Medical Writing

A virtual workforce

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EMWA EUROPEAN MEDICAL WRITERS ASSOCIATION

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Medical Writing

A virtual workforce

"The almost seamless shift in the practice of office-based working to home-based working was possible primarily due to recent technological advances in communication, connectivity, and data storage and transfer. This would have been an impossible achievement a couple of decades back."

– EMWA President Satyen Shenoy, p. 4

Virtual workforce:
A force to reckon with!

T he last 2.5 years have been challenging and unprecedented for all of us at various levels. As things slowly return to a semblance of normality, including return to work in the office for many people, I think it is a good time to evaluate the good and the not-so-good of working remotely (which includes, but is not limited to, work from home [WFH]).

Surveys on working from home

Tim Hardman, Catherine Lee, Peter Llewellyn, and Steven Walker present the results from their second survey on working from home, conducted midway through the pandemic. The first survey was published in Volume 30, Issue 1 (March 2021, Social

GUEST EDITORS

Archana Nagarajan
archananag0611@gmail.com

Media) of *Medical Writing*. They raise the important issue of workplace health and safety requirements in case of hybrid working or WFH.

The second article is from **Daniela Kamir, Natalie Gavrielov, and Cheryl Berkowitz** who present the results of a WFH survey among the medical writers at their company, Bioforum, and share the positives of WFH.

Remote working – experience and views

Alejandra Gonzalez Diaz and her co-writers, the medical writing team at P95, share their experience of working as a team across oceans in different time zones in a company that functions fully remotely.

Katharina Friedrich shares her experience of being an employee as well as freelancer, working remotely during the pandemic, and how she coped with the loneliness of working alone.

Wendy Hartig-Merkel discusses how the pandemic acted as a catalyst for digitalisation in Germany and remote working became a reality in that country.

I think it is a good time to evaluate the good and the not-so-good of working remotely (which includes, but is not limited to, work from home).

Remote working done right

Working remotely requires an infrastructure set up that compliments the work and allows for seemless productivity. **Alison Kirsop and Peter Kirsop** share their experience of optimising IT services at home and how to keep the IT gremlins away!

Effective communication is a pillar of any business and perhaps is more pertinent when we work remotely. **Tiago Silva and colleagues from Trilogy Writing and Consulting** share good practices for remote meetings, including meetings with regulatory authorities.

If working remotely requires adjustments, leading a team remotely calls for ingenuity. **Shima Shaikh, Sapna Chhabra, and Ashwini Somayaji** – all managers of medical writing teams – share their knowledge on leading teams virtually and on maintaining effective employee engagement.

An interesting article from **Bilal Bham and Lesley Taylor** is up next where they tell us how they went about setting up a medical writing business and how they built up their companies remotely.

Finally, we conclude the feature articles with one from **Ana Fernandes and Laura Tobias Prezado** on the do's and don'ts of remote work for both employees and employers.

As we get back to offices at some places, hybrid working and remote working are here to stay. Perhaps we'll develop clarity in the coming months on policies that keep employee engagement intact and provide a safe and healthy remote working environment.

I would like to thank the authors for their contributions. I hope you all enjoy the various perspectives on remote working shared by medical writers from across the globe. Happy reading!

About the Guest Editor

Archana Nagarajan, PhD, has been a medical writer and consultant for almost 4 years. She has an extensive scientific research background and experience in writing medical communications and regulatory documents. She is also a supporting member of EMWA's sustainability SIG.

President's Message

Working from home: What's old is new again

Satyen Shenoy
EMWA President
2022–23
president@emwa.org

Dear EMWA friends and colleagues, we have witnessed a sea change in work practices in the last two years with terms like "remote working", "home-office", and "work from home" becoming increasingly common parlance. In the September 2022 issue of *Medical Writing* on the theme of a virtual workforce, we present you with different perspectives, challenges, advantages, and predictions on working from home (WFH).

The concept of WFH is not new to the medical writing profession; our industry comprises a large number of freelance consultants for whom WFH is standard practice. Of course, as pandemic restrictions were put into place globally, the only resort to keep businesses running was for the workforce to operate from their residences and since then WFH has become a norm.

Technology has played a large part in facilitating WFH, especially in the medical writing industry. The almost seamless shift in the practice of office-based working to home-based working was possible primarily due to recent technological advances in communication, connectivity, and data storage and transfer. This would have been an impossible achievement a couple of decades back. The curb on human interaction in person was more than adequately compensated by online video conferencing platforms that allowed colleagues, clients, and other stakeholders to meet virtually. High-speed internet and 5G telecommunications ensured that teams stayed connected globally and with access to all digital resources. Cloud-based services enabled storage and sharing of large volumes of digital information. Harnessing the power of these technologies is what enabled the medical writing industry to not only continue to operate without disruptions throughout global

> The curb on human interaction in person was more than adequately compensated by online video-conferencing platforms that allowed colleagues, clients, and other stakeholders to meet virtually.

lockdowns but to also increase its output to match the increase in regulatory submissions and medical communications.

Despite the apparent ease in WFH in the presence of adequate technological support, its practice is not entirely without inconvenience. Setting up an efficient WFH environment requires investment of personal space even when hardware and infrastructure are provided by the employer. The 'flexi-time' that WFH cites as an advantage can and does blur the line between work time and personal time, especially for those with young families. WFH can be a lonely experience since it curtails other social aspects of office-working, especially human contact. A number of cultural and social nuances also come into play when it comes to feasibility of WFH. In densely populated countries in Asia with large families cohabiting, it is challenging to apportion a dedicated space in the living quarters, a problem not as common in Europe or America. Moreover, implementing WFH is a massive challenge in the resource-deficient global south where poor connectivity, lack of personal space, and the high cost of building infrastructure act as deterrents.

So what would the future of WFH be as the world limps towards normalcy and pre-pandemic work practices? One certainty is that WFH will be offered more and more as an option to those in the medical writing industry in developed nations; the pandemic revealed how the industry can continue to be prolific even with WFH. Another equally important driver of WFH, at least in developed countries, has been the sustainability initiative. WFH eliminates the need for daily commute to workplaces, thereby reducing the need for fossil fuels, and the burden on public transport infrastructure. If WFH becomes an option, we would all be in a better position to judge whether to avail of it or not.

Happy reading!

From the Editor

Changes afoot: Open access, DOI, remote work, and more!

Raquel Billiones
Editor-in-Chief
editor@emwa.org
doi: 10.56012/PAEQ1446

Welcome to the autumn issue of *Medical Writing* (MEW). We are excited to highlight two new features of our publication.

Open access

MEW online is now fully open access. What does this mean? Previously, feature articles were available to the general public whereas the regular sections (and the articles therein) were only accessible to EMWA members. Since June 2022, MEW and all its sections are fully open access. EMWA members retain their privilege to receive the paper copy of the journal. We thank the EMWA executive committee for endorsing this initiative.

DOI

A Digital Object Identifier (DOI) is "a unique alphanumeric string assigned…to identify content and provide a persistent link to its location on the internet".[1] Most style manuals, including the APA and AMA recommend to include the DOI in the reference list entries.[1,2]

A *PLoS One* research article reports that the use of digital identifiers like the uniform resource locator (URL) or the DOIs in data availability statements for publications was positively associated with data accessibility and availability over time.[3]

In this issue, we are pleased to now be assigning DOIs to our articles. I would like to give full credit to Sampoorna Rappaz for doing all the DOI research and planning and to Vicki White for bringing our plans to fruition.

Having an official publication that is open access, with DOI for each article, highlights EMWA's commitment to transparent communication.

GPP 2022

Another reason to celebrate is the publication of the 2022 update to Good Publication Practice (GPP 2022) guidelines (p.6).[4] Congratulations to the International Society for Medical Publication Professionals (ISMPP) for this major milestone in scientific communications and the biomedical industry as a whole.

Finally, I would like to thank Archana Nagarajan for compiling this amazing issue on remote work. The pandemic unprecedentedly changed our ways of working. But the basic principles of medical and scientific communications remain the same.

So go forth and write whenever you want, wherever you are! Words have no temporal or spatial boundaries.

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The DOI has 3 parts:

https://doi.org/10.56012/xxxxxx

DOI resolver	prefix	suffix
	This is the unique EMWA prefix	This is the unique suffix for each article

Now published: 2022 update to Good Publication Practice Guidelines for Company-Sponsored Biomedical Research

The 2022 update of the Good Publication Practice (GPP 2022) guidelines, a key guidance document for the publication of company-sponsored biomedical research, was recently published in the *Annals of Internal Medicine.* Access GPP 2022 in the August 30, 2022, issue of *Annals.*

"We are pleased to deliver the updated GPP 2022 guidance to the medical publications and communications community, and we encourage all in the profession – individuals and organisations – to adopt these contemporary best practices," said co-author Dan Bridges, Global CEO of Inizio Medical and Chair of the International Society for Medical Publication Professionals (ISMPP) Board of Trustees.

GPP 2022 is the third update of the original GPP guidelines, which were published in 2003 and updated under the auspices of ISMPP in 2009 and 2015. ISMPP was pivotal in ensuring that the authors of GPP 2022 would be a globally diverse group representing academia, industry and medical communications companies, publishers, and journal editors.

"We are honoured to support this continued commitment to ethics and integrity in publishing company-sponsored biomedical research," said Lisa DeTora, PhD, lead author and Associate Professor at Hofstra University, speaking for the authoring group.

GPP 2022 specifies principles for ethical practices, such as inclusivity and transparency, and for responsible planning of biomedical publications. An accompanying supplement provides a series of sections that outline important elements of the publication profession, such as forming steering committees and authoring publications. New information includes the possible role of patients as authors or contributors to publications and working in alliance settings. The authors also encourage the use of enhanced content, such as plain language summaries.

Before the updated guidance was submitted to *Annals*, the authors solicited feedback from 38 invited experts. A subsequent call for volunteer reviewers, issued through ISMPP, resulted in an unprecedented level of involvement from those who use GPP every day; over 120 sets of comments, representing the collaborative input of hundreds of professionals, were received.

"ISMPP is honored to recognise the contributions of our membership to the updates in GPP 2022," said Robert Matheis, President and CEO of ISMPP. "We also congratulate the authors of GPP 2022 on this significant accomplishment that will advance the medical publications profession and its practices."

The authors hope the updated GPP guidelines and accompanying supplement will help everyone developing biomedical publications to better interpret and apply GPP principles, thus promoting transparency and integrity. "We thank ISMPP and its membership for the huge outpouring of support for this GPP update," said DeTora.

Source: International Society for Medical Publication Professionals

EMWA History

Thirty years on: In at the beginning

John Carpenter, PhD
john.medcom@gmail.com
Retired, previously proprietor of
John Carpenter Medical Communications

I left academia in 1992 to join a medical communications company, and once I had found my feet, I felt it appropriate to find a professional association. I found the American Medical Writers Association, which had what it listed as a European Chapter. I joined. This soon launched as a separate entity – the European Medical Writers Association (*see Geoff Hall's account of the early history of EMWA at*: https://www.emwa.org/about-us/about-emwa/history-of-emwa-1992-2008/). So, in a sense, I was a founding member of our organisation. But my company wasn't prepared to fund my attendance at conferences – and my professional life was pretty hectic and didn't leave much time for them anyway. I had to be content with just reading the newsletter. In 2001, I managed to find time (and the funds) to attend the Montpellier, France, conference. Wow! What a blast! Everyone was so helpful and friendly.

This positive experience prompted me to offer my services as a workshop leader and over the next few years, I developed and delivered workshops, and, until COVID-19 spoiled things, I had run at least one workshop at almost all of the conferences since Montpellier.

Highlights? Well, the general ambience of conferences – everyone is approachable and keen to give advice, no matter how senior in the organisation. In those early days the conferences were small enough that you could always find whoever you wanted to meet by visiting the bar. And there was always a little crowd in the bar in the evenings surrounding a jolly, white-whiskered man with a happy, ruddy face – all laughing and generally enjoying life. This was Geoff Hall. We were much of an age and became instant friends. I don't know how it started, but on the coach to the Conference Dinner, Geoff and I started singing *Clementine* to the tune of the Welsh hymn *Cym Rhondda* (https://en.wikipedia.org/wiki/Cwm_Rhondda). This became something of a tradition. The Association owes much to Geoff and I miss him – he died too soon.

The conference dinners were, to me, a highly enjoyable and valuable experience. OK, it was an excuse for a bit of a booze-up, but they allowed new members to see the "establishment" as they really were. I like to think of the Conference Dinner as a genuine symposium (*Greek: sun – with, together; potes – drinker*). And we ate in

Sharing reminiscences at the EMWA conference in Berlin, May 2022

some remarkable places, sampled a variety of local cuisines and local entertainment. For example, I'll never forget the opportunity to play an alpenhorn duet with Adam Jacobs in Basel, Switzerland.

By 2002 I had much more freedom – I was now freelancing and the children were independent – so my wife, Jane, began joining us at conferences in a social capacity. Members may remember the VW van that we drove to several conferences, camping in it on the way there and back. The first trip in the van was to Barcelona, where we parked outside the hotel between two very expensive-looking Ferraris – this was the day after the Spanish Formula 1 Grand Prix. The longest trip we made from England was to Ljubljana. The drive to Lisbon was interesting, to say the least. Sat-nav took us to what it said was our destination in Lisbon. We were on a busy, one-way street, but couldn't see the hotel. We went round the block several times, and still couldn't find it. Eventually, we parked on a back street and asked a local. He said we should follow him, and sure enough, he took us to the same location on that busy one-way street, then pointed behind us. There was the hotel. We had missed it several times, because the signs all pointed the wrong way down the one-way street!

How has the Association changed over 30 years? Well, the biggest change has been in membership numbers. This is a good thing in many ways, but a small downside is that conferences have lost a little of the family feeling of when we were smaller. On the other hand, conferences are still friendly gatherings – nothing too formal and members only too happy to share their experiences. I always look forward to meeting members that I first met at the first few conferences; all of us older and perhaps wiser now, but I also enjoy chatting to new members whenever I get the chance.

What about the next 30 years? Well, you'll have to bumble along without me, I'm sure, but judging from what I've seen over the last 30 years, new members will continue to volunteer to steer the association and continue the valuable training that we provide. No doubt conferences will be different, and I imagine that more of the training will be delivered remotely. I hope, however, that there will always be a place for real, in-person meetings – it would be a shame if we tried to hold all our symposia (see above) by Zoom! There will always be a need for people to make information about drugs, medicines, and devices accessible, clear, unbiased, and understandable. That's what we medical writers do and will continue to do. And we will continue to need a professional body to represent us.

John, a glider pilot, takes 5

EMWA News

SECTION EDITOR

Somsuvro Basu
info@sombasu.com

Recipient of the Nick Thompson Fellowship Award 2022: Raquel Billiones

The **Nick Thompson Fellowship Award** recognises service to EMWA above and beyond the standard responsibilities of membership or elected office.

It is a pleasure to recognise a 16-year member and current MEW editor-in-chief **Raquel Billiones**, as one who has contributed to the evolution of EMWA in many ways since becoming a member in 2006. She has worn many different hats, including co-founder and co-chair of the Medical Device Special Interest Group, which led to establishing the medical device education track. Medical device training has become an integral part of EMWA's curriculum and nearly all workshops are fully booked, demonstrating the recognition of the value of training in this discipline.

Raquel marshals her energy and dedication to embody the very spirit of the Nick Thompson Fellowship, and it is with great pleasure that we welcome Raquel to the Band of Fellows.

Art Gertel presents Raquel Billiones the Nick Thompson Fellowship Award at the Berlin EMWA Conference in May

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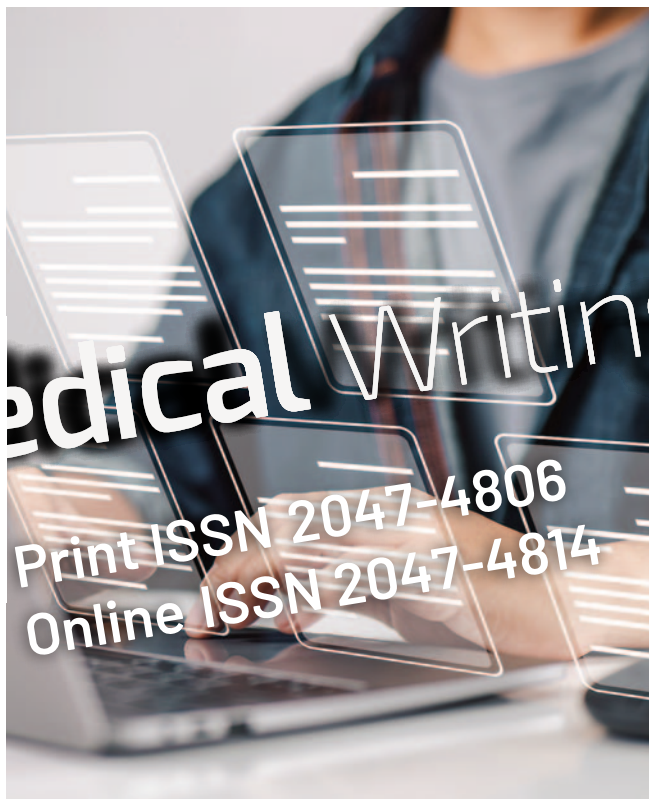
EMWA's official publication Medical Writing goes fully OPEN ACCESS in 2022!

All content, from full feature articles to contributions in the regular sections are now publicly accessible. Check out https://journal.emwa.org/

Save the date!

Freelance Business Group subcommittee: come join the team!

The Freelance Business Group (FBG) focuses on all things freelance. We have a subcommittee of 5 people and are looking for new volunteers. We have several new initiatives that we want to push forward this year and seek proactive freelancers who can dedicate some time every month to these projects. If you are a freelancer, enthusiastic about volunteering for EMWA, and have some time to spare, please contact FBG chair **Laura A. Kehoe** at freelance@emwa.org

Ambassadors Programme News

The EMWA Ambassadors Programme is continuing its efforts to reach out to new audiences to promote medical writing and EMWA.

On June 11, **Sally Hill** introduced medical writing and EMWA to a group of 18 translators, interpreters, editors, and copywriters in Utrecht. These language experts attended a workshop organised by SENSE, the Society of English-language professionals in the Netherlands. The SENSE Medical Special Interest Group organised the full-day workshop on medical translation, medical editing, and writing. Some attendees were old hands, while others were at the early stages of their careers. Several expressed an interest in EMWA, and one medical editor based in Germany has already become an EMWA member!

In October 2022, **Beatrix Doerr** will present an online webinar in German to young scientists who are members of the German Association for Medical Informatics, Biometry and Epidemiology (GMDS). The topic and date of the webinar will be announced.

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

The 54th EMWA Conference: Riga (November 3–5, 2022)

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

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

Registration for this event is due to open in September 2022.

