veterinary medicine particularly in animal welfare, and improving the lives of animals beyond the clinic.

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Medical Communications and Writing for Patients

Editorial

Dear all,

Happy New Year! Welcome to the first issue of 2024's *Medical Writing*. I hope that you and your loved ones had a wonderful Christmas break.

EMWA's Special Interest Groups (SIGs) carry out a range of activities throughout the year, including hosting the very popular Meet & Share sessions. These sessions aim to encourage open and honest discussion between medical writers on a variety of topics (usually identified ahead of the session), and never disappoint!

Last September, the Communicating with the Public SIG's Meet & Share session delved into the issues surrounding the roles and responsibilities of ethics committees in the UK and the US. The September meeting was the first of a two-part series on "Protecting the public from undue harm during research studies," and the incredibly experienced Alison Rapley and Art Gertel presented and led the session.

As expected, the September session stimulated a lot of discussion and questions and so we hosted part 2 of the topic in January 2024. A special thanks to the SIG's ever-trusty and talented reporter, Sam Rappaz, who was cajoled into producing another engaging, and very readable article for those unable to get to the session in person. If you did miss this Meet & Share, a recording of the session is available on the EMWA website, and please do keep your eyes peeled – there are more Meet & Share sessions on the way!

I hope that you enjoy this article, see you at the next Meet & Share, and see you in the next issue.

Bestest,
Lisa

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Meet and Share session on protecting the public from undue harm during research studies (part 2): A report

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The Communicating with the Public Special Interest Group (CwP SIG) held in January 2024, was the second part of the two-part Meet & Share series on "Protecting the public from undue harm during research studies". The speakers were Alison Rapley, freelance medical writing trainer and consultant, and Art Gertel, principal consultant at MedSciCom LLC. SIG Chair Lisa Chamberlain James moderated the session.

Writing for "true" consent

Continuing from the discussion in part 1 on the composition, roles, and expectations of UK Research Ethics Committees (RECs),[1] Ms Rapley elaborated on how RECs ensure that potential study participants can give "true" informed consent, i.e. truly understand what they are agreeing to. The parts of the ethics submission that are scrutinised for appropriateness are: Lay Summary (section A6-1 of the Research Application Form), sections A10 to A13 of the Research Application Form, and all participant-facing documents.

Lay summary

Applicants are asked to provide a summary of the research in a maximum of 300 words in "language easily understood by lay reviewers and members of the public."[2] The answers to the following questions need to be provided in the lay summary:

- "Why?": What is the research question and why is it important?
- "What?": What disease, therapy, or service is being studied (broadly speaking)? For therapeutic studies, what is the drug, device, or procedure being tested?
- "Who?": Who would be eligible to participate? Who is funding the research? Who is conducting the research?
- "Where?": Where will the recruitment be done?
- "How?": How long will the study last? What is the study design? What will the participants undergo? Do the participants need to submit anything?

Other plain-language sections of the Research Application Form

Sections A10, A11, A12, and A13 also need to be written in a language that is easily understood by a member of the general public. In section A10 applicants must clearly state the study's primary research question or objective and in section A11 all the secondary research questions or objectives. In section A12 applicants must provide the scientific justification for the research. The information must clearly and simply answer the following questions:

- What is the "knowledge gap" the research is designed to fill?
- Why is the research question important?

- What will be gained by answering the research question?
- Has similar research on this topic been done before? If so, why do we need an additional study? What is being done that has not been done before?

In section A13 applicants must "summarise their design and methodology. It should be clear exactly what will happen to the research participant, how many times and in what order".[2] Depending on the study type, the applicants must also address the following points:

- The null and any alternative hypotheses and why such an alternative hypothesis was chosen
- Scientific and practical justification for the study design and methodology. If patient groups, carers, service users, or members of the public were involved in decisions on study design, explain how their inputs were incorporated into the final design. Ms Rapley highlighted that RECs give importance to suggestions generated from Patient and Public Involvement (PPI) projects in clinical studies
- Justification for including control arms to a trial, particularly for use of a placebo arm
- Procedures to detect and compensate for any

possible "researcher effects" and "researcher bias"
- Sampling: how participants will be identified, approached, and sampled; calculations of study power and sample size
- Broad timetable for the stages of the research, such as preparation, convening meetings or conducting interviews, interpreting and analysing findings, preparing the final report
- Site(s) for interviews
- Plans for interim analyses or reports

Advice for drafting an effective research application form
- **Meet reviewers' expectations.** Reviewers should be able to easily ascertain whether the research is useful, whether the study can answer the research question, the current state of the field, and whether the participant inclusion and exclusion criteria are justified and as inclusive as possible. These and other aspects of the study that are scrutinised by RECs are presented in the report of part 1 of the Meet & Share series.[1]
- **Ensure that the language is easily understood by a general audience.** Remember that a third of the REC membership com-