Changes to working practices in medical communications during the COVID-19 pandemic:
Insights from two surveys

Timothy C. Hardman[1], Catherine Lee[2], Peter Llewellyn[3], Steven Walker[4]

1 Niche Science & Technology Ltd., Richmond, UK
2 Envision Pharma Group, Wilmslow, Cheshire, UK
3 NetworkPharma Ltd, Oxford, UK
4 Stgilesmedical Ltd London, UK, and Stgilesmedical GmbH, Berlin, Germany

Correspondence to:

Timothy C. Hardman
tim.hardman@niche.org.uk

Abstract

Successive waves of COVID-19 have altered opinions and working practices. We conducted a survey in early 2020 among 759 members of the medical communications community, recruited via our network, seeking their experiences, opinions, and insights. The survey was repeated 13 months later (N=925 respondents) using similar methodology. In both surveys respondents had a generally positive attitude to homeworking and appreciation for the lack of commute and time saved. In contrast, distractions in the home, inability to "switch off" at the end of the day, and concerns about potential impact on career development and/or connections with colleagues were highlighted. Notable findings include working longer hours as the pandemic progressed and an increase in feelings of isolation and loneliness in comparison to before the pandemic. Companies generally appear not to have used the time since the start of the pandemic to formally define home or hybrid working, including consideration of workplace health and safety requirements.

Introduction

Early in 2020, we left our offices to work from home.[1] Changes were introduced hastily, with little time for contemplation or preparation. Our work lives suddenly included information technology (IT) issues and balancing home-schooling, barking dogs, and fitting multiple "at-home" workers into cramped spaces.[2] The impromptu interruption of Professor Robert Kelly's live BBC interview by his daughter became synonymous with our shared experience.[3]

COVID-19 fundamentally changed our working world. Collectively we believed the changes were temporary, except weeks soon stretched into months. The authors conducted a multifactorial survey during the first lockdown to investigate how well we had adapted to our new, remote working environments.[2] The survey reported that most respondents felt they had

adapted positively and yet many were feeling lonely and isolated, with some adopting unhealthy lifestyle habits.[2]

With the immediate crisis subsiding, one thing is eminently clear: we are not the same. We look and speak the same, and some may be returning to the same offices. Yet the way we view the world has changed fundamentally, perhaps permanently. The 2020 survey's overwhelming consensus – that we would not return to the old ways of working – appeared to be substantiated when the introduction of vaccines and the easing of lockdowns did not see a tide of commuters returning to the office. We ran a second survey 13 months after the first to discover whether, given time for our working practices to evolve, we had addressed the challenges associated with remote working that were expressed at the height of the pandemic.

Methods

Study design and procedure

Two confidential online surveys were developed in English using Google Forms, which enabled secure and anonymous data collection.[4] Voluntary completion was considered to signify consent for participation in the research. The surveys followed similar designs: the first was conducted from May 20 through June 11, 2020;[2] the second was conducted from July 24 through August 16, 2021. In both cases, potential participants were approached by email with a link to the survey, through the authors' professional networks. The surveys were also publicised on social media platforms. The clearly described aims of the surveys were to better understand the changes and challenges faced by home workers during the pandemic.

Questionnaires

Both questionnaires were designed to be completed in under 10 minutes and followed an evidence-based model developed by the UK Department for Works and Pensions to examine well-being in the workplace. The model's components included health, relationships, security, environment, and purpose.[5] We also included an assessment of anxiety by employing adapted elements of the Generalised Anxiety Disorder Scale (GAD-7).[6]

The surveys differed slightly in the information they collected. The first survey included 50 multiple-choice, fixed-response questions and four free-text entry fields. The second survey included 54 multiple-choice, fixed-response questions and three free-text entry fields. Both surveys followed the same format and were divided into seven sections:

1. survey aims;
2. demographics;
3. workplace;
4. emotional health;
5. the working-from-home experience;
6. the psychosocial impact of working from home; and
7. views on positive/negative aspects of the lockdown, recommendations, and learnings.

The demographic questions collected basic personal and professional data. Subsequent

> The clearly described aims of the surveys were to better understand the changes and challenges faced by home workers during the pandemic.

sections followed a standard five-point Likert-scale approach using a randomly selected mixture of positive and negative bias.

Data analysis

Our analysis methods have been described previously.[2] In brief, participant responses were collected automatically and exported into a Microsoft Excel spreadsheet. After harmonisation, quantitative data analysis was performed using IBM Statistics SPSS 25.[7] The responses for each of the five Likert grades were counted and calculated as a percentage. After reviewing responses to Q8 ("What is your job title"), data were transformed into a new metric variable where responses were identified as being either "medical writers/ editors", "VP [vice president]-level managers or executives", or "other". Negative questions were reversed for better interpretability. Where entries were not provided, the data fields were left blank. Free-text responses were scored according to the number of respondents mentioning specific points. The Mann-Whitney U test was used to test for differences between groups.

Results

Overview

There were 759 respondents in the first survey (S1). Most were women (71.4%) and based in the UK (76.8%) (Table 1). The second survey (S2) included 925 participants who were mostly women (66.6%), with proportionally more respondents (vs. S1) from outside the UK (39.1%). The two survey cohorts shared similar characteristics.

Employment and roles

A high proportion of the respondents were engaged in the medical communications/ education/publishing industry (S1, 67.1%; S2, 49.4%) and had been in their role for 1–5 years (S1, 42.8%; S2, 39.5%) (Table 2). Most respondents were employed (full-/part-time: S1, 75.5%; S2, 80.3%). There were more freelancers in the first survey (25.6%) than the second (19.7%). The largest group comprised medical writers or editors in the first survey (39.9%) whereas, in the second survey, the

Table 1. Survey participant sociodemographic characteristics

		S1 – 2020 (N=759)		S2 – 2021 (N=925)	
		n	%	n	%
Sex	Male	217	28.6	309	33.4
	Female	542	71.4	617	66.6
Age	<25 years	43	5.7	48	5.2
	26 – 30 years	104	13.7	105	11.5
	31 – 40 years	161	21.2	212	22.9
	41 – 50 years	216	28.5	234	25.3
	50+ years	235	31.0	326	35.2
Domestic status	Married / living with partner	584	76.9	718	77.6
	Single	137	18.1	155	16.8
	Lone parent	25	3.3	21	2.3
	Other	13	1.7		3.3
Accommodation	Own home	579	76.3	718	77.6
	Renting with others	74	9.7	97	10.5
	Renting alone	63	8.3	63	6.4
	Living with parents	29	3.8	34	3.7
	Other	14	1.8		3.4
Living with children	No	466	61.4	666	72.0
	Yes	290	38.2	352	28.0
Location	United Kingdom	583	76.8	632	61.9
	Canada and USA	67	8.8	104	11.3
	Europe (not UK)	71	9.4	102	11.0
	Other	38	5.0	86	9.3

largest group comprised vice presidents and directors (35.4%), although both surveys reported similar proportions with managerial duties (S1, 56.0%; S2, 47.5%).

Commuting and homeworking
Before lockdown, although most commuters faced journeys of 30–60 minutes, many spent a longer proportion of their day (>60-minute commute) travelling (S1, 19.1%; S2, 21.2%). In both surveys, freelancers were generally working from home before lockdown, as were a number of employed respondents (Table 2). Over half of the survey participants had the option to work away from the office occasionally before the pandemic (≥2 days per week; S1, 58.6%; S2, 56.0%) but most were not availing themselves of this opportunity consistently (Table 2).[2] At the time of both surveys, the majority of respondents were working from home (S1, 97.1%; S2, 93.1%).

Homeworking during lockdown generally went unregistered formally with employers, landlords, and insurance companies raising legal and safety concerns regarding the work spaces adopted by employees. For example, by the time of the second survey, only 15.1% had informed their insurer, 7.2% their landlord, and 5.2% their mortgage providers of their change of status. Overall, 22.1% had informed a combination of potentially interested parties but only rarely had they confirmed their reporting with employers (5.3%).

Working hours and finances
The survey data strongly suggest that many of us were working for longer hours than before the pandemic and often at times outside of usual contractual hours (Table 2). The number of respondents who reported being busier than

> At the time of both surveys, the majority of respondents were working from home (S1, 97.1%; S2, 93.1%).

before the pandemic increased significantly from 63.9% in the first survey to 77.8% in the second (*P*<0.001). This observation was substantiated by the number of working hours respondents reported, most notably with a marked shift between the two surveys in the proportion of those working over 40 hours a week (S1, 21.7%; S2, 42.2%: *P*<0.05). Furthermore, over a quarter (27.9%) of responders in S2 reported delivering >10% of their work outside of standard office hours; with 27.6% delivering up to 10% and 33.3% up to 5% of their work outside standard hours. The proportion of respondents who considered themselves to be worse off during the pandemic was lower in the second survey (8.8%) than in the first (17.9%).

Table 2. Responder work profiles

		S1- 2020 (N=759)		S2- 2021 (N=925)	
		n	%	n	%
Which part of the industry do you work in?	Medical communications/ education/publishing industry	509	67.1	457	49.4
	Biomedical, pharmaceutical, or device industries	127	16.7	237	25.6
	Clinical research organisation	84	11.1	104	11.3
	Other	39	5.1	127	13.7
Time in current role	<1 year	145	19.1	193	21.6
	1 – 5 years	325	42.8	395	39.5
	6 – 10 years	101	13.3	148	16.0
	10+ years	187	24.6	189	20.4
Weekly hour worked	<15 hours	18	2.4	11	1.2
	16 – 29 hours	101	14.5	88	9.5
	30 – 40 hours	465	61.3	424	46.0
	40+ hours	165	21.7	394	42.2
How busy have you been during the pandemic?*	Busier than ever before	270	35.5	423	45.9
	Relatively busy	215	28.4	294	31.9
	No different than before the pandemic	157	20.7	162	17.5
	Some of the time	85	11.2	37	4
	Never	32	4.2	6	0.7
Employment status	Full time	493	65.0	658	71.2
	Part time	71	9.4	84	9.1
	Self-employed/Freelancer	194	25.6	182	19.7
Job Description/Role	Medical writer or editor	303	39.9	263	28.4
	Vice President or Director	284	37.4	328	35.4
	Other	172	22.7	303	32.7
Managing others		425	56.0	439	47.5
Financial status	No change in status	623	82.1	843	91.2
	Financially worse off (All)	136	17.9	82	8.8
	Freelancers (S1 = 194/S2 = 185)	70	36.1	28	15.1
	Non-freelancers (S1 = 565/S2 = 739)	66	11.7	54	7.3
Primarily homebased working before lockdown	Contractors / freelancers	153 / 194	78.9	152 / 185	82.1
	Full-time employees	51 / 565	9.0	94 / 922	10.2
Occasional working from home before lockdown[a]		445	58.6	519	56.0
Working from home at the time of the survey		738	97.1	861	93.1

[a]Option to work from home at least 2 days per week. *P<0.05 comparing 2020 with 2021 data

Table 3. Responses to questions on working from home environment, feelings of self-worth, the homeworking experience, and work-life balance

Considerations on their feelings of self-worth

S1 Q#/S2 Q#		Strongly agree	Agree	Neutral	Disagree	Strongly disagree
Valued Q38/44*	2020	27.9%	45.3%	14.1%	9.4%	3.3%
	2021	52.5%	30.0%	7.3%	6.8%	3.3%
Engagement Q34/37	2020	25.4%	47.0%	19.2%	7.5%	0.9%
	2021	27.4%	50.4%	8.3%	12.7%	1.2%
Recognition Q35/42*	2020	17.9%	37.9%	27.0%	13.2%	4.0%
	2021	49.2%	30.5%	8.6%	8.9%	2.7%
Motivational Q30/36	2020	22.3%	36.0%	25.6%	13.5%	2.6%
	2021	14.3%	47.4%	14.9%	19.8%	3.6%

Considerations of their experience of working from home

		Strongly agree	Agree	Neutral	Disagree	Strongly disagree
Daily routine Q47/52*	2020	21.3%	48.3%	14.7%	12.7%	3.0%
	2021	18.7%	46.7%	21.0%	11.4%	2.2%
Workload Q31/19*	2020	35.5%	28.4%	20.7%	11.2%	4.2%
	2021	45.9%	31.9%	17.6%	4.0%	0.7%
Concentration Q42/47	2020	15.0%	39.0%	19.5%	19.4%	4.2%
	2021	17.0%	43.5%	14.2%	15.2%	1.7%
Productivity Q26/41*	2020	32.5%	37.6%	12.6%	13.4%	4.0%
	2021	39.4%	46.7%	8.2%	5.1%	0.7%

Considerations of work-life balance and lifestyle behaviours

		Strongly agree	Agree	Neutral	Disagree	Strongly disagree
Desk eating Q43/48*	2020	31.0%	33.3%	12.7%	13.6%	9.5%
	2021	13.5%	18.5%	14.0%	28.9%	25.1%
Lunchtime Q44/49	2020	9.5%	25.7%	20.6%	31.3%	20.8%
	2021	4.7%	22.4%	23.1%	33.3%	15.8%
Alcohol intake Q45/50*	2020	26.1%	26.6%	15.5%	25.1%	6.7%
	2021	5.1%	17.3%	17.0%	28.3%	32.2%
Exercise Q46/51	2020	19.9%	24.9%	11.5%	25.7%	17.9%
	2021	14.5%	27.3%	12.9%	25.9%	19.4%
Gen health anxiety Q40/45	2020	37.2%	42.4%	9.3%	10.2%	0.9%
	2021	44.2%	42.3%	8.1%	4.7%	0.8%
Social media Q48/53	2020	11.8%	31.1%	23.2%	27.2%	6.6%
	2021	4.5%	28.2%	23.3%	30.6%	13.3%
Isolation Q41/46*	2020	5.6%	22.5%	15.9%	35.2%	20.8%
	2021	11.6%	34.0%	15.2%	23.4%	15.8%
Work-life balance Q50/17*	2020	21.4%	48.2%	14.7%	12.7%	3.0%
	2021	13.4%	34.5%	18.3%	27.2%	6.6%
Relationships Q49/54*	2020	6.9%	19.7%	44.8%	24.0%	4.6%
	2021	5.8%	17.4%	45.5%	25.2%	6.1%

Dark blue shaded areas = modes*P<0.05

Q38/44: I don't feel valued.

Q34/37: I feel engaged and able to contribute to team decisions.

Q35/42: I am getting less recognition for my hard work and effort.

Q30/36: I find working from home motivational.

Q47/52: I have been able to establish a good daily routine.

Q31/19: I have been busier than ever during the pandemic.

Q42/47: I find it easy to concentrate.

Q26/41: I have found myself working less productively during the pandemic.

Q43/48: I eat lunch at my desk more frequently.

Q44/49: I take more time for lunch.

Q45/50: My alcohol consumption has increased since working from home.

Q46/51: I worry that I am taking less exercise now I am working from home.

Q40/45: I have been anxious about health issues

Q48/53: I am spending more time on social media.

Q41/46: I have felt lonely and isolated

Q50/17: I have managed to keep my work and domestic life separate

Q49/54: I have felt less strain in my relationships

Information, equipment, and safety

Most respondents (>90% in both surveys) felt that they had ready access to the information they needed to do their job. Similarly, most considered that they were appropriately equipped for homeworking (S1, 87.7%; S2, 85.4%). The second survey also asked participants to provide information on the facilities available to secure equipment that might contain potentially sensitive client information. Absence of safe storage was reported by 42.2%.

Health and safety at home was highlighted as an issue in the first survey, with only 15.2% of respondents having been asked by their employer to complete a formal health and safety assessment of their workspaces. This had increased to 43.9% by the time of the second survey, and over half of the respondents (56.1%) had received some guidance on health and safety while working from home.

Interacting with colleagues and clients

Data in Table 3 and Table 4 suggest that most respondents during both survey periods were able to work well from home, interact with colleagues, and serve their clients. These findings mirror the free-text statements that demonstrated a generally positive view of arrangements during lockdown.

The second survey also included questions regarding how concerned respondents would feel if they were expressly required to travel to a face-to-face meeting. More than half (63.9%) felt comfortable with such a request, despite the majority (88.4%) reporting that they had not had COVID-19. This appears to coincide with fewer than half being concerned about their own health during lockdown.

Opportunities for training

In the first survey, a third of respondents felt that they had experienced reduced opportunities for training and growth, but this had dropped to under a quarter by the time of the second survey ($P<0.05$) (Table 4).

Work-life balance and lifestyle behaviours

In the first survey, most respondents indicated that during lockdown they had established a good daily routine, remained productive, managed their (increased) workloads, and felt supported (Table 3). Approximately 20% reported experiencing difficulties with concentration. Most (84.3%) felt that they had not experienced any issues keeping their work and domestic lives separate. However, this value was lower in the second survey (66.2%,

$P<0.05$). Marked differences in the reporting of "eating at the desk" ($P<0.05$) appear to corroborate a change in working patterns and workloads. The data did not indicate widespread adoption of negative behaviours in terms of consuming more alcohol or exercising less, although there was increased social media usage. Levels of stress in personal relationships were generally unchanged, and more than half of respondents (69.6%) reported that they had not experienced any issues in keeping their work and domestic lives separate.

Emotional well-being and self-worth

Overall, most respondents reported that home-working was associated with positive well-being (Table 4). However, in a small number of cases the responses to questions about vigour and rest suggested that the experience of some participants could, in the long term, impact mental health (Table 4). Concerns over job security were relatively low and did not appear to be associated with reporting of poorer emotional well-being scores.

Nearly one-third (28.1%) of respondents in the first survey reported that they had experienced episodes of loneliness or isolation (Table 3). These responses were markedly higher (45.6%; $P<0.001$) in the second survey. Interestingly, this was despite there having been episodes of "lockdown release" between peaks of infection around the time of the second survey.

In the first survey, a high proportion of respondents (87.3%) considered themselves valued by their co-workers and clients and trusted by their employers.[2] Similarly, they felt engaged and able to contribute to team decisions (Table 3). By comparison, 16.1% reported a lack of motivation and 17.2% reported less recognition of their work. In the second survey, levels of self-value were generally similar to the first (89.8%) as were those of engagement. However, there was a markedly higher proportion of respondents feeling that their work was getting appropriate recognition ($P<0.05$).

Future working practice

Most respondents in the first survey (85.6%) felt that work practices would not return to the way they were before the pandemic. A year on, this proportion had increased (93.1%).

The second survey asked respondents to provide information on any consultation their employers had conducted with employees. Over half (59.2%) had been asked for their opinion on future working arrangements. A smaller pro-

Table 4. Responses to questions on emotional well-being

		All of the time	Most of the time	Half the time	Some of the time	Never
Enjoyment Q19/35	2020	30.9%	43.5%	9.8%	14.5%	1.3%
	2021	26.0%	50.5%	11.5%	11.3%	0.7%
General anxiety Q21/38	2020	37.2%	42.4%	9.3%	10.2%	0.9%
	2021	44.2%	42.3%	8.1%	4.7%	0.8%
Vigour Q22/39*	2020	11.4%	43.2%	19.1%	19.6%	6.3%
	2021	10.8%	36.0%	16.7%	30.5%	6.0%
Job security Q25/20*	2020	39.1%	37.4%	9.8%	8.2%	4.2%
	2021	48.6%	38.6%	5.0%	4.7%	3.1
Rest Q23/40*	2020	13.7%	42.3%	18.2%	19.4%	6.5%
	2021	8.4%	39.1%	16.0%	27.3%	9.2%
Training/growth Q36/43*	2020	17.0%	50.7%	22.3%	7.8%	2.3%
	2021	41.7%	35.2%	9.8%	9.7%	3.5%

Dark blue shaded cells = mode* $P<0.05$

Q19/35: I enjoy working from home.
Q21/38: I have felt nervous, anxious and/or on edge since working from home.
Q22/39: I have felt active and vigorous while working from home.
Q25/20: I have been worried about job security since the COVID situation.
Q23/40: I currently wake in the morning feeling refreshed and rested.
Q36/43: I feel that there are fewer opportunities for me to learn and grow my skills at home.

portion had been involved in initiatives seeking to develop hybrid guidelines or working-from-home charters (36%). Only a handful had been involved in discussions on modifications to employment contracts to reflect changes in their working situation (13%).

Free-text statements
In the first survey the four free-text entries generated over 41,000 words of insight on what respondents found either difficult or rewarding during lockdown. Comments included recommendations on how to optimise homeworking and words of advice to employers.

Not surprisingly, isolation from colleagues was the most frequently mentioned issue. Some negative responses described feelings of paranoia, withdrawal, and loneliness.[2] Childcare, home-schooling, and distractions at home were also major concerns. The challenge of balancing these issues with a busy work commitment was mentioned by more than a quarter of those living with families. In apparent contradiction to their response to questioning (Q50), many clearly found it difficult to establish a satisfactory work-life balance. The importance of maintaining lines of communication was often raised (e.g.,

scheduling employer/manager catch-up calls and morning briefings). Little things mattered, such as acknowledging that a message had been received and would be addressed. Although slow responses fostered a lack of trust, instant-messaging applications were noted to be both an irritation and a lifesaver.

Eighty respondents mentioned that there was no natural end to their day. Typically, they found themselves working longer hours, which stretched into the evening. Activities included replying to emails and performing administrative tasks. They were not able to "switch off".

Practical advice included not working at the dining table and attempting to recreate the office set-up away from family areas. Several took the concept of adopting a formal working environment further by recommending that people should dress for work. Many liked having a (metaphorical) door that could be closed when working, which is then "shut" at the end of the day, at which point they could "walk

away".[2] Respondents highlighted the importance of taking regular breaks and planning their day. Many thought that taking a proper lunch break and not eating at their desk was important.

One clearly welcomed benefit of lockdown was the absence of the daily commute. A quarter of respondents noted that the time gained allowed them to be more productive, save money, and feel energised. Freedom and flexibility were also frequently mentioned.

In the second survey, the three free-text entries generated over 40,900 words of insight. For the question, "Which three aspects of working from home do you find most difficult?" 818 respondents provided answers. Interestingly, a small number reported no difficulties (n=38; 4.6%). By comparison, over a third (36.1%) reported feeling isolated and missing contact with colleagues, closely followed by issues relating to work-life boundaries, long hours, and not being able to "switch off" (29.8%).

Other concerns were related to distractions

> Perhaps the most striking observations were around patterns of working. Many respondents in the first survey observed that they were busier than before the pandemic and finding it difficult to "switch off."
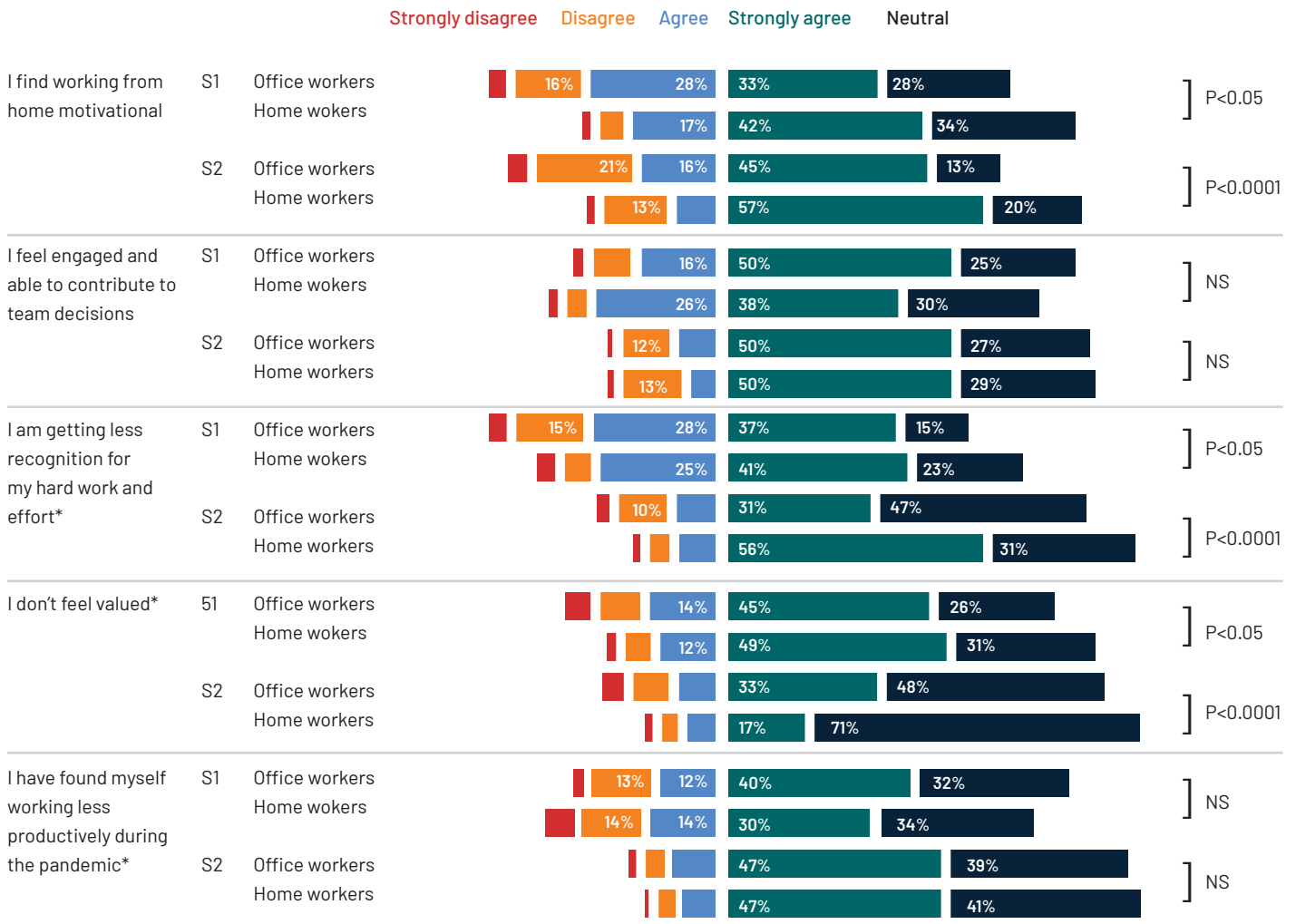
Figure 1. Comparison of work profile in office versus home workers prior to lockdown
*Represents data for negatively posed questions where data demonstrated were reversed for better interpretability.
Abbreviations: NS, not significant; S1, survey 1; S2, survey 2.

(16.0%; though only 3% specified children/childcare issues), "sameness" of the daily routine/reduced creativity/lack of motivation (11.9%), and suboptimal team/management communications (10.6%). The remaining frustrations included IT (6.9%), home office limitations (5.7%), and lack of visibility (3.1%). Interestingly, 14 people (1.7%) said they missed the daily commute, 6.1% reported that working under lockdown had reduced their physical activity (the daily commute), and 1.5% felt that working from home was not as fun as being in the office.

Eight hundred and nineteen respondents provided an answer to the question, "Which three aspects of working from home do you find

most rewarding?" A small proportion (1.0%) provided the response "None". The most frequently expressed benefits were "no commute" (43.9%) and "time saved due to not having to commute" (38.2%). Another popular response was the benefits of flexibility (43.2%) enabling more convenient working, multi-tasking home chores, and juggling workflows. A fifth of respondents (21.1%) reported fewer distractions and being able to concentrate better. Other perceived benefits were the absence of office politics, requirement to dress smartly, or need to engage in social interactions (14.0%). Some liked the comfort of being in their own "work space" (11.1%), not having to get up early or leave the office late (10.7%), convenience of working near

home (8.0%), and saving money on things such as travel and childcare (8.1%). Overall, 7.5% reported that they were more productive. Only 1.3% reported that they had reduced their environmental footprint, mostly by not commuting; this was similar in size to the proportion who saw a benefit in no longer having to book meeting rooms for client calls (1.9%).

Eight hundred and twelve respondents expressed a view on "hybrid" working models. Two thirds (66.5%) were positive about homeworking and considered that a hybrid approach was the way forward. What this should mean in practice was less clear. Among the 75 people who offered a personal preference, 35% felt that going to the office 1 or 2 days a week

would be ideal whereas 42% suggested that once or twice a month was appropriate. A small proportion (n = 56; 6.9%) stated that they never wanted to return to the office, whereas 28 (3.4%) people said that they wanted to return full time.

It was agreed that hybrid working would not be good for everyone, most notably, younger team members. Here, 5.5% of respondents felt that those with less experience would benefit particularly from time in the office, enabling appropriate training and greater visibility. Whether a good idea or not, a small proportion (9.8%) recognised that the future adoption of hybrid working models could be challenging and would require careful consideration and implementation. Again, concerns about lack of social interaction and isolation were expressed along with the complexity of how defining specific "office days" might be managed (9.2%). Whether productivity would be affected was unclear, with some (1.3%) respondents expressing a view as to the greater benefits to be had from homeworking.

There was clearly confusion among some respondents (16.6%) regarding the difference between "remote" and "flexible" – that is working at a time of the employee's choosing rather than employer-set office hours. Some felt that the onus should be on employers to be flexible in terms of when people choose to work and to address any managerial and/or legal challenges that arise with "out of hours" working. Finance was another issue, with some recommending that any (perceived) employer savings in terms of reduced office costs should be passed on to their employees.

Comparison with established home workers

In the first survey, 207 (27.3%) respondents identified themselves as pre-existing home workers, and of them, 69.6% (144 of 207) identified themselves as freelancers/consultants. In the second survey, 182 (19.7%) respondents said they were home workers before lockdown. Home workers were generally >40 years of age (82% vs. 51% of office workers) and more likely to be living with children (47% vs. 35%). Nearly

> The increase between our two surveys in feelings of loneliness and isolation from 28.1% to 45.6% is of concern. This occurred despite the time between the surveys spanning a period in the UK when lockdown was lifted and life appeared to return to some normality.

twice as many established home workers responding to the second survey felt they were worse off financially since the start of the pandemic (27% vs. 14%, respectively).

There were many similarities between the responses provided by office workers and those who worked at home before lockdown. In particular, the cohorts were similar at both time points in terms of their opinions on ability to engage with their team (Figure 1), rest (Figure 2), and establishing a daily routine and general health concerns (Figure 3; NS in all cases). Although most respondents enjoyed working from home, there was a statistically significantly difference between the groups in both surveys. More home workers stated that they enjoyed working from home than office workers in the first survey[2] and in the second survey ($P<0.0001$; Figure 2). The same was seen in terms of feelings of vigour ($P<0.005$; Figure 2) and motivation ($P<0.05$; Figure 1). In the first study, home workers felt less valued than office workers ($P<0.05$; Figure 1) and home workers felt they were not getting recognition from their employers ($P<0.05$; Figure 1). This difference in recognition appeared to have increased further by the second study ($P<0.0001$; Figure 1).

Significantly more office workers in the first survey reported being busier than before the pandemic than home workers ($P<0.0001$; Figure 3), but there was no difference between the groups by the time of the second survey. Office workers were also eating at their desks more frequently; however, they also reported taking more time for lunch (Table 3). In the first survey, home workers were clearly finding it easier to concentrate ($P<0.05$; Figure 3), but there was no discernible difference between the groups by the second survey.

> However, employers did score some successes. Not only had respondents remained equally motivated and engaged between the two surveys (despite the ongoing pandemic), but there was also a significant perceived improvement in opportunities for growth.

More office workers than home workers in the first survey felt that they were missing opportunities for growth ($P<0.05$), but there was no difference between the two groups by the time of the second survey (Figure 2). A slightly greater proportion of office workers (28.1%) in the first survey felt lonely and isolated, but almost a quarter of home workers (23.5%) reported similar feelings ($P<0.05$). Markedly more office workers reported loneliness and isolation than home workers by the time of the second survey ($P<0.001$; Figure 3).

Although significantly more office workers were concerned about job security in both surveys ($P<0.05$; Figure 2), general reporting of anxiety was higher in the home workers ($P<0.0001$ both surveys; Figure 2). Both groups were similar in terms of alcohol intake, social media use, and relationship strain in the first survey (Table 3). Although alcohol consumption in the groups remained similar in the second survey, office workers reported strain on their relationships more frequently and spending more time on social media. Home workers took less exercise in both surveys (Table 3, $P<0.05$).

Discussion

The context of lockdowns

The first "lockdown" in the UK was announced on March 23, 2020. Our first survey opened on May 28 and closed on June 11, 2020, meaning survey participants of this survey had experienced homeworking for 10–12 weeks. Around this period, lockdowns were being enforced by most governments across the world as a primary measure to reduce the spread of COVID-19.

At the time of the second survey (July 24 to August 16, 2021), the UK government was implementing stepwise measures to ease COVID-related restrictions and encourage a general return to offices. This occurred in parallel with a programme of mass vaccination. In other countries, the situation varied depending on infection levels, hospital capacity, and speed of vaccine roll-out.

These surveys detail the experiences, opinions, and insights
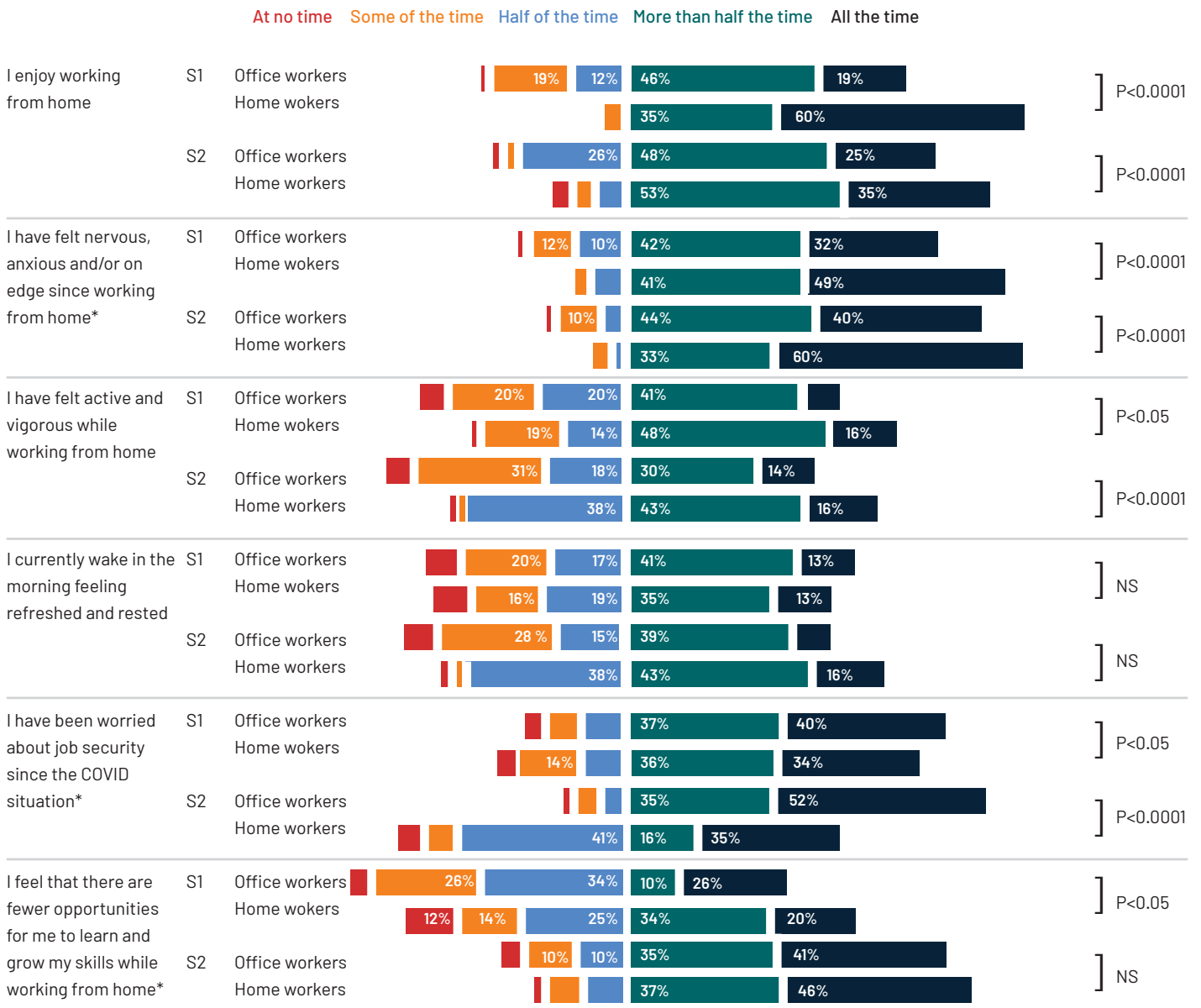
Figure 2. Comparison of emotional well-being responses in office versus home workers prior to lockdown

*Represents data for negatively posed questions where data demonstrated were reversed for better interpretability.

Abbreviations: COVID, coronavirus disease; NS, not significant; S1, survey 1; S2, survey 2.

into working practices of full-time, part-time, and freelance workers during the time of COVID-19-related lockdowns and other restrictions.

Changing working patterns

An underlying theme in both surveys was that office workers generally welcomed home-working, appreciating the lack of commute and the time saved. This observation reflects the findings of similar surveys.[8,9] Perhaps the most

striking observations were around patterns of working. Many respondents in the first survey observed that they were busier than before the pandemic and finding it difficult to "switch off". The data suggest that respondents were busier still by the time of the second survey – with the number of those working over 40 hours a week increasing markedly. It is reasonable to assume that this affected efforts to establish daily routines and a reasonable work-life balance as well as

affecting behaviours such as working out of standard hours, taking less exercise, and eating at your desk. Employers may have become more demanding during the intervening period, but many respondents commented on how they found it difficult to walk away from their computers. It could be that, as Parkinson's law states, "activity expands to fill the available time", and respondents filled time at their desks that would otherwise have been spent commuting.

Win–win for employer and employee?

The increase in working hours not only coincided with a boost in reported productivity, but also with a high proportion (43.2%) of respondents remarking having the freedom to complete home chores during their working day – perhaps contributing to their levels of satisfaction. In an experiment undertaken with call-centre workers in 2015, the Ctrip study, sales staff were randomly assigned to either home- or office-working for 9 months.[10] The study found that performance increased in the home-working group (13%). Reasons for the increased productivity included working longer hours, taking fewer breaks, and having fewer distractions. Home workers also reported improved work satisfaction. However, promotion rates conditional on performance fell.