prises members of the public (i.e. not registered healthcare professionals or professionally involved in clinical research). Language-related issues are the most common issues faced by RECs. Ms Rapley had the following suggestions to improve the understandability of a lay summary:
- Test it out on a non-specialist who is not intimately involved in the research. This could also be part of the PPI aspect of the study.
- Use readability scores. The scores calculated using the Microsoft Word® Editor function (Flesch Reading Ease and Flesch-Kincaid Grade Level) are good enough to get a rough estimate of the language level. There are also plenty of web-based applications that can be used to analyse readability.
- Use plain-English guides and glossaries. The National Institute of Health Research (NIHR) plain English summaries guide, published in April 2021, is useful for writing and reviewing lay summaries.[3] Use plain-language substitutes for technical language and acronyms. These can be found in plain language glossaries such as the
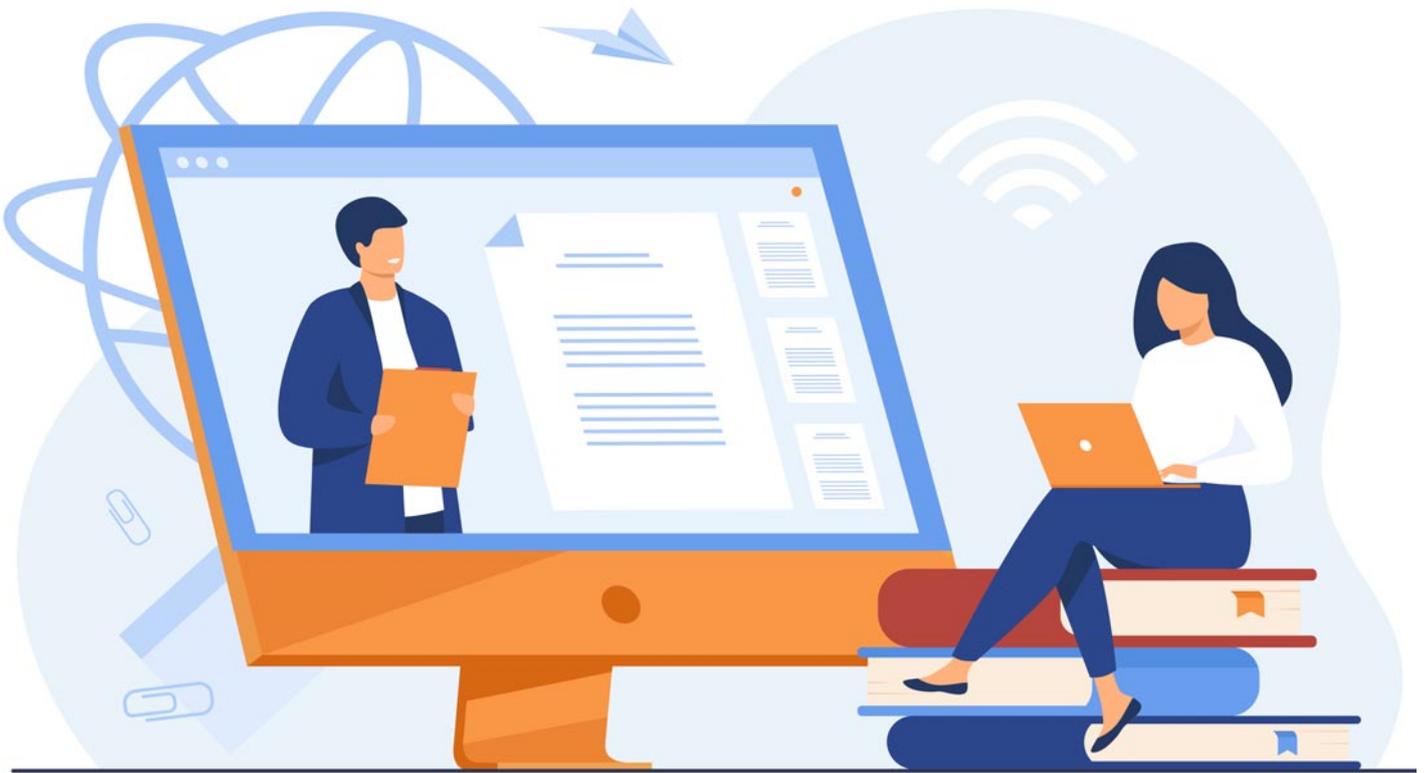
Multi-Regional Clinical Trials (MRCT) Center Clinical Research Glossary.[4]

- Use generative AI tools, such as ChatGPT (https://openai.com/chatgpt), to evaluate and rewrite text in plain English. Ms Rapley has found ChatGPT's outputs to be "not too bad"; she suggests using them as a good starting point.
- **Use visuals to make processes and information clearer**, such as flow charts, diagrams, tables, etc. Information in section A13 is especially hard to grasp when presented just verbally and should be accompanied by well-designed visual elements.
- **Do not simply reproduce or refer to the protocol**, especially when answering sections A12 (scientific justification) and A13 (study design and methodology). Ms Rapley requested all medical writers who work on ethics submissions to highlight this advice in their organisation's standard operating procedure (SOP) document. The text from the protocol will not be appropriate for the REC membership, making it not fit-for-purpose and copy-pasting also signals to the member-

Do not simply reproduce or refer to the protocol.

ship a lack of empathy and diligence, which may alter their perception of the study.

- **Ensure that the information in the application form clearly reflects the protocol and the Patient Information sheet.**

What is the consequence of submitting an ethics application that is not easily understood by the lay reviewers and members of public? The REC will point out the problem and have more questions and requests, which means it will take longer for the study to be approved. Ms Rapley pointed out that while RECs do not have the power to request a resubmission of the application form (although they wish they could), they can keep asking questions until they get what they want. In her experience as a REC member, she has reviewed applications that have been rejected due to ethical concerns arising from poor language. Dr Gertel, who in part 1 of the series had discussed the composition and functions of Institutional Review Boards (IRBs) in the US,[1] added that IRBs do have the power to label an application as unacceptable and request a rewrite and resubmission. He finds this to be very useful

when IRBs review decentralised clinical trials (DCTs), where screenshots of interfaces are provided for assessment; these interfaces need to be understandable as the participant is isolated and has no access to immediate support.

Participant-facing documents

The contents of the Patient Information Sheet, Informed Consent Form, and other participant-facing documents (recruitment posters, diaries, debriefing documents, etc.) are scrutinised by the RECs for comprehensiveness and understandability. The RECs can send back these documents if deemed inappropriate and will do so until they are satisfied that the information provided will enable participants to provide "true" informed consent.

RECs check for the following features when reviewing these documents:

- Is the information provided in a language the participants can understand? Are the explanations clear enough?
- Is everything that happens to the participants and is required by the participants clearly explained and logically organised? For example, number of visits, time needed, what happens at each visit, any restrictions during

the study (such as "no alcohol"). Ms Rapley suggested using the point of view of the participant when designing this information.

- Have visuals been used? Ms Rapley strongly suggested using diagrams, flow charts, etc. to augment the text. She warned against using the schedule of events meant for investigators and study site managers – these would need to be adjusted.
- Is the content age-appropriate? If participants from different age groups are to be recruited, separate sets of documents must be designed for each age group.
- Is the content relevant to the UK population? Ms Rapley noted that it's common to see US-centric content meant for IRBs reused when applying to UK-based RECs, such as reference to cost of payment (which does not apply under the NHS) and usage of words and phrases common to the US and not the UK.
- Are the risks and benefits of the treatment clearly explained, in enough detail and in a balanced manner? This is a key piece of information. Participants want to know if others have been exposed to the drug or treatment and what that experience was like.
- Is there information on what happens to leftover samples? Will the samples provided by participants be destroyed and stored in tissue banks? If the samples are stored, it must not be assumed that they can be used for future studies. Consent must be sought for use of samples.
- Is there coercive language? For example, "This study needs to be carried out."
- How are expenses and loss of earnings borne by the participants being compensated?
- Will the overall study results be shared with the participants? Ms Rapley highlighted that participants give a lot of time and put in considerable effort and should be given the overall results of the trials.

Ms Rapley noted that participant-facing documents are the hardest to get right and are almost always sent back for rewriting. A session attendee asked Ms Rapley what her suggestion would be to convince applicants (who are the clients or employers of medical writers) to use plain language as they sometimes push back against changing terminology. Ms Rapley clarified that the RECs have requirements and make suggestions. While the applicant has to meet the ethical requirements, the suggestions are more subjective and sometimes cannot be incorporated for practical reasons (for example, terminology needs to be consistent across multiple study sites in a multi-centre trial). So, if it's not an ethical issue the REC can be flexible but would hope that the applicant presents a better written application next time.

New guidance and standards for ethics submissions in the UK

The Health Research Authority (HRA) in the UK has created a new set of guidelines for drafting participant information called the Design and Review Principles[5] and mandatory quality requirements called the Participant Information Quality Standards.[6] The requirements came into effect in December 2023. The Design and Review Principles are meant to show applicants and RECs "what the important ethical considerations are for participant information." They will support applicants in creating information that meets the Quality Standards. The Quality Standards will be applied by research ethics staff at the HRA to check if the applications are compliant before forwarding them to the RECs. The application will be returned if it doesn't meet all the requirements.

Both the Design and Review Principles and the Quality Standards include general advice that a professional medical communicator should already be following when designing and writing for a general audience. Below are the main guidelines and requirements; detailed information is available online.

The Design and Review Principles are as follows:

1. Involve public contributors in the design and review process to ensure that participant information is relevant and understandable for the intended audience.
2. Information provided should be succinct, and the quantity proportionate to the complexity of the study. (Note: Ms Rapley advises to "shrink the 30-pager!").
3. Language should be as clear as possible so that the key points of the information are easily understood.
4. The format of the information should be appropriate for the intended audience.
5. Written information should be formatted to optimise comprehension.
6. Participant information should always be tailored to the intended study population.

The Participant Information Quality Standards are as follows:

1. All acronyms and abbreviations are explained the first time they are used.
2. British English is used throughout.
3. The information starts with a summary of the study specific details.
4. Approved HRA-UK General Data Protection Regulation (GDPR) text is used.
5. Contact details for more information, support, complaints, concerns, etc. should be provided.
6. Adaptation of approved templates is explained.
7. Captions or other appropriate accessible alternatives are used for images or graphics.
8. Where a video has been proposed, a transcript has been provided. All videos should be subtitled.
9. It should be clear that people with relevant experience as patients, family members, carers, or members of the public were involved in the development of the participant information.

Writing in plain language – a worthy challenge

In the next part of the session Dr Gertel discussed the importance of communicating in plain language. Given how easy it is to access health information, patients and the public can inadvertently cause undue harm to themselves if the information they access and believe to be trustworthy is not from a reliable and fact-based source. Dr Gertel highlighted that medical writers are ethically obligated to provide medical information to the public that is not only factually accurate but also presented in a manner that is easily understandable, i.e. written following the plain language and health literacy principles. Medical information provided in plain language empowers patients to participate in the healthcare decision-making process as they understand what options they have and what the consequences of their choices may be. Medical writers who are used to using technical language in their everyday work live in a "bubble", according to Dr Gertel. "I have to rewire myself in how I address concepts to people who are not in the bubble." The struggle for medical writers when it comes to writing in plain language is that one has to be willing to sacrifice some precision to be more understandable, which is hard for most medical writers as they are scientifically trained, and science is built on precision and accuracy. But the lesson here is that if science is not understood (or worse, misunderstood!) science has no value, and so some allowances must be made.

> I have to rewire myself in how I address concepts to people who are not in the bubble.

The principles of health literacy

The classic definition of health literacy refers to an individual's capacity to obtain, process, and understand basic health information and services to make appropriate health decisions.[7] The elements of health literacy are as follows:[8]

- **Plain language:** According to plainlanguage. gov, information is said to be in plain language if the reader can easily find what they need, understand what they find, and use what they find to meet their needs.
- **Numeracy:** Important biostatistics (e.g., risk of adverse events) and numerical information related to health (e.g., managing diet, measuring medicine doses, following medicine schedule) are easily understandable.
- **Clear design:** Using graphic design techniques to present content clearly and meaningfully. Dr Gertel noted that visual communication should be used mindfully as they could hinder understanding and may not work as standalone communication tools.
- **Usability testing:** Evaluating the content, design, and delivery of the information by testing it with users will help determine if it's fit-for-purpose.
- **Cultural considerations:** When approaching a potential participant population due consideration must to given to the population's attitudes, beliefs, and history when to comes to healthcare research.

Development of the MRCT glossary

Dr Gertel had briefly introduced the Multi Regional Clinical Trials (MRCT) glossary[4] in part 1 of the series.[1] In the present session he outlined the process used to develop the glossary and the benefits of having a harmonised glossary. The initial task force, which began its work in 2020 as part of a pilot project, included representatives from various stakeholder communities, such as patient or patient advocates, non-profit or academia, life sciences company (pharma or biotech), medical writing, and independent communication consultants. The first and the most time-consuming step in developing the glossary was building a multi-stakeholder consensus for a term's plain-language definition. Dr Gertel highlighted that it was rare to get everyone to absolutely agree on a definition; the group would eventually agree on a "good enough" definition, which would then be submitted for review. The glossary is being developed using sound governance processes, with the intention of getting endorsed by governing and regulatory bodies such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), FDA, and the International Committee of Medical Journal Editors (ICMJE). The MRCT glossary would then serve as the go-to resource for harmonised plain-language definitions of clinical research terms.

Such a resource would have the following benefits:

- Ensures understanding and alignment ween stakeholders by offering consistent terminology and accurate definitions
- Increases efficiency
- Streamlines the translation process
- Eases adoption of machine learning technologies
- Makes communication more transparent and trustworthy

The MRCT glossary includes definitions for common clinical research terms. And this, Dr Gertel noted, was by design: the task force did not intend to create a dictionary. Ms Rapley noted that therapy area-specific plain language glossaries exist that may be useful to fill in the gaps, and Dr Gertel added that such glossaries need to be used mindfully, by checking that the definitions they provide are truly in plain language. For further information on the MRCT glossary, please read the article "Promoting equity in understanding: A cross-organisational plain language glossary for clinical research" published in the December 2020 issue of *Medical Writing*.[9]

In closing…

Ms Rapley reminded the UK-based medical writers that joining a REC would offer invaluable experience and exposure. More details can be found on the HRA's website: www.hra.nhs.uk/ about-us/committees-and-services/res-and-recs/become-rec-member/. The CwP SIG and the speakers are happy to receive your questions or comments. Please write to the SIG at CwPsig@emwa.org. The SIG thanks the speakers and the attendees for their time and effort and looks forward to welcoming everyone again in their next session, which will be advertised through the usual EMWA communication channels. These sessions are open to all EMWA members so do join!

Acknowledgements

Disclosures and conflicts of interest

The author declares no conflicts of interest.

New Special Interest Groups

Welcome to our new special interest groups!

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My First Medical Writing

Editorial

After a short break, I'm glad to be sharing the work of a rising star in the medical writing and science communication world. On this occasion, I had the pleasure of working with Valentina Torres Monserrat, who has a degree in biotechnology and a specialisation in human embryology. She is a dedicated health professional passionate about demystifying complex scientific concepts and making them relatable to everyday life. Over the past decade, she has devoted herself to human fertility, genetics, and assisted reproductive medicine. However, in recent years, she stepped away from the bench to undertake another mission: democratising scientific knowledge. Valentina is committed to bridging the gap between the scientific community and society. She is passionate about creating informative documents for patients that will empower them to make informed decisions about their reproductive health.

I hope you enjoy this inspiring read as much as I did!

Evguenia

Epigenetics unveiled: The Cinderella story in genetics

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In the grand ballroom of genetics, where we share 99.99% of the human genetic code, a hidden sister dwells in the shadows. The enigmatic Cinderella in this tale is epigenetics, a process regulating gene expression through biochemical mechanisms by altering the proteins that structure chromatin without tampering with the genetic code.