At the end of the Ctrip study, employees were given the option to continue working from home and about half decided to return, citing isolation and loneliness as their reason.[10] Interestingly, the data we collected appears to indicate that people are missing the office. The increase between our two surveys in feelings of loneliness and isolation from 28.1% to 45.6% is of concern. This occurred despite the time between the surveys spanning a period in the UK when lockdown was lifted and life appeared to return to some normality. It is difficult to determine whether these feelings were a consequence of COVID-related restrictions or brought on by working in seclusion for long hours.

A legal framework needed

One of the other concerns to emerge from the present work was the legal employment framework. It is of particular concern that people were working more hours than those dictated under formal/legal working time directives.[11] This puts employers at risk, even when the work is performed voluntarily/informally. It also threatens the health and well-being of employees.

> a company could make modest savings assuming it was possible to exit leasing contracts, take on smaller premises, and manage additional hardware requirements in moving to homeworking. In contrast, each employee had the potential to make savings approximately double those available to a single employer.

The attraction of flexibility

Another issue was the variable interpretation of remote and flexible working. Many respondents simply assumed that working from home meant working flexibly, whereby they could fit work commitments around housework and childcare, catching up with emails, and "finishing-off" work late into the night. When implementing necessary changes during the first lockdown, the onus was for employers to be fully flexible as to when people chose to work, addressing any managerial challenges of out-of-hours working without regard to the interests of the business. Although flexibility is clearly attractive, it adds challenges and should not be considered the same as general homeworking. The desire for employers to be "flexible" was a key demand made by many respondents in both surveys, a desire that mirrors the findings of a survey by the consulting firm Insigniam conducted in early 2021.[9] The company sought the views of 1,110 people working for worldwide companies and found that people wanted more flexible work arrangements. This will need to be given appropriate consideration by both employers and employees when defining future working agreements.

A learning curve for employers

In addition to possible "overworking", it was particularly disappointing to note that over half of employers had still not performed appropriate health and safety checks of the informal workspaces. Many employers had not provided specific safety information or instructions on working from home, including employees' responsibility to report their status to insurance companies, landlords, and mortgage holders. However, employers did score some successes. Not only had respondents remained equally motivated and engaged between the two surveys (despite the ongoing pandemic), there was also a significant

> Most respondents had a positive early lockdown experience: they enjoyed time at home, liked the freedom, felt secure in their posts, and were cheerful. Most established a daily routine, coped with an increased workload, and felt valued.

perceived improvement in opportunities for growth. In addition, significantly higher levels were reported of respondents feeling valued and getting appropriate recognition from employers for their contributions. This coincided with fewer concerns being expressed in the second survey over poor communication at a company level.

In summarising the key learnings (for employers) given by respondents to the first survey we identified six key points.[2] These included: flexibility (on the part of employers), trust, optimisation of communication, ensuring that work activities (meetings and instant messaging) were not intrusive, adopting health and safety policies that are optimised for the homeworking environment, and offering the necessary tools/ equipment to do their jobs. In reviewing feedback from the second survey, it seems that these issues were no longer as relevant after 12+ months of working from home. Only a few comments were aimed at employers not trusting employees, IT issues, or poor communication, while dissatisfaction with video meetings was rarely mentioned. It seems that we have adjusted to the new working environment and many of the immediate concerns were simply a response to change and teething problems that have been reported previously.[12]

Making successful change permanent

Reflecting on the way ahead, a recent BBC article made the point that the transition to the more permanent adoption of hybrid or homeworking will take time and needs to be completed with sensitivity if resentment is to be avoided.[13] Although progress has been made in supporting those employees who remain working, at least in part, from home, what is clear from all surveys is that employers' dialogue with their employees must be open and continuous and that formal home/hybrid working practices need to be established. The office is undoubtedly a positive environment for many workers, but there will be situations where being in the office full time will be impractical or undesirable. The potential environmental benefits of reduced commuting have yet to be calculated. Nevertheless, the COVID-19 lockdowns have demonstrated that there is a feasible alternative.
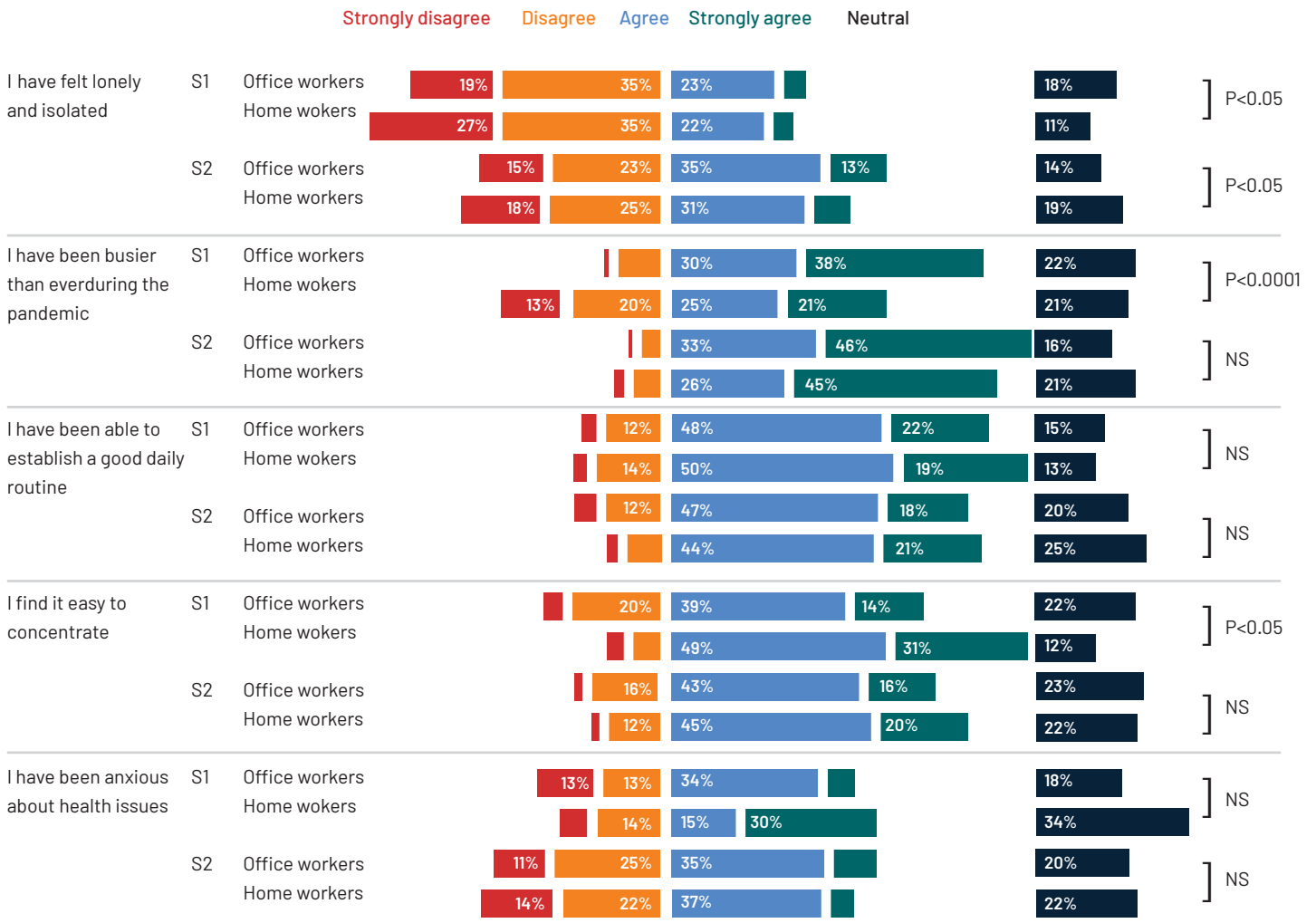
Figure 3. Comparison of factors of concern in office versus home workers prior to lockdown
Diverging Likert data plot with neutral responses (black data bars) off-set.
*Represents data for negatively posed questions where data demonstrated were reversed for better interpretability.

Abbreviations: NS, not significant; S1, survey 1; S2, survey 2

Sharing the benefits of homeworking
On a related point, it was frequently raised in the comments how employers should share the benefits of reduced office costs with their employees. Interestingly, the authors have previously modelled just such a cost-saving scenario.[14] The analysis showed that a company could make modest savings assuming it was possible to exit leasing contracts, take on smaller premises, and manage additional hardware requirements in moving to homeworking. In contrast, each employee had the potential to make savings approximately double those available to a single employer. The analysis was performed before the recent changes in fuel and energy costs and did not consider any increase in insurance premiums that may occur with a change to working from home.

Limitations
As with any survey, our work has limitations. Although surveys are a valuable research tool, they benefit from a protracted evaluation and refinement process to provide robust data.[15] By necessity, the first survey was developed quickly. Though it was based on a recognised template, it has not been validated. The second survey was created to relate directly to the first.

Recruitment of responders for both surveys was via dissemination through the authors' networks, meaning that the study population was open to selection bias and although they recruited from a similar pool of potential responders, it cannot confirm the proportion of responders that took part in both surveys. There was no baseline measurement to compare our data against – these responses may be nothing more than what we would have seen if the survey had been conducted before the pandemic. The survey populations are UK-centric and location may have affected the overall findings. A recent BBC article highlighted possible cultural issues regard-

ing homeworking patterns across Europe.[16] For example, the French and Japanese appear to be reluctant to work remotely, their workplaces being inextricably linked to their identity and an organisational sense of belonging. Among the study's strengths are the sample size and the coherence of the two study cohorts, allowing us to compare opinions from two key times during the pandemic.

Conclusion

An article published in *The Spectator* magazine early in 2020 posed the question, "Will Covid kill off the office?"[1] Our survey highlighted how lockdown has changed working practices and it seems unlikely that the industry as a whole will return to a pre-pandemic work model. Most respondents had a positive early lockdown experience: they enjoyed time at home, liked the freedom, felt secure in their posts, and were cheerful. Most established a daily routine, coped with an increased workload, and felt valued. However, all was not well for some, with many reporting loneliness or isolation.

The present study showed that it is not only those who have remote working sprung on them that suffer from loneliness and isolation – it also occurs in established home workers. For some,

this experience may have been a consequence of the wider societal lockdown. Our data appear to confirm the findings of other research that continuous homeworking can be detrimental to good mental health.[17,18] We saw that it is associated with overworking that may have long-term health consequences.

Discarding the office altogether may affect personal development as the surveys indicate that home workers struggle for recognition of their work and possible advancement. This is of particular concern for the development of younger employees, who, when working at home, may miss out on serendipitous and anecdotal learning. Social interaction and building company culture are also important. We must conclude therefore that an office-homeworking hybrid will be a likely path for many. However, to be successful it will be necessary for employees and employers to negotiate optimal working patterns that are beneficial for all parties. Such arrangements need to be formalised and recognise issues such as shared responsibility for employee safety. Although the office has been identified as part of the problem, it is clear that it will also need to be part of the solution.

Data availability statement

The original data are available to all for purposes of further research, upon reasonable request to the lead author.

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Author information

Timothy C. Hardman, PhD, is Managing Director
of Niche Science Technology Ltd., a contract
research organisation that he formed in
1998. A keen scientist, he has over 100
publications across a wide range of
subjects.

Peter Llewellyn, Founding Director of
NetworkPharma Ltd, has developed
recruitment and educational support
services for individuals working in and
around the pharmaceutical industry and
the global MedComms Networking
community
(MedCommsNetworking.com).

Catherine Lee is Senior Portfolio Director at
Alligent Europe, part of the Envision Pharma
Group. She is an experienced medical
communications professional who has
worked from home for >18 years and has a
particular interest in communicating
complex information simply.

Steven Walker, MD, MMedEd, MmedSc, is
Director at St Gilesmedical in London and
Berlin. He has an interest in scientific
writing, health films, research, and
education. During the pandemic, Steven
and colleagues have been providing pro
bono support to the end-of-life care
community.

Home office: Yay or nay?

Daniela Kamir, Natalie Gavrielov,
Cheryl Berkowitz

Bioforum Group, Ness Ziona, Israel,
and San Francisco, California, USA

Correspondence to:

Daniela Kamir
Daniela.Kamir@bioforumgroup.com

Abstract

In the first quarter of 2022, Bioforum performed an anonymous internal survey among its medical writers to understand if our employees would like to return to a physical office or prefer to stay in the home office despite the lifting of most of the COVID-19 restrictions. Bioforum's Medical Writing Team reported working from home as a positive experience overall and highlighted both an increase in work productivity and work-life balance. The possibility of working remotely spurred our team's growth by 366% during the pandemic. Stemming from our success with this business model, we will be working from home even following the pandemic.

Home office – Yay or nay?

If the home office is your new reality, then you are not alone. Many people who require only a computer to complete their work tasks began working remotely during the COVID-19 pandemic. Even now, when things are slowly returning to their pre-pandemic state, some employers are willing to keep working from home. Airbnb has just announced its new work policy allowing its employees to decide for themselves whether to work from home or the office.[1] The Remote Collaborative Worker Survey, conducted by ConnectSolutions (now CoSo Cloud), surveyed 353 US employees. Of those employees who were working from the home office at least a few times per month, 77% reported greater productivity while working offsite; 30% accomplished more in less time, and

24% accomplished more in the same amount of time.[2]

We, the medical writers (MW) at Bioforum, have embraced the work-from-home idea to the fullest by becoming a global team. During the pandemic, our team grew by 366%. We now have team members residing in Israel, South Africa, USA, Canada, Germany, Greece, and Bulgaria, all working remotely, and we are looking to expand further. To draft this article, a survey was sent out to all MW at Bioforum to better understand how our remote employees feel about certain aspects of remote work, especially regarding the home office and the near-total lack of non-virtual meetups. We analysed the results and report them here, as well as suggest some practical steps for remote teams to take so they can foster the feeling of being part of a team and to take care of the well-being of their employees.

Methods and findings

To examine a microcosm of employees' experiences with remote work, we surveyed the entire MW team at Bioforum, a data-oriented clinical research organisation (CRO), using an anonymous computerised questionnaire; we sought feedback on employee personality type, advantages, disadvantages, and difficulties of remote work, as well as productivity, collaboration, support from managers and colleagues, personal connections, and professional development in a remote workplace.

Remote work and employee personality

Based on our survey, 7.7% of our employees are extroverts who at times experience feelings of loneliness and isolation while working remotely. Of the employees interviewed, 61.5% identify with being introverts and often describe relief upon working in small teams, even alone, and being less exposed to large groups of people, since the interaction required to be part of a big team is stressful and uncomfortable for most of them. Finally, 30.8% of our employees describe themselves as ambiverts and are fine either way.

During the pandemic, our team grew by 366%.

Advantages of working from home

The most frequently reported advantage of working from home reported by survey respondents

was productivity. The majority (84.6%) of our MW team stated that they are more productive at home and are not eager to return to the office, while 15.4% of the team reported equal productivity between home and office work. Airtasker, an Australian company providing an online marketplace for outsourcing tasks/jobs, surveyed 1004 full-time employees across the US, of whom 505 work remotely. The study revealed that, on average, remote workers were more efficient than those who worked in an office with more distractions available.[3] Working from home cuts down on the time "wasted" during hallway and coffee-break chatter, gossip, or any kind of non-work-related conversation, leading to increased productivity and actual working time.[4] By avoiding commuting, workers save time and money and are often more rested and balanced due to lower stress levels. Work-from-home allows for more flexible work hours, making it easier to attend to other aspects of life, such as school meetings, going to a medical appointment, or just taking the dog for a walk.[5]

Overcoming disadvantages and difficulties of working from home

Based on our internal survey, 38.5% of MWs never miss face-to-face interaction, while 38.5% sometimes miss face-to-face interaction, and only 23.1% generally miss face-to-face interaction. Remote work may create a somewhat isolated working environment, physically and emotionally. Therefore, measures should be taken to avoid feelings of loneliness, isolation, and to improve team cohesiveness. Bioforum has implemented activities such as outings and team events to encourage socialisation. Over the last year, we have had wine-tasting and breakfast events, as well as remote team meetings to bring the team closer together by providing meaningful interactions. All of this aims to keep the employees happy in the long run. Remote team-building games and activities can be implemented easily and immediately. They are fun, and an easy way to spark conversation, get to know one another and create a casual atmosphere. Our team organised a game of having to guess colleagues' favourite foods; others included a Bucket List Challenge or even a simple remote get-together where everyone brings coffee/tea and colleagues just chat away.[6] Team-building activities should be adjusted to the team and not be "off-the-shelf",

so that the team will engage in them and not feel bored or uninterested. A pre-activity survey could engage the participants by having them actively take a part in choosing the activity. Templates for such surveys are freely available online.

Remote work-life balance

Based on our internal survey, 85% of employees have a well-defined workday; however, 15% of employees stated a lack of clear division between work and personal time. In total, 38% of our colleagues expressed that working from home feels at times like never getting off work and

invites checking work emails during off-hours, as well as squeezing in more work ("getting just one last thing done") instead of letting things wait for the next day. Some employees might have a harder time turning off and relaxing at the end of the day or workweek. However, this may be managed with certain technological and behavioural adjustments.[7] Project management platforms can help a team or a single worker in structuring their workday and tasks, minimising unexpected workload, and allowing for a "hard stop" from work at the end of a day due to better time planning. Maintaining a well-defined workday with set work hours might be harder for some employees, especially if kids are around. However, now that companies are becoming more inclined to implement work-from-home policies and most children are transitioning back to in-person learning and care, the work-from-home employees will have the ability to create and stick to more conventional schedules. Depending on the organisation's level of flexibility, companies might

still allow for the occasional doctor's appointment in the middle of the day, or for employees to go for a short run during lunch break, coming back to work more refreshed.[8] It is the responsibility of the remote employees to establish the right boundaries for a well-rounded work-life balance.

Collaboration in the workplace

The use of communication software not only allows for face-to-face meetings, but also for screen sharing. With this option, collaborative work is enhanced and feels natural. Based on our employees' previous experiences at various workplaces, we might even argue that it is more comfortable than sitting close to colleagues, sometimes squeezing more than two people in front of one tiny laptop screen while working together on a project. Some employees find this situation quite uncomfortable and would go so far as to describe these collaborative situations as ones in which one person is typing, and the other colleagues are breathing down their necks.

Support from manager(s) and colleague(s)

Based on our anonymous survey, 100% support from the managers was reported, as was the ability to reach out to colleagues for further assistance if needed. However, this might not be true for every remote team in all work sectors. Remote work requires support systems, and the most important one is the manager himself/

Figure 1. Open-ended responses from Bioforum's MW team members regarding the advantages of working from home are displayed in a word cloud infographic.

herself.[9] At Bioforum, we remain in close communication by holding meetings at least every week. These meetings help with prioritising projects, discussing deadlines, and, most importantly, being in tune with the existing workload. As mentioned earlier, project management tools are a useful source for time planning, workload expectation management, and synchronising multiple deadlines.

Personal connections within the remote team
Our MW colleagues know each other on a personal level; however, as in the office, strong friendships are formed between some colleagues and less with others. Managers should ensure that team-working tasks are not always assigned to the same group of people but expose colleagues to new or other employees who have never worked together before. This can be a good starting point to get to know colleagues, even the quiet ones. The onboarding process is generally a stressful time for a new employee, perhaps even more so for remote workers. Based on our experience, a good remote onboarding process should not deviate too much from in-office onboarding. Employees should meet the entire team, get an introduction to the organisational structure, company culture, and policies, and receive access to important resources like standard operating procedures (SOPs) and additional tools or software that are used by the team. Switching on the camera during video conferences might feel strange in the beginning, but seeing colleagues' faces and expressions during a meeting reinforces the feeling of connectedness and generally invites a more dynamic and friendly interaction. Virtual "happy hours" to ring in the weekend may be a great way for employees to bond while being mindful of employees' preferences.

At Bioforum MW and in other companies, e.g., Encepta, it is common practice to hold virtual workout sessions, like 'deskercise' stretching sessions, via an online meeting platform, that are fun and viable options to relieve muscle strain from the hours of working in a seated position, all while increasing team connectedness.[10,11] On-site health and wellness programs like Jaxfit, organised by The Jackson Laboratory for its employees, can now easily take place virtually.[12] Virtual training apps available on Android or Mac platforms have the same goal as on-site health and wellness programs, but their usage could be organised in a bigger setting, allowing for more flexible workout schedules.

Professional development in a remote work environment
In times of online university and online further education programmes, inviting speakers or organising online professional development courses on topics such as statistics or regulatory affairs can be organised both within the company and by engaging professional development schools. Investing in ongoing professional development allows for continued growth and staying up to date on industry knowledge, providing multiple benefits to both employee and employer. Professional development expands employees' current knowledge and boosts their confidence. Furthering an employee's education effectively trains and/or reskills employees to meet the company's own workforce needs. Employers gain from their employees being up to current standards by having more knowledge on hand without necessarily having to do new hiring. Another major benefit of continued education for personal enhancement is increased employee retention. Fulfilled employees are less likely to leave a company if they feel challenged, appreciated, and an asset to the company.[13,14]

Conclusion
This article provides a short glimpse into remote working, focusing on its advantages, disadvantages, and employees' feelings regarding this newly acquired work culture at Bioforum, which began to hire globally with the start of the pandemic. The results of our anonymous survey show that we, the medical writers at Bioforum,

believe that having a positive remote work experience is in no way inferior to on-site work. We found that most employees are happy and satisfied to have the option of remote work, are more productive at home than in the office, and feel well supported by managers and colleagues on their projects. From a strategic management perspective, the overall conclusion is that our experiences with remote work support further expansion of our remote team.

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

Disclosures and conflicts of interest
The authors declare no disclosures or conflicts of interest.

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

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Author information

Daniela Kamir, PhD, has been a medical writer with the Bioforum Group, a global data-focused clinical research organisation, since 2020. Daniela has an extensive research background in molecular biology and bioinformatics. She is experienced in writing pre-approval regulatory documents for both drugs and medical devices, as well as in scientific writing.

Natalie Gavrielov, PhD, joined the Bioforum Group in 2021. Natalie is a digital health scientist with a passion for public health and real-world evidence. She specialises in advanced statistical analysis and data quality assessment.

Cheryl Berkowitz, PhD, joined the Bioforum Group as a medical writer in March 2022. Following a research background in molecular virology, Cheryl has gained extensive experience in writing, editing, and proofreading scientific manuscripts and pre-approval and lifecycle regulatory documents for small molecules and biologicals.

International teams:

How to survive a long-distance work relationship among medical writers

Alejandra Gonzalez Diaz, Ana Goios,
Elvira Carrió, Marc Baay, Michelle Rubbrecht,
Neha Agarwal, Wendy Hartig-Merkel
P95 Epidemiology and Pharmacovigilance,
Leuven, Belgium.

Correspondence to:
Alejandra Gonzalez Diaz
alejandra.gonzalez@p-95.com

Abstract

How does a team of medical writers working in different countries navigate different time zones and cultures to get their work done remotely? In this interview, a team of six medical writers and one editor working at P95, a private research organisation focused on epidemiology and pharmacovigilance, share their insights about the main benefits and challenges of remote work, how it affects their everyday medical writing tasks, and how to make a long-distance colleague relationship work.

What are the main benefits of being a remote medical writer working with other remote teams?

- **Wendy Hartig-Merkel (WHM. Based in Germany):** The possibility to have this type of work despite residing in a small town far away from everything. With this remote work, I can live in a town and still have the same work opportunities as people working in big cities do. Also, I can move if I want to or work from anywhere as long as I have good internet. I don´t spend money or time commuting. I can work full time and still have a family and take care of (almost) everything.
- **Elvira Carrió (EC. Based in Spain):** It's enriching to have colleagues from other

countries, at the personal and professional level, as I get their insights and perspectives. It keeps my mind open! I get involved in interesting international projects while working from my preferred location.

- **Marc Baay (MB. Based in The Netherlands):** The most obvious professional benefit is the opportunity to focus. I used to be in an office of five people, walking in and out, talking among themselves. In my home office, no one distracts me. If I really need to focus, I switch off Outlook and Teams to get more work done. And although I love seeing my colleagues face-to-face occasionally, after a few days, I long for the solitude of my home office.
- **Ana Goios (AG. Based in Portugal):** The main benefit of being a remote medical

writer is working with medical writers and other professionals from around the world, in a team of highly qualified and skilled individuals, with major players (public and private) in human health worldwide and at a higher level than if I stayed in my home country.

What are the main challenges you face? (Are there times when you wish you could just meet your coworkers in person?)

- **Michelle Rubbrecht (MR. Based in Belgium):** Signing off mentally is a big challenge for me. In previous jobs, at the end of the day, that was it. I left work at work. With remote work, the lines between work and private time have become blurred. Also, working remotely and

being a medical writer are both new to me, so sometimes I struggle with something work-related, and I think it's just me feeling this way. If I was in the same physical space as my co-workers, I could talk to them and see if someone else was in the same boat, so

it would make it easier to support each other.
- **Neha Agarwal** (NA. Based in Germany): Yes, some issues are easier to discuss and show in person. Though, the screen-sharing option in most communication apps (e.g., Teams) allows us to navigate these problems to some extent. Also, it's nice to have a coffee break with a colleague and share thoughts about projects.
- **EC:** The downside of work flexibility is that we end up being more connected to work, and we might extend the working hours to adapt to other regions. I often end up checking the work mail and chat outside working hours, while if I was working in an office, I might not do so. Also, personal relations are harder to build online, as we don't share lunch and coffee breaks.

Spontaneity is also harder with online communications.
- **MB:** Indeed, sometimes a complex issue can be solved with a quick meeting, but this meeting can be held online. As a rule, we never just call; we always ask first if it would be convenient to call and I truly appreciate that. Time differences are a bigger challenge than physical distance.
- **AG:** Remote working can be lonely, and I miss those coffee table conversations that help you know what is going on "behind the scenes" and exchange experiences with coworkers. We barely have the opportunity for these conversations remotely. On the other hand, this leaves less space for gossip (which is both good and bad).

How did you adapt to this position knowing that you wouldn't step foot in an office?

- **Alejandra Gonzalez Diaz** (AGD. Based in Colombia): I was used to remote work due to the pandemic, but starting a new job with people I've never met and who are on the other side of the world was a challenge. I've had to be patient and adapt to work flexibility, changing my schedule, and turning on cameras, which is something we never did at my previous job.
- **AG:** I prioritised getting a proper office space where I feel comfortable and have my ideal setting. While this space is inside the house, it helps that it is in a separate area that I can leave behind at the end of the day and on weekends. I also found ways to leave the house every day: for exercise, to drop off/pick up children, for errands, etc.
- **EC:** I got myself a coworking space, so I could better differentiate work and personal life. We set up regular meetings where we turn on the camera to improve the team spirit. Those team meetings are not necessarily productive in terms of work but keep us connected. Besides the work chat, we use informal channels to communicate with colleagues, so we can also keep a personal relationship.

> While working remotely, a medical writer can focus better and be more productive. On the other hand, in the absence of an appropriate workplace (at home), there can be more distractions.

- **MR:** The pandemic came along just as I left face-to-face work and was looking into a career change. I was already in a foreign country, and the added isolation perhaps made it easier to adapt. This job requires extended concentration, and I can't think clearly with many distractions, so solitude helps me focus. Being an introvert by nature also helped ; this isn't the best job for highly social people who thrive on the energy of others.
- **NA:** I established social contacts outside work to fulfil the need for human social contact, stuck to a routine, and allowed space for flexibility whenever needed. Quick walks after work have also helped.

Do you think remote working makes a difference in the way a medical writer works with clients/other teams?

- **EC:** Sometimes, it's more efficient to work remotely, as we can just share our screen, which facilitates communication. Online meetings can be shorter and more efficient than in-person ones, and it's easier to get back to my tasks after. Being a virtual rapporteur is easier than taking hand notes in a face-to-face meeting.
- **MB:** Within the company, I don't think it makes a difference. As a rule, we turn on the cameras during meetings unless the internet connection is bad. With clients, I have seen the change from using Teams as an online phone call to using cameras. I think that it improves the interaction, it is easier to bond, and provides feedback from non-verbal communication.

  As a team lead in a remote setting, it all comes down to trust. I have to trust my team to get their work done. And I have to build a relationship with the team, so they have the confidence and trust to come to me to discuss any issues.
- **MR:** Not really. Many writers do best in solitude but working with clients or other teams is another issue. I think it takes longer to establish a good working relationship or cultivate trust online than it would face-to-face.

- **AG:** In my experience, we are more productive. While it may be more difficult for us to meet with other people in person because we are all in different countries, it also means that we are more used to reaching out to people all around the continent/world, so in a way, we are more reachable. On the other hand, we can't exchange experiences as often, so we mostly learn from doing, not from witnessing others do it.

- **NA:** Yes, there are both pros and cons. While working remotely, a medical writer can focus better and be more productive. On the other side, in the absence of an appropriate workplace, there can be more distractions.

What would you recommend to remote medical writers working in large companies to improve their work/ communication with other teams?

- **WHM:** Be active, call people/have online meetings, reply quickly, and be reliable. All this shows that you are a living person and not just an email address. Also, be nice. Make sure to meet in person regularly; perhaps just one or two times a year might be enough to keep the spirits up. It is extremely fun to meet with your online colleagues in real life (at least if you have a nice workplace and cool colleagues).

- **MR:** If possible, attend company gatherings or conferences together. It makes it less

awkward to interact on screen after meeting in person. You can't express yourself or read body language or facial expressions as easily online. In-person time can lead to serendipitous discoveries about one another and bonding. Sharing during remote meetings requires more effort.

- **AG:** Be available to speak/help others during office hours, ask all the questions from the beginning or whenever in doubt. Accumulating doubts while working remotely can lead to accumulating errors and, if this goes on, it might be difficult to correct in the end. So to prevent this, maintain open communication, and reach out regularly. Also, regular team/project calls help to get a notion of the whole and realise that we are not alone.

- **NA**: Have regular online coffee meetings where you can talk about work-related and non-work-related issues. Also, share your work schedule/out-of-office calendar with colleagues, follow the work ethic, and have professional conversations.

How is the daily remote interaction with people from other countries/cultures?

- **MB:** It is very enriching to be in a company with people from so many countries and cultures. Of course, it's important to be sensitive to cultural differences, such as different holidays, different schedules for

lunch and dinner (both of which may impact availability for meetings), and more complex differences, such as religions. But most of the time, these differences do not affect the work/interaction at all.

- **AGD:** It's a learning process. I've learned to pay attention to other people's paces, work habits, and demeanours. It's interesting because many of those things are related to cultural reasons and personalities, so I try to learn and be respectful. When it comes to deliverables, being seven hours behind plays in my favour because I can work on

Author information

Ana Goios has a PhD in Genetics and postgraduate work in Population Genetics and Population Health. She joined P95 as Medical Writer in 2020 and has been hosting the EMWA Workshop "Essentials of Data Visualisation" since 2021.
LinkedIn: https://www.linkedin.com/in/ana-goios/

Alejandra Gonzalez Diaz has a BA in Communications and a master's degree in Journalism. After working as a journalist, translator, and medical interpreter, she became Clinical Editor at a pharma company and is currently the Medical Editor at P95.
LinkedIn: https://www.linkedin.com/in/ alejandra-gonzalez-journalist/

Elvira Carrió has a PhD in Genetics and a postgraduate degree in Global Health. She started working as a Medical Writer at P95 in 2020.
LinkedIn: https://www.linkedin. com/in/elvira-carrio-gaspar-phd-3a475996/

and cultural differences are in themselves a challenge, but that also happens with face-to-face work, on-site.

Same topic, different points of view. When it comes to remote work, there is not a one-size-fits-all manual. Just like a physical office, remote working poses benefits and downsides: besides the obvious commute time saving, it allows a team to gather highly skilled talent worldwide and work with international clients. Even if for some colleagues, this work setting is better for focusing, occasional opportunities for socialising are key; in-person gatherings now and then and virtual coffee breaks can help to bring people together. At the end of the day, finding the right balance between virtual and in-person settings, and solitude and company, might represent some trial and error, but it is vital for the success of any remote-working team.

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> The main benefit of being a remote medical writer is working with medical writers and other professionals from around the world, in a team of highly qualified and skilled individuals, with major players (public and private) in human health worldwide.

documents while others are sleeping, which gives us more time for each project.

- **MR:** It varies. There are days when I don't interact with anyone at all or one or two at most. Project team meetings are time-restricted, so apart from the brief pleasantries, it's all business. I do love being part of a multi-national team/company, but informal interactions are curbed under the circumstances.

- **WHM:** The time differences are challenging and lead to online meetings that are too late for my taste, but if I schedule online meetings too early, my colleagues on the other side of the globe might not be able to join. Personal

Marc Baay: After earning an MSc in Biology, a PhD in Medical and Health Sciences, and a Postdoc position in oncology, Marc started as a medical writer at P95 in 2014. He was appointed Head of the Medical Writing team when the team started to expand in mid-2020. LinkedIn: www.linkedin.com/in/marc-baay-44a52b1b

Michelle Rubbrecht holds a BSc in Chemistry, an MSc in Forensic, and a Master of Pharmacy (MPharm). Michelle joined P95 as a medical writer in January 2022. LinkedIn: https://www.linkedin.com/in/michelle-r-a2545b208/

Neha Agarwal holds MSc in Biotechnology and PhD in Gene regulation. Neha joined P95 as a medical writer in May 2021. LinkedIn: https://www.linkedin.com/in/neha-agarwal-ph-d-9b571399/

Wendy Hartig-Merkel has a PhD in veterinary science and has been working as a medical writer at P95 since 2020. LinkedIn: https://www.linkedin.com/in/wendy-hartig-merkel-90349a16

How remote working can affect mental health: Work-life balance and meeting fatigue

Katharina Friedrich

Medical Writing Consultant, Heidelberg, Germany

Correspondence to:

Katharina Friedrich
k.friedrich@katylistic.com

Abstract

When it comes to remote working, we often think about the many benefits this approach brings, such as being more flexible and productive, or improving our work-life balance. However, remote working without the right framework to profit from all these benefits can leave us feeling fatigued, isolated, or even depressed. I experienced the pros and cons of remote working both as an employee and a freelancer and searched for preventive strategies to improve wellbeing and preserve mental health.

The bright side of remote working

T he global pandemic has made remote working more popular than we could have imagined, and it is also seen as the future of work for many people.

I worked at an international medical device company when the pandemic forced my colleagues and me to work from home. Before that, I spent more than two hours commuting each day on a crowded train that was always delayed. That is why I really enjoyed the first few months of working from home.

My apartment is located in a nice, peaceful area, with enough space to set up a workplace, and I never had to manage homeschooling or similar tasks besides my work. I was aware that remote working caused huge challenges for other people.

As an early bird, I now had the chance to focus on my work without any distractions before

my colleagues showed up online. As soon as my focus diminished, I could go out for a short walk to clear my mind.

In the middle of the pandemic, I quit my job and started freelancing. Working from home saved money for expensive office space and allowed me to collaborate with clients spread all over Europe.

Overall, the benefits of remote working seem pretty obvious. The magazine *The Economist* published an article in Apri 2021 saying that although most people work longer hours when working from home, they are happier and more productive.[1] For those who prefer to work remotely but not from their home, there are companies that provide coworking spaces and services. These companies claim that most people have a better work-life balance, and experience more freedom, which improves their wellbeing.[2] According to a 2021 survey,[3] while remote working was associated with better mental and physical health status, among the characteristics analysed, higher productivity was associated with female workers, older workers, and high-wage (annual income between $100,000 to 150,000 US$) workers. As always, every coin has two sides.

The dark side of remote working

Besides all the benefits of remote working, I also experienced the downsides as an employee and freelancer, and I also noticed them with family and friends. One of these phenomena now has a name: meeting fatigue. We all know these situations: we join a virtual meeting where all but two or three participants turn their cameras off, mute their microphones, and there is almost no interaction. Microsoft studied the phenomenon of meeting fatigue using physiological signal monitoring (EEG).[4]

A study in the company's Human Factors Lab "found that brainwave markers associated with overwork and stress are significantly higher in video meetings than in non-meeting work like writing

> It is harder to feel like part of a team when working from home.

emails. Further, due to high levels of sustained concentration, fatigue begins to set in 30-40 minutes into a meeting. Looking at days filled with video meetings, stress begins to set in at about two hours into the day. The research suggests several factors lead to this sense of meeting fatigue: having to focus continuously on the screen to extract relevant information and stay engaged; reduced non-verbal cues that help you read the room or know whose turn it is to talk; and screen sharing with very little view of the people you are interacting with."[4]

Besides meeting fatigue, research confirms that stress, emotional exhaustion or distress, and anxiety and depression are psychological symptoms that are associated with remote working.[5,6]

Meanwhile, a significant number of my family and friends work (at least partially) from home. It's just a personal observation, but many people seem to struggle more with stress or frustration while working remotely than when they worked in the office. I sometimes miss the informal chats with my colleagues at the coffee maker. Especially as a freelancer, most of my meetings are dedicated to business questions with little time for personal interaction.

For people like me who have always worked in an office, it is also harder to feel like part of a team when working from home. But feeling part of a team and exchanging your thoughts, feelings, and struggles with your colleagues helps you cope with stress. To prevent isolation or meeting fatigue, we have to re-think team building strategies, project management, and virtual meetings. That is why companies, managers, employees, and freelancers should not underestimate the potential negative impact of remote working on mental health. Although the benefits of remote working still outweigh the drawbacks for me, I summarised my personal pros and cons (Table 1).

Table 1. Pros and cons of remote working

Pros of remote working	Cons of remote working
More flexibility and freedom	Isolation
Higher productivity	Meeting fatigue and longer hours at the workstation
Better work-life balance	Blurred lines between work and home life

Table 2. Online sources with tips for remote workers

National Health Service (NHS): 7 simple tips to tackle working from home[7]	NHS provides nicely illustrated tips for remote workers. One of the recommendations highlights that staying connected can boost your wellbeing.
Mental Health First Aid (MHFA) England – My Whole Self: Supporting your mental health while working from home[8]	This printer-friendly poster promotes a healthier workspace by getting into a morning routine, getting moving and connected, and getting support when you need it.
World Health Organization:Doing what matters in times of stress: An illustrated guide[9]	This guide does not exclusively address how to deal with stress when working remotely. But it mentions five tools (grounding, unhooking, acting on your values, being kind, and making room) that are probably useful in every stressful situation.