In 2003, when The Human Genome Project was completed and the Cinderella sisters resulted in disillusion, the fairy godmother of science brought epigenetics into the spotlight. Despite the wealth of information we had gained about the human gene code, mysteries persisted, especially in understanding the prevalence of disorders such as diabetes, heart disease, and infertility.[1]

Over the past three decades, exhaustive studies in both humans and animals have unravelled the unique characteristics and profound significance of epigenetics. This regulatory gene expression mechanism is responsible for an organism's phenotype and is not determined. Environmental conditions can shape epigenetics during critical developmental periods – preconception, prenatal, and early postnatal stages – collectively known as the first 1,000 days of a newborn's life.[2,3] These studies promoted the groundwork for the Developmental Origins of Health and Disease (DOHaD) hypothesis, putting forward that the early-life environment profoundly shapes the future health of the developing organism.[3]

Epigenetics is essential for setting cell diversity and permitting adaptation to different environmental conditions. This plasticity during the first 1,000 days of life is physiologically relevant, as it endows the developing organism with a mechanism to acclimate to the intrauterine environment, which reflects the external conditions. This kind of heritable mechanism has a unique characteristic that can be induced by endogenous and external signals, thus endowing the organism with additional complexity. Epigenetics modulation of gene expression can occur in four main ways: chemical modification of cytosine in the DNA molecule; posttranslational modification of chromatin structure through Histone proteins; genetic imprinting; and modulation via non-coding RNA.[4]

Infertility is a multifactorial disease that affects both women and men equally. Today, this disease has a prevalence of 17.5% of the reproductive population, which means that 1 in 6 adults has this pathology.[5] Fertility in humans depends on a perfect interaction of the hypothalamic-pituitary-gonadal (HPG) axis. This neuroendocrine system involves aspects that are developed and fine-tuned during different developmental stages, especially during the embryological period. To date, within the area of reproductive medicine, the diagnostic capacity of infertility needs to be improved, having a decisive intervention on the symptoms but not on the origins.

In the last two decades, preclinical and clinical studies have consolidated the DOHaD hypothesis and its impact on reproductive development and function later in adulthood.[6,7] Just as Cinderella transforms from a maid to a princess due to the circumstances in her background, the intrauterine environment can modulate transgenerational effects via epigenetic mechanisms on the human precursors of gametes (oocytes and sperms). Gametogenesis and the development of the HPG axis occur during the gestational gastrulation phase. This is why environmental effects during the first 1,000 days of a newborn can explain numerous neuroendocrine deregulations adults suffer during their reproductive life. Clinical results have shown that maternal malnutrition during pregnancy and breastfeeding is a crucial factor influencing the offspring's reproductive health, impacting pubertal maturation, gonadotropic function, and gamete quality.[8]

Interestingly, the parental periconceptional environment has also proven to play a funda-

> In 2003, when The Human Genome Project was completed and the Cinderella sisters resulted in disillusion, the fairy godmother of science brought epigenetics into the spotlight.

mental role in the determination of the reproductive phenotype of progeny.[9,10] Paternal and maternal malnutrition and stress previous to conception can induce changes in the oocyte and sperm, which modifies the heritable epigenome pattern that may enhance susceptibility to diseases in adulthood. In humans, it is challenging to address environmental conditions before and after conception separately. In animals, reciprocal embryo transfer allowed dissection of the impact of diet before versus during pregnancy on metabolic features in the offspring. It could be of scientific interest to do longitudinal studies on the life births of patients who received donated embryos.

Although the mechanism groundwork for the intergenerational transmission of non-genetic traits from parents to offspring is not yet fully elucidated, recent evidence suggests that epigenetic processes may be the primary agents. Gonadotropin-releasing hormone (GnRH) neurons in the hypothalamic area are the central regulatory mechanism leading the HPG axis. These neurons regulate the HPG axis at different developmental stages and play a fundamental role in controlling puberty onset and reproductive function.[11] During the last two decades, kisspeptin proteins have emerged as the master regulators of GnRH neurons.[12] Kiss1 neurons, also located in the hypothalamus, encode these regulatory peptides. Preclinical studies show that epigenetic regulation operates on these key neuronal populations, and adverse external conditions can affect various aspects of adulthood reproduction, such as puberty maturation, brain sex differentiation, and gametogenesis.[13]

The difficulties in setting the mechanistic basis of epigenetic phenomena have two main reasons: the difference in timing between the stressor and the physiological result and the tissue-dependent nature of this regulation. More epidemiological studies in different human populations, fertile and infertile, could bring more light to the crucial regulation program.

The Cinderella that is epigenetics is in the centre of the grand ballroom of genetics. However, the mystery behind her transformation is still to be elucidated. Epigenetics may be the clue to infertility diagnosis and also possible

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future neuroendocrine therapies. Today, evidence shows that the DOHaD hypothesis applies to both metabolic and adulthood fertility conditions.

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Leap year

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Skudår

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Schrikkeljaar
Schaltjahr

Schaltjahr

Rok przestępny

Přestupný rok

Année bissextile
Schaltjahr

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The Crofter: Sustainable Communications

SECTION EDITOR

Kimi Uegaki
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Editorial

Greetings from the croft. One of the things that I appreciate about the UN Sustainability Development Goals (SDGs) is how they made me realise that sustainability extends beyond climate change. The SDGs also remind me about inter-relatedness between environmental, social (including health), and economic issues, and how there are multiple ways to make a positive contribution. I'm inspired by the contributions fellow EMWA member Nicole Bezuidenhout makes to sustainability through her volunteer work for a nonprofit called Lightup Impact. In this edition of the Crofter, Nicole and her colleagues from Lightup Impact, Valeria Santoro and Jeniffer Muganda, delve deeper into the concepts of sustainable development, the SDGs that Lightup Impact aims to address, and how effective communication has been key to their success. We also asked Nicole some questions to learn more about how she became a volunteer with Lightup Impact, how her volunteer work and day job complement each other, and other things.

It's also my pleasure to introduce Louisa Ludwig-Begall and Sarah Kabani who are taking over the reigns as co-editors of the Crofter. Both have been directly involved in much needed sustainability-related healthcare research and are keen sustainability enthusiasts. Be sure to get in touch with them to discuss ideas and share your sustainability experiences.

Happy reading!