Strategies for preserving mental health in a virtual workforce

After almost 3 years of working from home, I decided to work at a coworking space from time to time. Most coworking places offer flexible rates that allow you to book a seat when you need it without the financial burden of monthly rates. It's a great way to meet new people who are happy to talk about things other than work. Coworking is my personal preventive strategy to preserve mental health as a freelancer. Besides that, I regularly meet with my freelance colleagues for virtual coffee breaks.

Of course, this is only a small step and doesn't solve the problem of overworking or meeting fatigue.

Companies should implement clear guidance on working hours to prevent overworking. They should also consider interactive meetings or joint working sessions as potential ways to avoid meeting fatigue. Meetings should always have one focus and a clear goal. They should be thoroughly planned and have a moderator to take the lead.

Some companies recommend their teams meet for virtual "workathons". During a "workathon", a group of people meets virtually for a dedicated time. Everyone focuses on a specific task, either as a team or as individuals, that is supposed to be finished by the end of the session. Although I never tried it myself, this could be a good option when you find it difficult to concentrate at home.

During the research for this article, I was surprised by the number of online sources dealing with mental health for remote workers. I want to share the ones that seemed to be most helpful to me (Table 2).

At the time of completing this article, I have upgraded my coworking membership to a fixed seat, meaning a desk and chair are mine, and no one else's. For me it's time to work among people again. How about you? I would love to hear about your stories and experiences. Please reach out to me at the email address at the beginning of this article.

Disclaimers

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

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Author information

Katharina Friedrich, Dr. med., MD, is a freelance medical writing consultant, providing regulatory documentation for medical devices and pharmaceutical companies. Katharina also leads workshops for EMWA and Life Science Academy.

The December 2022 edition

Open science and open pharma

Open access ensures that the highest quality, peer-reviewed evidence is available to anyone who needs it, anywhere in the world. This issue will focus on how open access and plain language summaries improve transparency, advance medical science and ultimately improve patient care. Focus will also be given to how Open Pharma, a group of pharmaceutical companies and other research funders, alongside healthcare professionals, regulators, patients, publishers and other stakeholders in healthcare, are driving this goal.

Guest Editors: Martin Delahunty, Tanya Stezhka, and Chris Winchester

The COVID-19 pandemic as a catalyst for digitalisation and remote working in Germany

Wendy Hartig-Merkel

P95 Epidemiology and Pharmacovigilance
Leuven, Belgium

Correspondence to:

Wendy Hartig-Merkel
wendy.hartig-merkel@gmx.net

Abstract

Remote working is ideal for medical writers, but up until a few years ago, was not widely available to those looking for a remote position with a German employer. Even though Germany is a developed country, its digitalisation has long been lagging, and moreover, the work culture is still in many places characterised by presenteeism. The COVID-19 pandemic has given the country a well-needed push in the right direction; one year after the first lockdown, five times as many people worked from home than before, and hopefully, many of those who appreciate it will retain this option. This article will give an impression of the 2020–2022 "home office revolution" in Germany. Hopefully, remote working will continue to be a possibility for German medical writers in the future.

Introduction

Back in 2019–2020, I was looking for a career change. The term "medical writing" had not really crossed my mind until then, but I was contemplating *what* I wanted to spend my workday doing, and *how* I wanted to do it. I discovered that I was going to become a medical writer, and importantly: one working *remotely*. This job seemed a perfect way to combine my professional and personal skills with my wish for flexibility. Unfortunately, I lived in a small town in Germany that was about 2.5 hours drive to either Munich or Stuttgart, the nearest metropoles with a pharmaceutical/medical device industry, and I could not relocate for family reasons. Originating from Scandinavia, where life is largely digitalised, and being an efficient and active person, I thought my geographical challenges could be easily overcome by working remotely. However, none of the potential employers who were hiring professional profiles like mine were willing to offer a regular home office arrangement. If I was lucky, it would be allowed occasionally – as an exception. I was both amazed and frustrated by this. Luckily, I widened my horizons beyond Germany, looked abroad, and was offered a 100% remote job with a Belgian company. I now work remotely, flexibly, and happily.

Development of remote working in Germany from 2019 – 2021

Digitalisation is one of Germany´s greatest challenges in modern civilisation. It has been a struggle, not because of financial constraints, but because of "the approach to innovation, the lack of specialists on the labour market, Germans' sense of unease towards new technologies, as well as previous mistakes made during the development of the transmission infrastructure".[1] Remote working depends on, among other things, digitalisation. The COVID-19 pandemic made "home office" a buzz-phrase in Germany; the topic was heavily discussed across society and the pandemic created a well-needed wave of digitalisation for many. Employees were freed from their offices (or shut out, if looking at it from the other side), enabling them to experience working from home. The proportion of Germans working exclusively or mainly from home increased rapidly from 4% before the pandemic to 27% during the first lockdown (March 2020 through May 2020), then sank to 14% in

November 2020, before it again rose to 24% in January 2021.[2]

Regulatory changes in Germany during the COVID-19 pandemic

The Infection Protection Act (Infektionsschutz-gesetz), was adapted/amended several times, especially when the disease incidence rose, and regulatory changes were implemented to ensure more people stayed at home. In some amendments, the employer was obliged to offer certain employees home office arrangements, while in others, the employees were obliged to accept this offer. Despite the joys of having a home office, keeping an overview of all the discussions and changes must have been exhausting to many

people. The changing rules were mixed with discussions about data protection, occupational health and safety, surveillance by the employer, technical equipment,[3] among many other discussions. The latest legal obligations to offer employees home office arrangements were in effect until March 19, 2022, after which employees could have been required to return to their offices.

Will remote working remain a possibility in Germany?

Currently, there is no legal entitlement to working from home in Germany, and many must enter a dialogue with their employer to try to retain the opportunity for remote working after

the pandemic. The discussion about what will be the new "normal" is ongoing. Spatial and temporal work flexibility are seen by many as a trademark of the modern working world and its digitalisation, and a way to accommodate the personal needs of employees better. Unfortunately, to some extent, it becomes "employers against employees" and vice versa. Many employees wish to continue to maintain a home office. However, especially in small companies, this conflicts with the plans of the employers, who may refuse a home office facility even if the nature of the job tasks allows it.[4]

A report by the German Institute for Employment Research,[5] based on surveys of 513 employers (in 2016) and 4830 employees (in 2017), showed that an incompatibility between work tasks and the home office was the most frequent argument employers gave against home office facilities (90% of respondents). This was followed by a difficulty to work with colleagues (22%), caution regarding data protection (16%), impossibility to lead/control (10%), lack of interest from employees (10%), lack of technical requirements (9%), and "has not been an issue" (3%). The employees also rated incompatibility between work tasks and a home office the highest (76%), but this was followed by other factors, such as: "presence is important to the supervisor"(66%), difficulty to work with colleagues (59%), importance to separate work from private life (56%), lack of technical requirements (54%), home office not allowed even though it would be technically possible (16%), and home office is harmful for the career (7%).[5] The employees´ high rating of supervisor control as a hindrance to the home office is worth noting. German work culture is traditionally a culture of presenteeism.[5]

When one is working in a well-functioning remote position, these discussions may feel distant and unnecessary, but if you are not allowed to work remotely/flexibly, even if the requirements for the job could allow it, you may likely be frustrated. What a relief it was for me to have had a normal remote position throughout the pandemic and beyond, without having to bother about any of the constant changes. I am happy about the awareness of this type of flexible working that has finally reached Germany. I hope the opportunities for flexible work for medical writers will not be dependent on various laws, but on openness, creativity, modern thinking, and trust.

> **Flexible working** *is an arrangement in which an employer allows people to choose the times that they work, whether they work in the office or at home, etc."*[6] In Germany, the terms "teleworking" and "mobile working" are often used synonymously, even if they are different, and "working from home" is often used to refer to both.[3] This article uses the terms "remote work", "home office", "flexible/mobile working" etc. interchangeably, without regard to the slight differences in the definitions of these and other related terms.

For the sake of completeness, it must be mentioned that some people may feel discomfort with flexible work facilities like a home office. Potential negative mental impact and other disadvantages of working from home are, however, beyond the scope of this article, which advocates flexible working for medical writers.

Disclaimers

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

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Author information

Wendy Hartig-Merkel is a veterinarian who progressed from "real veterinary work" to a PhD, and from there to the veterinary nutraceutical and pharmaceutical industry. Her work aspirations and some very inspiring encounters with EMWA brought her to medical writing and a 100% remote position in 2020.

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Clinical trials

Medical writers and communicators are involved in clinical trials, from writing the trial protocol to reporting and publishing the trial results. This issue will focus on our roles, responsibilities, the documents we create, and our audience. Furthermore, we will also cover the regulations and best working practices governing documentations for clinical trials.

Guest Editors: Raquel Billiones and Ivana Turek

Sluggish downloads, lagging video calls: Tips for the remote worker to tame technology

Allison Kirsop, Peter Kirsop

Scientific Writers Ltd., The Beacon, Hunterfield Road, Gorebridge, Edinburgh, UK

Correspondence to:

Allison Kirsop
a.kirsop@scientific-writers.com

Abstract

What are the various broadband options to consider when working from home and how can you ensure you're getting the best from yours? Broadband failures can mean a headache for your clients and you risk looking unprofessional, so having a backup system is vital to continue providing the high-quality service your clients deserve. This article covers what you need to know about IT to either run a successful business from home or work remotely for someone else. If you've ever wondered why your system seems to run faster on some days than others, some simple checks and changes to your broadband service will allow you to cope with anything the IT gremlins throw at you.

O ptimising your home internet service is one of the most important considerations for freelance medical writers or employees who now work from home. If you want to build lasting collaborative relationships with your clients or employers, you need to be reliable. Life events happen to everyone but telling clients or colleagues you can't meet your agreed-upon deadline because you have IT problems may not be met with much sympathy. However, learning how to optimise your internet service isn't easy when it's not your area of strength (or interest, let's be honest!). We just want it to work! This short article will hopefully provide you with some guidance on what you can do before calling in the expensive telecoms engineer.

What service do you choose?

The first consideration is the service that you have coming into the property as this will be the limiting factor in the performance of your internet service. The incoming signal is fed to a hub, sometimes referred to as a router, which then connects to your computer and other devices. The minimum speed you need for general office work and video calls is around 10 megabytes per second, but at this minimum level you may struggle if anyone else in your property is using the connection at the same time – important if you have gamers in your family or others streaming video at the same time as you are trying to have a video call.

Connecting the signal to your computer: Ethernet cable or Wi-Fi?

Connecting by Ethernet cable

Cable is the better option and the most reliable and secure way to connect your computer to the hub. You have a direct connection between your computer and the internet giving you the highest speeds and cannot be intercepted by another user. The cable, referred to as Ethernet (traditional technology for connecting devices), plugs into the hub at one end and

There are three different ways of bringing the internet into your property.

1 The most common method is via your telephone line (Figure 1A). Optical fibre is run to a cabinet – fibre to the cabinet (FTTC) – which will then serve several properties. There will be a small dongle (a micro filter or splitter) plugged into your telephone socket into which the hub and telephone are plugged. The telephone line is by far the most common way to access the internet with speeds of up to 40 or 50 megabytes per second. To get the best speed, it's important to use the master phone socket for the hub, the socket nearest to where the phone line enters the premises. Avoid the use of extension sockets or cables as this will slow the connection due to signal loss in the extension cable. This method is reasonably reliable, but the speed can vary depending on the time of day due to loading from other users in your area.

2 The second method, and by far the best and most reliable, is via fibre cable access to the property, or residential fibre to the premises (FTTP) – where a fibre optic cable is brought into the property (Figure 1B). Rather than delivered via the telephone line, the internet signal is brought in by optical fibre with speeds of at least 100 megabytes per second. FTTP is not available globally yet, but coverage is steadily increasing as more areas acquire the infrastructure. It is worth checking to see if FTTP is coming to your area soon. If so, be careful not to tie yourself into a long-term contract with an internet provider who only offers FTTC as you will not be able to upgrade until that contract ends. FTTP costs more than FTTC, certainly at the time of preparing this article, but it's a worthy investment to ensure reliability and speed of service. A speed of

Figure 1. Common methods of providing internet to properties

(A) Fibre to the cabinet (FTTC) and via telephone lines to several properties. (B) Fibre to the premises (FTTP) direct from the cloud.

1000 megabytes per second (1000 megabytes = 1 gigabyte) is also possible with this method, although anything >100 megabytes per second is only worth the extra cost if you have multiple users on your network.

3 The third method is via the "mobile Wi-Fi" (MiFi) device and is best considered as a back-up if your internet service goes down, as well as being useful for travelling. The device connects to the mobile phone network to access the internet. If you have a strong mobile phone signal on your provider's network, then this method can work well. However, speeds are usually limited and can vary depending on the time of day due to the number of users on the network. Also, the amount of data you can download may be capped. Of course, a mobile phone can be used as a hotspot and although this works reasonably well, the speeds are not as good as those achieved with a dedicated Mi-Fi device. Using your phone as a hotspot will also drain your phone battery quickly.

your computer at the other. If your laptop does not have an Ethernet port, it may be possible to buy an adapter.

There are usually at least two sockets on the hub for this and will be marked LAN (local area network). The socket type is RJ45 on both your hub and computer and will look like the image shown in Figure 2.

Ethernet cables are cheap and widely available for purchase. The cables can be up to 100 m long without incurring loss of speed. As well as conventional round cable, flat profile cable is also available for running under carpets or doors; this is preferable for the home office.

The downside of Ethernet is that you must route the cable through your property. This is time consuming and, if you are unlucky, may require drilling holes through walls. If you are moving from one house to another, it's a good idea to get this done before you move in, and certainly before any carpets or floors are laid.

An alternative is available if it is not practical to run an Ethernet cable throughout your home. You can buy power line adapters (Figure 3), which use the electricity cables between sockets to carry the signals. You connect an Ethernet cable between your hub and one adapter, and your computer to another adapter, both plugged into convenient sockets. You can use as many of these as you need so if you have more than one computer, or printer or scanner, you can use an extra adapter for each one.

Once you connect your computer with Ethernet it should work straight away with no configuration required. If you need to connect more than one computer, printer, or scanner to a single Ethernet cable from the hub, this is easily done using a switch (Figure 4). The switch enables multiple devices to be connected, but it's recommended to buy a 1GB switch or better to maintain best speeds. There are some older models around that may be slower than your internet connection.

Connecting by Wi-Fi

If running an Ethernet cable is not possible in your home then you will need to use Wi-Fi, which is, of course, required for tablets, phones and devices that do not have Ethernet ports. Although not as fast or reliable as Ethernet, with care, good performance is possible.

The hub will have a Wi-Fi network, which will be on 2.4 GHz, and if the hub is relatively new a second network on 5 GHz. If your device offers a choice when connecting, choose 5 GHz as this is a faster network, although the signal will not travel through walls as well as 2.4 GHz. The 2.4 GHz frequency has a greater range but is slower. In either case, if your Wi-Fi signal on the device shows less than full strength, then performance will suffer. The thickness of your property's walls will significantly affect the Wi-Fi signal.

You can buy Wi-Fi boosters (Figure 5) to help improve signal strength; however, how they receive and transmit data also reduces your speed so it's a trade-off. These plug-in devices are easy to set up, and ideally should be placed roughly halfway between your hub and where you need reliable Wi-Fi coverage.

Checking your internet speed and performance

Once you have everything connected and working properly, you should check your internet speed and performance using a speed test tool. A good example is the browser-based Speedtest by Okla, available at https://www.speedtest.net/ (Figure 6). There is no need to log in or create an account and when you access the page you should see a GO button as shown in Figure 6A.

At the bottom of the page, you will see your network provider, your IP address and which server is to be used for the test. No changes need to be made here and you simply click GO and

wait for the test to finish, which takes around 30 seconds.

The download speed will have a maximum value of the speed claimed by your internet service provider although this is rarely achieved, particularly if you are using Wi-Fi. As a rule of thumb, if you are getting around 70% of the promised speed you are doing well.

The upload speed will always be lower and may be as little as 10% of the download speed on a domestic service. In Figure 6B, the numbers represent a more than adequate speed for the home office with a minimum 10 Mbps for download and 2 Mbps for upload speeds. Gamers look for the lowest "ping" value possible – the example shown is perfect for the gamers in your home.

If your reported speed is much lower than expected when you are using Ethernet direct to the hub, you should first restart the hub. If that doesn't help, you need to contact your internet service provider as the issue will be with your service.

If your reported speed is low when using Wi-Fi, try again using a device very close to the hub. If this improves the speed, the issue is caused by either Wi-Fi signal strength or interference. Signal strength is easy to check – if you don't get full Wi-Fi bars on your device, either add a Wi-Fi booster or move the hub closer to where you work.

Selecting the optimum channel

Interference to the signal is trickier to check as it is caused by interference from networks in neighbouring premises. This can be particularly troublesome if you live in an apartment with many neighbours.

The Wi-Fi system has several channels and on checking you might find your signal strength

> As a rule of thumb, if you are getting around 70% of the promised speed you are doing well.

Figure 2. RJ45 Ethernet sockets

Figure 3. Power line adapters

Figure 4. Five port gigabit Ethernet network switch
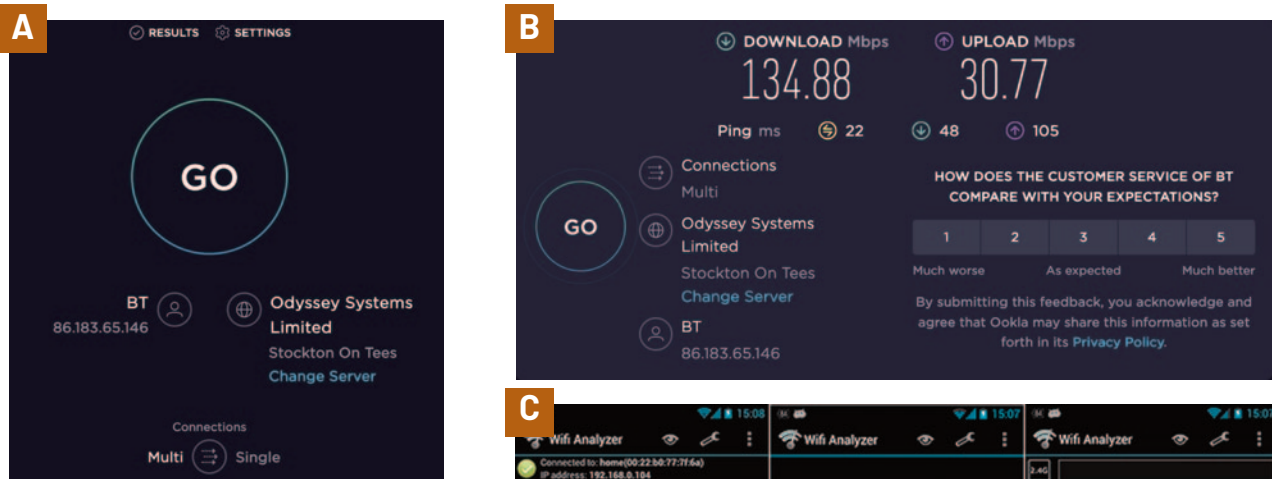

Figure 5. Wi-Fi booster

Figure 6. SPEEDTEST home page
(A) SPEEDTEST home page.
(B) Example results.
(C) Windows Wi-Fi analyser report
(https://www.netspotapp.com/wifi-analyzer)

looks good. However, if you and your neighbour are using the same channel this will cause conflict resulting in slow speeds. You can check for this problem using a Wi-Fi analyser app. These are available for Android and Windows devices, and many are free.