Best,
Kimi

Breaking barriers in sustainable development in East Africa:
How Lightup Impact is leveraging communications to shift the power to the right actors

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Lightup Impact is an online community of 125 early-stage, locally led nonprofits (also known as grassroots organisations) focusing on gender and health in East Africa. As part of the grassroots movement, these organisations represent everyday people coming together to address local challenges, like poverty, lack of healthcare and education, and discrimination against marginalised groups. They mobilise resources and develop projects and programmes to drive social- and systems change from the ground up, focusing on addressing root causes rather than symptoms. Lightup Impact shifts the power to these young visionary leaders, located across Kenya, Uganda, Rwanda, and Tanzania, and supports them with networking, trust-based partnerships, skills development, and guidance to increase their visibility and long-term success.[1]

Together we address seven of the UN's Sustainable Development Goals (SDG):
- No poverty
- Good health and well-being
- Quality education
- Gender equality
- Decent work and economic growth
- Reduced inequalities
- Partnership for the goals

Lightup Impact envisions a society where grassroots organisations are empowered and sustainable. To achieve that, we want to create a mindset shift towards collaboration, where grassroots leaders in East Africa can work together with one another or with external partners to achieve shared goals. We have embraced the global #ShiftThePower movement to shift the power away from external agencies toward local people by giving them the tools, know-how, and guidance to design and deliver programmes for community development. Thus, we are reforming the practice of development aid and institutional philanthropy.[2]

An essential component of the work we do as a nonprofit is communications (comms). That being said, there are enormous obstacles associated with comms in the nonprofit sector, especially one that focuses on a complex subject like sustainability. Additionally, nonprofit comms differ immensely from that in the for-profit sector, which most of us are more familiar with. At Lightup Impact, we are a small core team of five members (only one of which is a comms professional) supported by part-time volunteers in graphic design, legal, and finance. Despite these limited resources, we regularly communicate with our stakeholders to maintain and build relationships and partnerships, share knowledge, raise awareness and funds for various causes, and spread the good news about our community's impact. In this article, we dive into the challenges of nonprofit comms and the key ways in which one can successfully communicate in this sector and about sustainable development.

A driving force

The UN SDGs comprise 17 goals of the international project that aims to end poverty and achieve equality while protecting the environ-

ment. It goes hand-in-hand with key strategies to improve health and education, reduce inequality, and spur economic growth.[3] For readers of the Crofter, terms or concepts like sustainability or the SDGs are quite recognisable. But most people do not have any idea about these and probably would not be able to name one SDG. This situation is actually not strange at all, as the SDGs are not very frequently or well-communicated to the masses. And this has likely also played a role in the slow progress toward achieving these goals.[4] On November 22, 2023, the www.sdgs.un.org/goals webpage sported 3,862 events hosted, 1,327 publications published, and 7,780 actions taken since the adoption of the 2030 Agenda for Sustainable Development by all of the UN Member States (193 countries) in 2015.[5] This appears to be quite impressive, but according to a *Nature* article, it looks like none of the goals and just 12% of the 169 targets set will have been met by the 2030 deadline.[6]

In September 2023, leaders from around the world gathered in New York City to develop a rescue plan that involved better international cooperation and coordination across various topics and disciplines. Jeniffer Muganda, who works as the Public Relations and Strategic Partnerships Manager at Lightup Impact, attended the Economic and Social Council (ECOSOC) Youth Forum 2023 in preparation for the UN SDGs Summit in September. At the forum, it became clear that young people, despite constituting the majority of the world's population, are often excluded from decision-making processes. This exclusion leads to decision-makers being out of touch with the realities of the masses, which can be detrimental to creating a sustainable future. It is important for young people to take an active role in shaping the future they desire. At the UN SDG Summit 2023, it became evident that young people are the driving force for change. This served as a wake-up call to global leaders, reminding them that it's time to engage in an inclusive conversation and commit to achieving the SDGs together.

At Lightup Impact, we acknowledge the importance of placing young grassroots leaders at the forefront of decision-making and ensuring their participation in the concerns outlined for rapid and effective action towards sustainability. We emphasise the significance of our work and that of our members in creating sustainable social change locally. On another note, for those keeping track, *Nature* is monitoring the progress toward and success stories of the SDGs at the local, regional, and global scale by collecting and featuring relevant articles.[7]

Table 1. Key differences in communication between nonprofit and for-profit organisations

	Nonprofit	For-profit
Driven by	Typically focus on communicating their mission and the social impact they aim to achieve. Messaging revolves around the organisation's values, purpose, and the positive change it seeks to make in the world.	Often emphasise their products or services, competitive advantages, and financial benefits for customers. Messaging is generally profit-driven and aims to highlight value propositions that attract customers and generate revenue.
Stakeholder engagement	Often engage a diverse range of stakeholders, including donors, volunteers, beneficiaries, and community members. Communication strategies prioritise building relationships and trust with these groups to garner support for the organisation's cause.	Primarily focus on customers, shareholders, and employees. Communications are geared towards customer satisfaction, investor relations, and maintaining a positive corporate image to enhance market position.
Funding and resource constraints	Frequently operate with limited budgets, relying on donations, grants, and fundraising efforts. Communications often involve crafting compelling narratives to inspire financial support and mobilise resources.	Generate revenue through the sale of goods or services. Their communications are geared toward promoting products, expanding market share, and increasing profitability.
Measuring success	Success in the nonprofit sector is often measured by the organisation's impact on its mission. Key performance indicators may include the number of lives improved, communities served, or social issues addressed.	Success in the for-profit sector is typically measured in financial terms, such as revenue, profit margins, and market share. Customer satisfaction and brand loyalty also play crucial roles.
Focus	Nonprofits often have a long-term focus on addressing social issues and creating lasting change. Communications strategies may involve educating the public about systemic problems and advocating for policy changes.	For-profit organisations are often driven by short-term financial goals, with communications strategies emphasising immediate gains, market trends, and adapting to consumer demands.

Effective comms for sustainable growth

Comms in the nonprofit sector differ enormously from the for-profit sector in several key ways, reflecting the distinct goals, structures, and audiences of these two types of organisations (see Table 1). For a communicator switching from one to the other, it can be challenging to get it right. Furthermore, comms in the nonprofit sector, particularly in the context of sustainability-focused organisations, presents its own set of challenges when it comes to communicating effectively, namely:

- **Limited resources:** Most nonprofits operate with incredibly limited budgets, impacting an organisation's ability to carry out comprehensive communication strategies.

- **Engaging diverse stakeholders:** From donors to policymakers and the average person with an interest, sustainability involves a wide range of stakeholders with many different interests. Navigating and engaging effectively with this diverse audience in a way that ensures that each communication resonates and encourages action is tough.

- **Complex messaging:** Sustainability is still not widely accepted, and sustainability issues are complex and multifaceted, differing immensely from one community to another. Communicating this topic and its many facets in a clear and accessible way to diverse audiences can be challenging. Additionally, finding the right language and visuals to convey specific concepts is important and needs expert execution.

- **Balancing impact and overhead messaging:** No one wants to hear about an organisation's concerns regarding administrative overhead – most people care more about the impact of the organisation's programmes. Herein lies the challenge of achieving the right balance between communicating these two aspects to donors and stakeholders who care about their investment in the organisation's cause(s).

- **Building and maintaining trust:** Probably one of the most essential aspects for ensuring long-term success is building and maintaining trust among donors, partners, and the public. It is an ongoing challenge requiring authenticity, transparent communication, accountability, and consistency.