As a recommendation, the Windows Wi-Fi Analyser is a free and easy to use tool and works on Android as well as Windows. Once installed, run a scan and you should see a report like that shown in Figure 6C. Other options are available for MacBook users and can be found from the link provided.

The centre pane shows the signal strength and is self-explanatory – more is better. The left pane shows networks with a signal in your room and the right pane shows the channel that each network is on.

Your network should be the strongest signal that you see, and the trick is to be on a clear channel with as little overlap as possible. Remember that there are often two Wi-Fi

networks, 2.4 GHz and 5 GHz. Switch between the two at the top of the right pane.

To change your channel, you will need to access your hub settings. This is done by opening a web browser and entering the hub IP address, which you should find on a sticker on the hub or in the user manual. When entering the address, note that it is a series of digits such as 192.168.0.1; do not prefix with www or https. You will also need the username and password supplied with your hub. Also, while you are in the settings, change the password to prevent hacking.

Summary

Getting the best from your internet connection can take some time and effort, but once it's optimised you will be rewarded with clear and smooth video calls, as well as speedy web

browsing and downloading. Importantly, you will be confident that you can provide a professional service for your clients with no freezing images or broken audio during your calls. Remember, moving to a clear channel can make a huge difference to Wi-Fi performance and it's well worth spending some time to optimise the signal.

Disclaimer

Content is based on observations in the UK through experience only and not specialist expertise. Although similar practices are assumed in Europe, there may be some differences regarding cost and infrastructure.

Disclosures and conflicts of interest

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Author information

Allison Kirsop, PhD, is a medical writer and founder of Scientific Writers Ltd., UK – a boutique MedComms agency specialising in medical education and writing support for the life sciences industry.
https://scholar.google.com/citations?user=mwnrRbQAAAAJ&hl=en

Peter Kirsop, PhD, is a senior lecturer at School of Chemistry, The University of Edinburgh, UK with research interests in radical chemistry and developing new strategies for effective learning.
https://scholar.google.co.uk/citations?user=1NoqoX4AAAAJ&hl=en

Remote meetings made easy: Good practices to keep in mind

Tiago Silva, **Catarina Silva**, **Tiago Campos**,
Maria Mascarenhas

Trilogy Writing and Consulting, Frankfurt,
Germany

Correspondence to:

Tiago Silva
tiago.silva@trilogywriting.com

Abstract

One core medical writing skill is effectively
communicating with the teams that will help
us author our documents. With remote
working playing an increasingly important
role in our workforce, medical writers must
adapt to this new reality. This article offers
guidance for medical writers to run effective
remote meetings, including a checklist with
suggestions of what to do before, during, and
after these calls.

Introduction

Medical writing is a collaborative effort.
Many of the documents we write require
cross-functional input and discussion and, thus,
medical writers need to be comfortable with
leading and managing a variety of multi-
disciplinary meetings on a regular basis,
including kick-off meetings, discussion of pend-
ing or conflicting input, alignment of key
messages, among others. Moreover, medical
writers often work with teams located all over the
world, and it may not be realistic to conduct all
meetings face to face. It is, therefore, not merely
a convenience, but a necessity, for medical writers
to be comfortable with leading remote meetings
to effectively communicate with the team
supporting the development of their documents.
Fortunately, the recent development of fast and
reliable remote communication, screensharing,
and filesharing methods (now speeded up by the
COVID-19 pandemic) has allowed for a lot of
work to be done quickly, efficiently, and remotely.

Nevertheless, leading such meetings can be
an intimidating experience, even for seasoned
writers, so proper planning is key to make this a
smoother experience. This article includes several
suggestions on how to efficiently prepare,
conduct, and follow up on remote meetings.

Before the meeting

Effective meeting preparation will help not only
the medical writer, but the whole team, allowing
everyone to align on expectations, to organize,
and to ensure a productive discussion. A list of
suggested steps to prepare a successful meeting
is shown in Table 1.

One way to ensure successful planning is to
adapt the technique of 5Ws 1H to this task: *who,
when, what, why, where, and how.*

Who and when

It is important to identify which attendees are
essential for each meeting, so that the relevant
team functions for a particular agenda are
present. Furthermore, the decision maker(s)
should be identified for each meeting and their
attendance guaranteed, as they are key to the
resolution of any conflicts and can provide
direction to the other attendees.

It is also important to confirm which virtual
platform should be used in case you are meeting
with external personnel (e.g. contractor writer
meeting with a sponsor team). If possible, the
sponsor's platform of choice should be used.

What and why

When planning a meeting, first consider its
scope. It is important to confirm
which discussion topics require a
meeting, and which can be resolved
via a different method (e.g. email).
A meeting may not be the most
efficient solution to every problem,
and an excessive number of meetings
can be difficult to manage and attend.
Prepare an agenda that clarifies the
scope of the meeting, the topics that
are going to be discussed, and what
is expected of you (the medical
writer) and of the other team
members. These topics vary depend-
ing on the type of meeting taking place, but here
are some common items addressed in typical
medical writing meetings:

- Kick-off meetings:
  - The scope of work
  - The team and roles/expectations for
    each member
  - How the document will be drafted,
    reviewed, approved, and published
  - How the medical writer will communi-
    cate and collaborate with the team
  - Timelines

- Comment resolution meetings:
  - What are the comments that will require
    discussion (usually, comments that are
    considered major in relevance and
    require cross-functional discussion) and
    their order/priority?
  - Key line functions should be identified,
    and representatives should be considered
    mandatory attendees.

- Data interpretation meetings:
  - What are the key messages the docu-
    ment will communicate, based on the
    data available?
  - Key line functions should be identified,
    and representatives should be considered
    mandatory attendees.

Make sure you allot sufficient time to discuss all
the topics planned for the meeting, that the team
is available during this time, and that the planned
overall duration of the meeting is appropriate for
its scope. If a given line function can only attend
part of the meeting, consider
addressing specific topics that
require their input while the
function expert is available.

> If a given line
> function can only
> attend part of the
> meeting, consider
> addressing
> specific topics that
> require their input
> while the function
> expert is available.

Where and how

Based on the team list and
their availability, the selected
virtual platform, and with a
meeting agenda and time plan
ready, you can now schedule
the call with the team. When
preparing an email invitation,
make sure the virtual platform
link is clearly visible, and important instructions
for successfully logging in are shown. Keep track
of who accepted and declined the call and make

sure mandatory attendees (or assigned backups) confirm their presence.

Other actions to take when preparing a call
On the day of the call, make sure you have the right environment and technical conditions to run the meeting, and aim to remove or mitigate any potential sources of distraction, as much as possible (detail in Table 1).

During the meeting

As a medical writer collaborating with sponsor teams, you will likely be the lead for document-based meetings. Therefore, the other participants will rely on you to follow the agenda, initiate, and mediate the discussion.

A list of suggested steps to keep in mind while leading a meeting is presented in Table 2. In addition, there are some key ideas on how to maintain the discussion flow:

1. **Set the rules:** During your presentation, be clear about your role in the meeting and how everyone should participate in the discussion. Throughout the meeting, continue to guide the team and ensure that they are kept on-topic.
2. **Be diplomatic:** Not all teams are aligned in their strategy and there may be different opinions on how to approach one question. If you are leading the group discussion, make sure you deal with these differences sensibly and effectively towards a common strategy. Use your knowledge of the project and judgment to engage the team in productive discussions.
3. **Be proactive:** Medical writers are experts in communication and in creating documents that are fit for purpose. You can propose solutions to conflicting comments or advise the team on the best approach to develop a document. A proactive attitude is appreciated and helps develop a trusting working relationship with your team.
4. **Appreciate the team's time and effort:** Do not forget to thank the team for their time and shared knowledge during the meeting. As part of a collaborative project, ensure that everyone is comfortable with the key decisions and resolutions, and make yourself available to clarify any additional queries, if needed.

The business etiquette of face-to-face meetings still applies in a remote meeting. Professional demeanour should be kept by all attendees, and interruptions or disrupting behaviour should be avoided. When leading remote meetings, it is important to establish and maintain a productive and efficient discussion.

Remember that, as a medical writer, you are primarily a communicator. Leading remote meetings with experts from different areas and backgrounds can be challenging, even for experienced medical writers. To be successful, you need to ensure you communicate your message in a clear, assertive, and respectful way.

After the meeting

A list of suggested steps to keep in mind after you lead a meeting is presented in Table 3.

The most important action to take after a meeting is to write down and share a summary of what has been discussed, including:
- Items that have been resolved, i.e. decisions.
- Action points, i.e. what needs to be followed up by attendees (and how).

This information should be shared with the team as soon as possible after the meeting, to ensure that all relevant team members are aligned, and pending items are resolved efficiently.

Table 1. Checklist: What to do before a remote meeting

Actions to take **BEFORE** starting the meeting   Check   Check

		Check		Check
Establish key contact(s) from the individuals outside your organisation who are expected to attend	If applicable, establish contact with a key person who will help you obtain the list of attendees, possible times for the call, and help following up in case mandatory attendees are unavailable to attend the meeting or miss it.	☐	Propose a day(s)/time(s) for the meeting (if not already set by project timelines).	☐
			Confirm virtual platform that will be used, and that all attendees (including the organiser, if applicable) have access and are able to use it.	☐
	Obtain a list of attendees: for each attendee, request name, email contact, line function, time zone, and confirm if mandatory/optional attendance. • If applicable, identify key decision makers, who will be key to the resolution of conflicts, depending on their field of expertise.	☐	If you plan to record the meeting, inform the key contact(s) in advance.	☐
Prepare meeting agenda	Define meeting rationale, objective, and list of topics by order of discussion.	☐	Establish a meeting duration that allows for all topics in the agenda to be discussed, or split the agenda across more than one meeting, if necessary.	☐
	If multiple topics, recommended to set a duration for each. For longer meetings, include breaks in the agenda. • It is recommended to reserve more time for topics that expect a cross-functional discussion, while straightforward sections can be streamlined.	☐		
Schedule the meeting	If you have access to the attendees' schedules, use it to schedule the meeting in the best possible time, keeping in mind different time zones and key attendees.	☐	Keep track of the attendees who accepted the meeting. If a mandatory attendee declines, confirm if a backup can attend on their behalf.	☐
	In the invitation, include the meeting agenda and the link to access the meeting, along with relevant instructions.	☐		
Prepare your room and space	Ensure you are in a calm environment, properly lit, silent, and with an appropriate background (you can virtually change your background in several platforms).	☐	Open and prepare all relevant documents so that you do not waste time during the meeting searching for those items.	☐
	Dress appropriately for the meeting.	☐	If you are screensharing, clean your desktop and only leave documents and applications relevant to the meeting open. Do not show any out-of-scope materials to avoid inadvertent disclosure of information.	☐
	Avoid having items near you that may be distracting (e.g. mobile phone).	☐		
	If possible, have a colleague take notes for you in addition to your notes.	☐		
Perform a test meeting (if necessary)	Check if your microphone and webcam work properly.	☐	If the platform is new to you, reserve some time before the meeting to understand how it works (e.g. muting options, screensharing, accepting attendees, recording).	☐

Table 2. Checklist: What to do during a remote meeting

Actions to take DURING the meeting		Check		Check
Present yourself properly	Be punctual and stick to the planned time.	☐	Speak slowly, cordially, and assertively. Use the mute function when you are not actively speaking.	☐
	Turn on your webcam meeting and speak to the camera. It is important to position the webcam properly to ensure your face is adequately captured.	☐	Avoid eating or using distracting objects (e.g. pen clicking).	☐
Initiate the meeting	You can leave some time to let the attendees join.	☐	If the meeting is intended to be recorded, inform the attendees before you start recording.	☐
	Make sure key attendees are present and follow-up if not.	☐	Introduce yourself and present the objective of the meeting and the topics that will be discussed. You can share the agenda, even if you have sent it to the attendees before. If applicable, the planned duration for each topic should also be shared and tracked during the meeting.	☐
	For large meetings (>10 attendees), you can mute the attendees when they join, to avoid excessive noise.	☐		
Establish discussion flow	If you are leading a presentation: set up periods for group discussion.	☐	Ideally, take notes of the discussion and conclusions reached in full view of the group.	☐
	If possible, have someone else at the meeting to keep track of the questions/suggestions written in the platform chat.	☐	If an answer/consensus cannot be reached during the meeting: • If a decision maker is identified, request their final decision on the topic. • If no decision maker is identified, offer to follow up after the meeting, and move on to the next topic.	☐
	When leading a meeting that requires group discussion: moderate the discussion, ensuring it does not go off topic and sticks to the planned timing. Once a resolution is met, reiterate the decision to the attendees to make sure it was well understood.	☐		
Keep track of attendees	Some platforms capture the attendees who join the meeting. If not, keep track of the attendees manually.	☐		
Wrap up the meeting	Summarise the key conclusions or resolutions agreed to during the meeting.	☐	Summarise next steps, if applicable.	☐
	Summarise any items that require follow-up outside the meeting, and if relevant, how they will be resolved (e.g. second meeting, email).	☐	Confirm if there are no additional questions from the group.	☐
			Thank the attendees for their contribution.	☐

Table 3. Checklist: What to do after a remote meeting

Actions to take **AFTER** the meeting		Check		Check
Write and share the meeting summary/minutes	Confirm with the team the best way to share the summary of discussion. Formal meeting minutes may not be necessary, but written summaries are important to keep track of the discussion, allow attendees who could not attend to catch up, and ensure alignment	☐	Summarise any action items to follow-up after the meeting and if relevant, how they will be resolved (e.g. additional meeting, email) and highlight any action items for specific attendees. If an additional meeting is required, set it up after sharing the minutes.	☐
	Summarise in writing the discussion by topics and any high-level conclusions/resolutions reached.	☐	Share the meeting summary/minutes with the attendees.	☐

You can choose the most appropriate way to share this summary (from an informal email to formal meeting minutes), based on the type of meeting and any arrangements agreed with the team.

Summary

Leading meetings with cross-functional teams is routine for a medical writer. Doing this remotely can be challenging and stressful, but with proper planning, even the most complex meetings can be run effectively.

Our skills as communicators must shine through, even remotely, and medical writers can bring much value to the team discussions through moderation as well as consulting as medical writers can offer advice and guidance to resolve comments and propose solutions that will improve the quality of the documents being written.

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

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The authors declare no conflicts of interest.

Further reading

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Author information

Tiago Silva, MSc, has over 10 years of regulatory medical writing experience in the pharmaceutical industry. He is also the current vice president of the executive committee of the Portuguese Medical Writers Association.

Tiago Campos, MSc, has approximately 10 years of medical writing experience in both regulatory projects and medical communications. Tiago has led remote meetings with large cross-functional teams spread across multiple regions.

Catarina Silva, PhD, is a pharmacist and has worked in the medical writing field for over 6 years. She is currently a medical writer at Trilogy Writing & Consulting, working on clinical regulatory projects. She is also a member of the Portuguese Medical Writers Association.

Maria Mascarenhas, PhD, started her career as a medical writer in the pharmaceutical industry after receiving her PhD in Haematology. Maria has been involved in preparing a large range of clinical regulatory documents, including writing and leading large multi-sponsor submissions with highly complex cross-functional teams.

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Leading a team virtually: A manager's perspective

Shima Shaikh[1], **Sapna Chhabra**[2],
Ashwini Somayaji[3]

1 Medical Writing Services, Parexel International, Hyderabad, India
2 Medical Writing Services, Parexel International, Chandigarh, India
3 Medical Writing Services, Parexel International, Bengaluru, India

Correspondence to:
Ashwini Somayaji
ashwini.somayaji@parexel.com

Abstract

Remote working is the new normal since the COVID-19 pandemic, so learning to lead a virtual team successfully is now an essential core competency for organisational leaders. The transition from co-located teams to virtual teams has benefitted leaders by facilitating hiring of diverse talent from different geographical locations and led to increased employee contentment due to flexible working hours, increased autonomy, and freedom to relocate. However, leading virtual teams creates challenges for leaders, such as employee engagement in the absence of face-to-face conversations, workplace isolation, and team cohesion. Overcoming these challenges will be crucial for leaders to be successful in the future. This article presents an overview of the advantages, challenges, and approaches to overcome the challenges in the virtual environment.
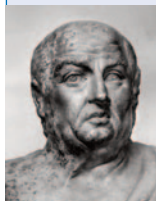
> **"Fire is the test of gold, adversity, of strong people."**
> *Seneca*

With the emergence of digital and broadband internet, working from home became more common in the 2000s.[1] During the COVID-19 pandemic, many workers were advised to work remotely full time. This had previously been allowed only for certain types of work, on an occasional basis, or as a result of unique circumstances.[2]

The characteristics of a virtual workplace change the ways teams work together and pose unique challenges for virtual leaders.[3] A cross-sectional study conducted in 2021 suggested that, to enable satisfying and efficient virtual collaboration, the leader's central task was to establish a feeling of "us".[4] The study also provided direct evidence of the importance of the leader's role in creating a shared social identity in virtual teams.

This article explores the advantages and challenges of leading a virtual team and provides approaches to overcome these challenges.

> **"Every cloud has a silver lining."**
> *John Milton*

The initial apprehension about remote working due to the COVID-19 pandemic faded over time, and teams adjusted to a new normal. As the pandemic wore on, the advantages of leading a virtual team became more apparent. Leaders soon acknowledged that virtual teams could be just as productive as office-based teams. A number of other advantages emerged.

A key benefit of working virtually is that leaders are able to hire diverse talent from different geographical locations, cultures, backgrounds, and expertise, all of whom come together to work toward a common goal. Working in global teams also facilitates the "follow the sun" approach for critical deliverables in which issues can be handled by and passed between offices in different time zones, increasing responsiveness and reducing delays.

Another key benefit is that team members no longer need to commute to work. This saves time, which team members can spend with their loved ones, maintaining a healthy lifestyle, pursuing their hobbies, and other activities. A healthy and happy team member is a great asset to the company.

Further, team members who were previously unable to relocate for family reasons, physical challenges, or other commitments have new opportunities. For example, team members from crowded cities can move to the suburban or rural environments, improving their quality of life and, often, reducing their cost of living. This has improved job satisfaction, which in turn has helped make obtaining a work-life balance easier.

Many companies believe that remote working is here to stay.

Virtual teams also enjoy more autonomy than office-based teams because employees have more control over their work and personal lives. They have the freedom to plan their day around meetings and other work commitments and can choose to work during their most productive hours. This motivates and empowers them to be more responsible and committed, which leads to better engagement and performance.

Working virtually is associated with reduced or no commute time, lower frequency of work breaks, fewer reported sick days, and a quieter work environment, all of which can enhance productivity. A study by Stanford University showed that employees who worked from home were 17% more productive (almost a full day per week), had over 50% lower job attrition rates, worked harder, and were happier overall,[5] indicating that the factors and benefits associated with working virtually can add to employee happiness and reduce attrition.