- **Adapting to evolving trends:** Sustainability is a rapidly evolving field with changing trends, technologies, and public sentiments. Nonprofits need to remain agile and change their comms strategies to stay relevant and responsive to emerging issues and opportunities.

- **Measuring impact:** A task that is difficult even among for-profit organisations. Nonprofits in the sustainability sector often struggle to quantify and consequently communicate

their impact effectively. Impact in this sector may involve more qualitative indicators, making it challenging to convey results in a way that resonates with stakeholders and in some cases, makes it difficult to apply for grants or report to funders.

The Lightup Impact way

Lightup Impact certainly faces many of these challenges and we continuously aim to address them with strategic planning, creativity, and a strong commitment to ongoing improvement in our comms practices. Our audience comprises a variety of actors, but our community of young grassroots leaders is at the heart of our strategy. To ensure they relate to us, we communicate in a young, creative, and inspiring way. Other stakeholders include our community of supporters and donors around the world, corporate organisations, other social entrepreneurs, partner non-governmental organisations, and civil society at large.

Despite being resilient and proactive, our overall approach is community- and youth-led, and we have implemented a strategy that relies on tapping into each other's networks for expertise or support; we want to learn from our community as much as we want them to learn through or from us. This was beautifully illustrated when we teamed up with the East African Philanthropy Network (EAPN) to co-host our 2nd annual conference, Lightup Impact Days 2023.[8] As the largest philanthropy support organisation in the region,[9] EAPN leveraged their extensive network and comms capabilities to elevate our event's reach and impact. They also supported us with improved design expertise, event coordination, and specialised insights into key topics of discussion, such as equity, systemic change, youth empowerment, support of marginalised groups, and impact in philanthropy. Additionally, we formed, for the first time ever, a

community-elected Founder Committee made up of young grassroots leaders and Lightup Impact community members to voice the needs and wishes of the community at large and provide support in many different aspects of the event's organisation and management. For example, they acted as moderators and speakers of key panel discussions during our conference and actively communicated with delegates throughout; one member even took over our Instagram account for a day, posting relevant content throughout and giving our online community an authentic look into our conference activities. This level of engagement and support from our community for our community is what sets us apart from other organisations. "Lightup Impact is the best consortia I have been part of so far", our member from Uganda, Bridget Kigambo from Girl Potential Care Center, told us. "What I like the most about Lightup Impact is that you truly do what you say. Expectations are clear, and you give opportunities to different organisations. We are part of shaping what Lightup Impact is all about", she said.

Operating in the same field, as the same type (nonprofit), and stage of organisation (early stage) as our members, we have a good understanding of their challenges and needs and the local customs and traditions that should be mitigated or navigated when communicating with them or our local audiences. Working closely with our members on the ground has been key to our understanding and learning how to communicate with them effectively. Moving our headquarters to Eldoret, Kenya, was critical in this regard, too. Now we can visit and form relationships with current and potential members, partners, and other relevant stakeholders in person.

In terms of technology, Lightup Impact has been quite good at learning and incorporating

> Lightup Impact envisions a society where grassroots organisations are empowered and sustainable.

Panel discussion during Lightup Impact Days 2023

Photo courtesy of Lightup Impact.

new comms tech. Like most for-profit companies, we make use of the latest available tools to communicate effectively and creatively. Social media has been a big asset to our organisation. It provides an easy, cost-effective way for us to stay in touch with the majority of our stakeholders. Other platforms, like our website, have been more challenging to learn since this requires specialised knowledge and time. Nonetheless, we have been able to put together an informative and engaging website, which is the best place for any newcomers to learn more about our organisation and members, purpose, programmes and activities, and impact.

Something that many might find interesting is that we communicate regularly and freely with our members over WhatsApp, a mobile chat application, where we can quickly share news, events, grant opportunities, and any other relevant information and celebrate each other's accomplishments.

When it comes to building and maintaining trust, we have to communicate frequently and in the right tone and stay up to date with the latest developments in the sustainability space, but also all the other areas within which we and our members operate. Though these activities are ever-evolving and require continuous efforts, we have managed to produce content quite regularly, making sure to prioritise communicating our impact and the impact of our members. We are quite transparent about how we operate, as can be seen in our annual-, event-, and financial reports, available for download from our website.[10] On our blog,[11] you can find many different types of content, from sustainable development to our latest impact programs and member profiles. We aim to post at least once a month but typically post more frequently to ensure that we provide longer-form communications to our audiences that cover topics more comprehensively and facilitate building trust.

Building and maintaining relationships is much more challenging and requires a greater investment of time. We care about what our partners and community think and often engage with them to gain a better understanding. For this purpose, we use email, chat, video calls (such as our community meetups and online public events), in-person events or meetings (Lightup Impact Days conference), on-site visits (especially our members), surveys, and focus group discussions. Through these approaches, we not only collect feedback but conduct needs assessments to design effective data-driven and human-centred interventions. But gathering data and feedback is not enough; we must listen and empathise with what our members have to say and develop and implement the necessary changes to our approach where and as needed.

In terms of our tone of voice, we want our messages to be as accessible as possible. We write for all readers, using casual, inclusive, and simple language, incorporating our values and culture, and being as authentic, positive, and inspiring as possible.

Bearing fruits and planting new seeds

Regardless of limited resources, our organisation has grown beautifully since becoming fully operational in January 2022. In 2023, we onboarded 50 new grassroots organisations from Kenya, Rwanda, Uganda, and Tanzania (50% more than in 2022) – bringing our total to 125 members; hosted our 2nd annual Lightup Impact conference, gathering 154 participants (50% more than in 2022); and redesigned our website and blog, drawing more than 6,000 visitors to our pages. We also hosted two successful crowdfunding campaigns raising €22,000 for two important causes: our Founder Tour 2022 and Skills Development and Innovation for Impact Program.[12,13] Last but not least, we doubled our

financial capacity between 2022 and 2023. Our impact in numbers can be seen in Figure 1 in the Sustainability spotlight below. Read more about our members' impact in our annual report for 2022.[14]

In the future, we want to continue to grow and increase our resources, including comms support, which is a crucial aspect of the sustainable development of grassroots organisations. We hope to host webinars and workshops and create a skills development programme to help our members build the necessary communication skills to help grow their organisations and create social change in their communities. In particular, we would like to offer our members the chance to learn or develop their skills in grant proposal writing, reporting writing, website creation, digital marketing, and online and visual content creation.

Disclaimers

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

Disclosures and conflicts of interest

The authors declare no conflicts of interest.

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Author information

Nicole Bezuidenhout has been a medical writer at TFS HealthScience since 2022, developing engaging scientific content for audiences across the pharma and biotech industries. She holds a PhD in General Medical and Services Sciences, specialising in oncology and cancer metabolism. She has been an EMWA member since 2020 and volunteers as the section editor for the Digital Communication section of Medical Writing and the content editor for Lightup Impact.
Connect with her on LinkedIn: www.linkedin.com/in/njbezuidenhout

Valeria Santoro is a cancer research scientist and Ashoka Visionary Leader. She holds a PhD in oncology and advocates for equal opportunities in health and gender in under-served communities. Today she is the Founder & CEO of Lightup Impact, through which she empowers young grassroots leaders in gender, health and education in Kenya, Uganda, Rwanda, and Tanzania to become sustainable and scale their impact.

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Jeniffer Muganda is the Strategic Partnership Manager at Lightup Impact and a passionate advocate for change. She strongly supports the United Nations Sustainable Development Goals, firmly believing that we all have the power to create solutions for a better tomorrow. She is guided by mentorship and strives to empower the youth to shape a sustainable world.

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Sustainability spotlight:
Nicole Bezuidenhout
EMWA member and volunteer content editor at Lightup Impact

Medical Writing (MEW): Hi Nicole, thank you for taking the time to speak with us and share your experience as a volunteer with Lightup Impact. We'd like to start by asking if you could tell us a bit about how you came to be a volunteer for them.

Nicole Bezuidenhuit (NB): I started volunteering at Lightup Impact in 2021, shortly after supporting a fundraiser hosted by another incredible

nonprofit called Together Women Can; they empower women and fight cervical cancer in Kenya (www.togetherwomencan.co). To make a long story short, the co-founder of Together Women Can, Dr Valeria Santoro, had recently founded Lightup Impact, a "movement of over 125 young grassroots leaders across East Africa, advocating equality in health, gender, and opportunities, as described on their website lightupimpact.com. Dr Santoro was looking for

volunteers to support its growth. Longing to do more outreach work in the areas of gender equality and women's health – two issues very close to my heart – I reached out to offer my support in communications. The fact that our community of changemakers is also addressing several of the United Nations Sustainability Development Goals (SDGs) was a huge bonus. In all honesty, I didn't know much about sustainable development or the SDGs when I

€29,000
Crowdfunded since 2021

7 Organisations participated in our Founder Tour

32 Organisations earned the Lightup Impact Badge

16 Sponsorships for our members to attend the Lightup Impact Days Conference

125 Grassroots members

185 Lives improved

7 Trainings provided

530+ Event participants

Figure 1. Lightup Impact by the numbers

first started and naively thought (I suppose, like most) that the focus was solely on the environment and climate; the learning curve was, and continues to be, steep. Now, I can confidently say that I'm not only aware but also 100% behind the "universal call to action to end poverty, protect the planet, and improve the lives and prospects of everyone everywhere".

MEW: Can you tell us some more about your role as content editor and the types of communications you are involved in producing? And can you speak to the transferability of skills between your day job as a medical writer and your volunteer work, and vice versa?

NB: When I joined Lightup Impact, I committed to writing one or two blog posts per year featuring topical issues and focusing on my area of expertise: health and well-being. However, as time went by and the organisation and community continued growing, both parties realised that there was a need for additional communication support. After the small glimpse into the impactful work of Lightup Impact and our members and my interactions with our amazing team, I desperately wanted to become more involved and fill that need to help the organisation grow by leveraging my experience and skills as a medical writer.

Today, my role has evolved into something much more involved, where I develop content for several of Lightup Impact's platforms, including our blog, website, and email communication. I also write and edit annual- and post-event reports and develop communication and content strategies. Although certain aspects of my job as a medical writer are not needed in my work for Lightup Impact (i.e., knowledge of scientific/medical information and regulatory guidelines), my writing and editing skills, attention to detail, ability to create and follow guidelines, and understanding of different communication platforms and digital marketing strategies, have been quite helpful in creating harmonised, well-written, engaging communications for the Lightup Impact audiences. Additionally, as a small team of five, supporting over 100 organisations, each member of our team is responsible for their own tasks and readily attempts any job that needs

> Naturally, some aspects of working with Lightup Impact have been somewhat challenging and unusual compared to my day job.

doing. Every deadline is a tight one, and so we all have to be well-organised and proactive, have good time management and planning skills, and be comfortable with quickly learning new areas and competencies to get the job done. Valeria has done a great job of selecting a team that functions well together, fostering a culture of learning and knowledge sharing – a common practice and core value of our Lightup Impact community. In this way, I've been able to fortify existing skills while continuously expanding my capabilities as a communications professional.

Naturally, some aspects of working with Lightup Impact have been somewhat challenging and unusual compared to my day job. Not only is

the subject matter different, but so is the audience, the style of writing, the tools we use, and the work environment. Due to limited time and working outside of normal business hours and so far away from our community, I sadly haven't had as much time as I would've liked to properly connect with our team or community. Nevertheless, I've had a pretty unique opportunity to gather new experiences and skills that I'm able to apply in my medical writing tasks. For example, we use many different digital tools to communicate and collaborate with each other, our members, and our broader audience. So far, I've had the chance to learn and confidently use at least five new digital tools/platforms and expand my capabilities using tools I was somewhat familiar with but never really had a chance to dive into. These include tools for project management (Asana), content management (WordPress), and graphic design (Canva). Compared to my daily work as a medical writer, I get to be much more creative, designing web pages, creating visual assets, developing content for different communication platforms, and working on completely different types of documents. Recently, in my job as a medical writer, I got the opportunity to quickly create a newsletter for a client (that was very well received) and assist our marketing department with writing and editing content pieces, press releases, business reference sheets, and creating visual assets, all of which were made easier by the experience I've gained working for Lightup Impact.

Through interactions with my Lightup Impact team and our community, I've also been able to develop my soft skills, including key leadership qualities like communication, decision-making, delegation, empathy, integrity, and humility, which will no doubt help me progress in my career as a medical writer. For that, I'm grateful to our Lightup Impact team and community, who beautifully demonstrate these qualities.

MEW: In speaking with others involved in sustainability endeavours, it seems that a common challenge that they encounter is overcoming resistance in others. Have you encountered "resistance"? If so, in what form, and can you share how you overcame this resistance? Can you share a "success story" with us?

NB: Resistance to sustainability endeavours is multifaceted. Some people don't understand what sustainable development is, and when they do, perhaps don't view it as a necessity in their here and now or even something that will affect them eventually. A lack of resources is another major block to being able to participate in sustainability activities.

In a nutshell, sustainable development is described as fulfilling the needs of current generations without compromising the needs of future generations, all the while ensuring a balance between economic growth, environmental care, and social well-being is maintained.

Members in our community are grassroots organisations, meaning these organisations are initiated and driven by locals to create and sustain social or political change to improve the lives of people in their communities – they are incredibly motivated. In the regions where our members are active, adopting sustainable development strategies can be exceptionally challenging, but for many, resistance is not a path they can afford to take. However, that doesn't mean resistance doesn't come into play. For community-based organisations, there are several key factors opposing social change and the sustainability movement. A lack of integration into national and regional development policies, a lack of support networks, and a lack of visibility and credibility to secure funding represent some of the main impediments to the growth and sustainability of grassroots organisations.

In general, most of the organisations we work with are aware that integrating sustainable development strategies into their development plans is critical to ensuring their long-term success. However, a lack of resources and know-how creates an inherent resistance to implementing these strategies. That's where Lightup Impact can offer support, and our members have demonstrated an extreme willingness to learn, grow, and embrace sustainable strategies.

> For community-based organisations, there are several key factors opposing social change and the sustainability movement.

It's difficult to single out one success story because all of our members are doing incredible work, from empowering women to become independent and run their own businesses, to providing critical menstrual healthcare and education to young girls, and giving the youth opportunities to further their education and uplift themselves from the social issues affecting them. You can read more about our amazing members on our blog (www.lightupimpact. com/blog).

MEW: The work you have been doing through Lightup Impact is clearly needed and changing many lives for the better. Would you like to share some last thoughts on what the rewards have been for you as a volunteer and tell us how others can get involved if interested?

NB: It's been an absolute pleasure working with the Lightup Impact team. They have given me so much freedom to explore how involved I want to be, supporting my learning of this field and the development of my skills every step of the way. I'm grateful and feel very privileged to be able to use my expertise to communicate about the wonderful work of our community of change-makers. When I look at the tremendous impact they are creating and all the work they are putting into improving the lives of others, it's absolutely inspiring and motivates me to keep going. I'm having so much fun working with Lightup Impact, so much so that even when things feel crazy and stressful, it still doesn't really feel like work. That's a pretty special feeling.

As a young organisation, Lightup Impact welcomes external support to build our own capacity and deliver the critical resources needed to empower grassroots organisations. We're always very happy when anyone with a suitable skillset or relevant experience is willing to volunteer. We've had volunteers from many different fields support us, from legal to graphic design. In the realm of communications, I can say that many nonprofits or grassroots can benefit

from support in website or graphic design, proposal or grant writing, and communication strategy development, or generally developing skills in writing and editing to support fundraising and overall communications activities. If anyone from the EMWA community would like to get involved, e.g., help create a relevant skills development programme or host a webinar, we'd love to hear from you. Please get in touch with me at nicole.bezuidenhout@lightupimpact.com or Lightup Impact (contactus@lightupimpact. com).

Additionally, we have recently launched our new monthly giving program to scale our initiatives and ensure our long-term success and that of our members – support in this regard is always welcome. With these funds, we will finance our operating costs, make possible our annual Lightup Impact Days conference, and expand our Skills Development and Innovation for Impact Program and locally-led founder meetups. Read more about it in our blog post (www.lightupimpact.com/our-new-giving-program-be-part-of-creating-sustainable-social-change) and on our donation page (www.lightupimpact.com/donate-to-lightup-impact).

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The author declares no conflicts of interest.

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- YouTube – www.youtube.com/@lightupimpact674

Good Writing Practice

Syntactic alternatives and distractions
Title to a journal article

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Introduction

The title is the most circulated section of a journal article. Its syntactic pattern ranges from the traditional descriptive type:

1. noun + post-noun modifiers as prepositional phrases,
2. pre-noun modifiers + noun,
3. coordinated nouns; to the assertive type,
4. question,
5. suspended title, and
6. declarative sentence.

(1) Descriptive: Post-noun Modifiers
A noun phrase followed by one or more prepositional phrases

Example
Intergenerational linkages <u>for</u> timing <u>of</u> family life course events (n=9)

Notes
Although traditional, this format impedes immediate comprehension because of the excessive constituent number in the form of consecutive prepositional phrases. Descriptive titles are often preceded by superfluous descriptive words such as: "studies on", "observations on", "the effect on", etc.

(2) Descriptive: Pre-noun Modifiers
A noun preceded by one or more adjectival nouns

Example
Family life course <u>intergenerational linkage</u> timing (n=6)

Notes
This traditional format also impedes immediate comprehension because of excessive constituents in the form of stacked pre-nouns, the opposite to "Descriptive Post-Noun Modifiers".

(3) Descriptive: Coordinated nouns
Example
Family life course intergenerational <u>linkage and timing</u> (n=7)

Notes
In this example format, the inexplicit relation between coordinated nouns is distracting.

(4) Semi-assertive: Question
Example
<u>How are</u> family life course intergenerational linkages coordinated with timing? (n=10)

Notes
This is a thought-provoking and interesting style that could be useful for a poster or presentation at a meeting. However, it is wordy, which is a distraction, and is non-traditional as a title for a journal article.

(5) Assertive: Suspended Title: Title: Subtitle. General topic: specific accomplishment
Example
Family life course intergenerational linkages<u>:</u> Coordinated with timing (n=8)

Notes
In this non-traditional example, key content words as to topic are followed by the assertive message. A colon replaces an interrelation marker such as a preposition. However, the colon between the title and subtitle could lack clarity.

(6) Assertive: Declarative Sentence
Example
Family life course intergenerational linkages can be coordinated with timing (n=10)

Notes
This assertive style is immediately comprehensible. It is like a mini-abstract but is wordy, and the style can by overly assertive for a controversial topic.

Conclusions
The presence of possible distractions in examples (1) to (5) and the lack of assertiveness in examples (1) to (4) may be the reason that there is a current tendency to use the declarative sentence (6), despite its wordiness.

Upcoming issues of **Medical Writing**

June 2024:

Soft Skills for Medical Writers

Medical writing is a highly specialised field that requires a unique combination of technical knowledge, writing skills, and soft skills to produce high-quality work. While technical knowledge and writing skills are undoubtedly important, it is how one interacts with people that can truly set medical writers apart and enable them to succeed in their careers. This issue will focus on how soft skills are used within the different areas of the medical writing industry, and we hope it will provide valuable insights and inspiration for medical writers at all stages of their careers.

Guest Editors: Clare Chang and Nicole Bezuidenhout
The deadline for feature articles has now passed.

September 2024:

Clinical Trial Transparency & Disclosure

The clinical trial transparency and disclosure space continues to grow at pace. With the EU Clinical Trial Regulation being applicable since the 2022 launch of the Clinical Trials Information System comes increased requirements for public-facing documents. Provision of a summary of clinical trial results in lay language is also now mandatory in the EU. Challenges continue in balancing protection of personal data of trial participants with transparency, especially in the wake of the COVID-19 pandemic. All of these bring opportunities for medical writers to drive best practice in authoring clinical trial documents with disclosure in mind.

Guest Editors: Holly Hanson and Alison McIntosh
The deadline for feature articles is June 1, 2024.

December 2024:

Medical Writing Around the World

Medical writing transcends geography, demography, language, and culture. To date, EMWA has over 1400 members from 48 countries on 6 continents, and we want to celebrate the diversity and global presence of the medical writing community. In this issue, we will focus on medical writing activities around the world and will delve into topics like the benefits of having geographically diverse teams, translation and language-specific challenges, the landscape of global freelance medical writing, etc. We hope that these insights will assist the medical writing community in strengthening interactions and collaboration with teams and freelancers spread across the world.

Guest Editor: Asha Liju and Evguenia Alechine
The deadline for feature articles is September 1, 2024.