> **"A smooth sea never made a skilled sailor."**
> *Franklin D Roosevelt*

According to the 2021 CEO Benchmarking Report,[6] 51% of chief executive officers identified "working well remotely" as a top challenge for their teams. As we navigated the virtual work environment during the pandemic, which extended from days to months and months to years, the real

challenges of leading virtual teams began to surface, and companies began to recognise that these are challenges leaders will continue to face. Communication gaps and lack of connection between leaders and their teams risked relationships and job satisfaction for both parties. Many of us were forced to socially isolate, and team cohesion seemed to erode. Leaders needed to be innovative to bring opportunities for the teams to connect better with their colleagues within and outside of specific departments, create an environment of empathy, and support work and knowledge sharing by team members.

Trust was a key aspect of work that was challenged by the new way of working. Trust amongst team members and between team members and leaders is important in creating a seamless work setting. Trust drives accountability at both ends and creates a safe space for open communication. The change from the physical to a virtual workspace momentarily jolted this setting which led to distrust between a leader and team members. Intrusive leaders that do not respect team members' privacy and off-hours work contributes to work stress.[7]

Another challenge of working virtually that emerged was an increased risk of burnout. A 2020 survey found that remote workers were burdened by having to help children with school activities and contribute to household chores.[2] Lines between work and family life became blurred, which was a significant contributor to "The Great Resignation of 2021".[8]

Communicating virtually presented a challenge because body language, an important part of communication, is frequently lost. The virtual mode of communication restricted the opportunities for managers to read the emotions of their direct reports, especially those who are not outspoken or do not easily verbalise their needs and aspirations.

The pandemic and working virtually also added to workplace isolation when employees missed out on opportunities to engage in developmental activities at work. This contributed to declining work satisfaction and increased stress, both of which affected the mental health.[9]

Onboarding and training periods lay the foundation for the satisfaction and future aspirations of employees and are critical in setting expectations. Working virtually created a challenge of creating human connections and opportunities for the new hires to get to know their colleagues and organisation.

> **"Being challenged in life is inevitable, being defeated is optional."**
> *Roger Crawford*

Every leader has their unique leadership style and ways of overcoming the challenges of virtual leadership. Below, we discuss a few approaches that can help.

Robust communication
Communication in the virtual world sometimes can be challenging due to technical faults and other unintentional disturbances of various kinds; robust communication is communication that can withstand these disturbances. It is one of the most powerful tools of leadership but ensuring it can be challenging in a virtual environment. We live in a virtual world with remarkable technologies that can help fill the

Table 1. Challenges of working in a virtual environment and suggestions to mitigate them

Challenges	Mitigation
Communication gaps between a leader and team members; within teams	Robust communication with the help of technologies
Increased risk of burnout	Offer flexible working hours and encourage team members to take regular out-of-office breaks
Employee engagement	Regular check-ins, continuous motivation, appreciation, and collecting feedback
Workplace isolation and mental health	Virtual team building activities; casual call and lunch invite; empathetic and flexible leadership
Virtual onboarding and training	Well-structured trainings and workshop; casual virtual chats with new hires; introduction to team

communication gaps between a team and its leader.

To address this challenge in a virtual setting, leaders can make themselves accessible through various channels such as emails, instant messaging, audio/video chats, regular team meetings, and a virtual open-door policy. The leader's quick responses to messages can help build confidence and trust and avoid communication breakdowns. Arranging virtual meetings, such as virtual coffee breaks, happy hours, birthday celebrations, and storytelling, can help build a close-knit team. Video calls are a necessary substitute for face-to-face meetings, and casual quick chats or calls can help foster personal connections and improve employee engagement.

Employee engagement

Employee engagement in a virtual environment may require additional effort, especially for reclusive team members. Regular check-ins, continuous motivation, and appreciation can confer a feeling of belonging to team members. Collecting feedback from team members in virtual meetings is also vital and empowers team members to speak up. A study of 208 virtual employees found that key factors affecting engagement in a virtual environment include regular contact with top management, adequate virtual training, improved tools for virtual work

> Although working virtually expanded talent pool across cities and towns, it was also accompanied by the challenges of virtual onboarding and virtual training.

(e.g. a stable, high-speed internet connection and the smooth functioning of personal computers).[10]

Onboarding a new hire and settling them within the team can also be difficult for a leader in a virtual environment. To help new virtual employees fit in with the team, leaders can:

● Use virtual chats to get to know new members personally and professionally. However, leaders should remember that not everyone is comfortable working in a virtual environment, so to help put new employees at ease, they should be patient and cautious.
● Help introduce new team members and help them settle in with the rest of the team
● Build trust and respect within virtual teams by rotating responsibilities for chairing virtual team meetings, sharing best practices, and telling personal stories
● Offer dinner or lunch vouchers to team members and their families.

Team cohesion

Team cohesion and building mutual respect among team members in a virtual environment

> Working in a virtual environment has created benefits and challenges for leaders.

can be challenging for a leader. The pandemic has forced leaders to be extremely creative, and virtual team building games like Bingo, Trivia, and Pictionary can be used as fun events to help build team cohesion.

Conducting productive virtual team meetings and workshops or training can also be challenging. This can be mitigated by planning well-structured meetings with clear goals and schedules; tailoring expectations to the team members' experience and knowledge; and adapting dates and times of meetings so that they respect the different geographical locations of their team members.

A further challenge to team cohesion in a virtual environment is isolation, which can lead to feelings of loneliness and disconnection and can distract employees from their work. Leaders need to be empathetic and encourage team members to take regular out-of-office breaks or offer some flexibility to avoid burnout. Even a simple call or a casual lunch invite can reduce feelings of isolation.

Conclusions

Benefits of remote work include access to an expanded talent pool across different geographies; increased productivity due to improved employee satisfaction resulting from increased autonomy, more flexible schedules, increased time for family derived from not having to

commute; and an overall better work-life balance. These benefits can add to employee engagement and satisfaction and help reduce turnover.

Challenges of working in a virtual environment include erosion of trust between leaders and team members, reduced employee engagement, and reduced team cohesion. The challenges can be mitigated by ensuring robust communication and by implementing new communication technologies (Table 1). For example, increased accessibility to a leader via new communication technologies can add to a feeling of "us" and can help build trust, respect, and bonding with the leader.

In this new paradigm, for companies to move forward, effective virtual leadership is needed. A good leader thinks, "Either I will find a way or make one" – the challenges of working virtually can be overcome by thinking intelligently, putting in additional effort, and trying new approaches.

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Author information
Dr Shima Shaikh has more than 10 years of experience in regulatory medical writing. She leads a medical writing group at Parexel. She has extensive experience in authoring clinical documents including clinical summaries and overview.

Sapna Chhabra has over 10 years of experience in the pharmacovigilance industry including 8.5 years of experience in medical writing. She is a subject matter expert in PADERs. She has a strong background in safety report writing and leads the medical writing group at Parexel.

Ashwini Somayaji has over 10 years of experience in the live science industry including 6 years of experience in medical writing. She is a subject matter expert in safety narratives and has ample experience in authoring clinical documents including protocols, informed consents, and clinical study reports. She leads a medical writing group at Parexel.

Growing a remote medical writing business: Two perspectives

Lesley Taylor[1], Bilal Bham[2]

1 Alchemy Medical Writing Ltd, Stirling, United Kingdom
2 Bham Pharma Ltd, Preston, United Kingdom

Correspondence to:

Bilal Bham
bilal@bhampharma.com

Abstract

Deciding to grow your own remote medical writing business can be daunting. In this article Lesley and Bilal, who each own and manage independent medical writing agencies, share how they founded and grew their businesses.

Lesley's story:

In a previous article in *Medical Writing*[1], I wrote about how I became a freelance medical writer. Things have rapidly evolved since then, and here I share about how I grew Alchemy Medical Writing into a small agency with 9 employees.

I went out on my own for two reasons: I knew there was space in the market, and I wanted to be the master of my own destiny. Within a year, customer demands outweighed capacity, so around 18 months after founding the business I hired my first employee. As everything was new to me and to keep the financial risks low, I employed an entry-level writer, Melissa Tombs (Mel) who was referred by Bilal. I decided Mel was a good fit as she wrote a great cover letter and displayed bags of enthusiasm. My instinct was right; Mel is a great person and has grown into a fantastic medical writer. Within another 2 months, my husband Adam Taylor (who is also a medical writer) joined me as a business partner. As Adam and I still do a lot of project work, we brought in a part-time project coordinator to help with administrative tasks and to liaise with clients. This has since grown into a full-time role we cannot do without.

From there we gradually expanded the business in line with increasing demand, employing a mixture of entry-level and experienced writers. We mainly support larger agencies but also work directly with a few pharmaceutical companies. A lot of our business comes from referrals, for example, former colleagues or clients that have moved on to new companies. Networking on LinkedIn has also been invaluable.

As Adam and I both worked as in-house medical writers before, we know how demanding the role can be, so we try to create a great company culture. We support diversity and inclusion, foster a good work-life balance, and care about people inside and outside of the company, as well as the environment. Some of the ways we do this are by accepting our teams' unique abilities and limitations, offsetting our carbon, having a no-overtime policy, having regular mental health catch-ups, rewarding staff with bonuses, perks, and fun activities, and by donating to charity. Often our charity events involve team members participating in physical activity campaigns, serving the dual purpose of also improving their wellbeing. Our plan is to remain a small close-knit team that works and plays well together going forward.

I have found that there are many upsides to expanding the business: getting to work with and learn from others, seeing the team grow in experience and confidence, receiving great feedback from clients, and increasing financial security. But everything is not smooth sailing 100% of the time. Running a business with employees is a big responsibility and a lot of work. It is also hard to fully switch off, unless the whole company closes (for example, over Christmas).

For anyone considering growing their business, here is my advice: You'll need to learn how to strike the balance between making sure there is enough work coming in – but not too much! A team is

> I have found that there are many upsides to expanding the business: getting to work with and learn from others, seeing the team grow in experience and confidence, receiving great feedback from clients, and increasing financial security.

also only as strong as its individual members, so remember to spend enough time considering the training, development, mentoring, and communication styles of individuals, in addition to their project preferences. When they thrive, the team does too.

Policies, insurance, human resource (HR) management, equipment, interviews, and contracts are the necessities of running a business and delegation is key here to ensure important details aren't missed. Our project manager handles a lot of the administrative tasks, ensuring the cogs keep turning.

How to bring the team together, structure your business, be fair to everyone's preferences, and determine what perks you will offer are all rewarding facets to work on. You must also be prepared to have difficult conversations with both clients and employees and have a plan of action as to how you will handle it when something goes wrong.

Tackling all this whilst also doing project work, liaising with clients, and doing the usual business administration can lengthen the to-do list. To relieve some of these pressures, we outsource functions like HR, accounting, and technology support; I would recommend doing this to all new agencies. In terms of where to start, I found it helpful to reach out to owners of similar companies to ask questions. You also grow to learn that, to some extent, we are all flying by the seat of our pants!

As we are a remote company, staying in touch is also a big consideration that influences all our tasks. At Alchemy, we stay in touch over Microsoft Teams. We have an open "coffee chat" to say hello, catch up, share GIFs and Netflix recommendations. We also have a "Q&A chat" where we ask for help with understanding briefs, acronyms, technical issues, or to offer support if we have time available. Personally, I love seeing the team collaborate over the Q&A chat. Their willingness to support each

other lets me know that we have a great team spirit. We also have a weekly catch-up call where we share news, recognition, any woes, and what everyone is doing in the coming week. Finally, we like to get together for virtual and in-person events. This year we will be catching up in Scotland for some Escape Room action, quizzes, a castle tour, and some great food.

So, if you are thinking about expanding your freelance business, there is a lot to consider. If I could start over, would I do it again? Definitely.

Bilal's story:

M y story of growing Bham Pharma Ltd is similar to Lesley's, although I took longer to get there! As I wrote in previous articles in *Medical Writing*,[2,3] I began as a freelancer back in 2011 for several reasons: I had been made redundant twice in 9 months in 2 different countries; I moved back to the UK to be with my mother after my dad passed away, and so moving for a new job wasn't an option; commuting 3 hours each day was unpalatable; and I had always wanted to be my own boss.

In terms of how I run my business, it is pretty much identical to Lesley's, so I won't repeat all of that, but I will share some key lessons. Echoing Lesley's journey, I had more projects coming in

than I could handle alone, so I began hiring. (I now have 15 team members.) I also started strategising and building the foundations of my business to support both the regulatory and medical communications pillars with experienced team members. Initially, we were top heavy, with more experienced team members, and then in came an intern, Emmaline Tregembo, with whom I wrote a blog;[4] thus began the mixing of experience and inexperience. My goal has always been to build a robust business where we can take experienced writers and newbies and train them into not only world-class medical writers but leaders. We focus not only on medical writing training but also personal growth and development, helping to fast-track the success of my team if they are up for it.

I have read, watched, listened to, and been mentored by highly successful business owners, and I have tried to incorporate their help and advice when and where appropriate.[5] I have delegated as much as I can, empowering my leaders to run teams as per their vision, with me being there to help and oversee things as necessary, and being the key decision maker when needed. I have tried to spend more time working on my business than in it, but workload pulls me back into projects, in which case I work

under my medcomms and regulatory writing managers. However, I am still the only salesperson, and I oversee marketing and social media activities, which are run by my team.

I have tried to take a relaxed but professional approach within my team, and in general, it seems to be working. Nothing is perfect, and we have our ups and downs, but I have tried to foster an atmosphere of high quality, team ethic, openness, honesty, and above all, fun and enjoyment. Microsoft Teams has been vital to us creating that close-knit team spirit, and we have great camaraderie amongst us. Currently, I am the only man in a company of women, and that has been because the best candidates were women, and because of our focus on women's health. I have always wanted to run a thriving, successful, inclusive, international, rewarding, interesting, and fun organisation. Work is important, but so is the relaxation aspect. Unless absolutely necessary, I ensure no one is on Teams after 6 pm, and recently, we switched to a 4.5-day working week, so we are finished for the week by 1pm on Fridays. I endeavour to always listen to my team, especially my leaders, and make changes as swiftly as possible. Switching to a 4.5-day week (we still work 37.5 hours) came about from a conversation at 10 am, and by 1pm, we had

spoken to the team and our HR company, and started a trial period, which was successful.

I want my team to love what they do, and having a healthy work-life balance is crucial for achieving this. Ensuring my team take all 25 days of their annual leave plus public holidays is important – to refresh, reenergise, and prevent burnout. I check in with everyone at least once a week to see if they are happy and content and help where I can if there are any issues, even personal ones. I want my team to know that I am always there for them. Our HR company also has monthly check-ins with every team member where they can discuss anything openly. Providing that unwavering support is key for me. As a leader, I have always endeavoured to be the boss and mentor I never had. Of course, I learned from my previous bosses, but I had my own ideas on running teams and organisations, which I am building upon now.

As we work remotely, I also want to get my entire team together, all expenses paid, at least twice a year. Before the COVID-19 pandemic, we did this regularly, and then in April 2022, I took all of us on an all-expenses paid trip to a spa weekend in the Lake District, which was wonderful. We relaxed, enjoyed good food and drink, got to know each other better, and made and strengthened bonds, which helped our team get a better understanding of each other. I don't believe in corporate teambuilding activities, but I do believe in relaxing in each other's company and getting to know each other. The only rule I put in place for that weekend was: No talking projects!

> As a leader, I have always endeavoured to be the boss and mentor I never had.

I echo Lesley's advice to new business owners and add the following points:

- Treat business as what it is – a business. We all win work (sales), we all do the work (delivery), and we all get paid for it (invoice). And then come the financial and legal aspects of having good accountants and HR companies in place.
- Focus on growing yourself. Personal growth and development are absolutely necessary; just being a great medical writer is not enough. Stresses and challenges come to you via conveyor belt on a daily basis, so you must be strong enough to handle them.

- Be flexible, firm, but fair. You know your business and you know what you want, but this isn't a dictatorship, so be prepared to change and adapt, and respond to business needs swiftly and efficiently. It could save you a lot of time and make you a lot of money.

Moving from freelancer to business owner and employer is a big step, but nothing ventured, nothing gained!

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Author information
Lesley Taylor has been a medical writer for over 10 years. She worked as an in-house regulatory writer at GW Pharmaceuticals Ltd for 7 years, mostly recently as a clinical pharmacology medical writing lead. Lesley founded Alchemy Medical Writing Ltd, a medical communications agency, in 2018.

Bilal Bham has been a medical writer for 16 years. He worked as a regulatory medical writer in Frankfurt am Main, Germany, at what was Accovion, (now Clinipace), moved to Sanofi, (also in Frankfurt am Main), then moved back to the UK for a role at a biotech company, Renovo, in Manchester. Bilal founded Bham Pharma Ltd in 2011, initially freelance, before moving to a medical writing consultancy model from 2018 onwards.

The June 2023 edition

Freelancing

Freelancing is becoming an increasingly popular option for medical writers and communicators, but it's not as straightforward as finding a few clients and getting paid. There's so much more involved. Freelancers are mini business owners and to be successful, you need a plethora of skills, be self-motivated, driven, and adaptable and take the highs with the lows. In this issue, the authors will discuss what options are out there for freelancers, how to get started, and all the challenges that you may come across. Freelancing can be a lucrative business but addressing all the factors is key to being successful.

Guest Editors: Laura Kehoe and Satyen Shenoy

Remote work do's and don'ts

Laura Tobias Prezado[1],
Ana Lucia Sobriera Fernandes[2]
1   Brinova Bioquimica LDA
2   Medpace, Inc.

Correspondence:
Laura Tobias Prezado
lauratobiasprezado@gmail.com

With the COVID pandemic, remote work is now part of our daily lives. It provides more flexibility to manage our jobs and the needs of our homelife, among other perks, but like a beautiful rose, it has thorns. Setting boundaries between home and work, staying productive, and feeling connected to colleagues, are just some of the challenges employers and employees have encountered.

While many medical writers worked remotely before COVID, it is now the "new normal" for many of us. Benefits have included eliminating commuting time and expense, and the cost of office apparel, lunches out, and other expenses. Of course, what's been lost has been the socialization, comraderie, and sense of teamwork that some people only feel when talking to colleagues face-to-face.

Over these 2 years, we've all learned a thing or two about making this set-up succeed. Below, we share some knowledge, the "do's and don'ts", if you will, of working at home for both employees and employers. Remote work, as we all know, is a situation that is clearly here to stay.

We hope these tips are helpful to you as we navigate this stay-at-home world.

For employees:

- First, get dressed every morning! It can help get you in the mindset of being "at the office" and ready to work.
- Establish a routine! Make time to have your morning rituals, whether it's having a cup of coffee, going to the gym, or doing yoga.
- If you can, establish a home office, a room (or spot) set aside just for work. It can help maintain a work-life balance.
- Organise your day by creating a to-do list of your daily tasks – keep it realistic!
- Use bright stationary, it can brighten your day.
- Have 15 minute breaks in the morning and the afternoon; it will increase your attention span in the long run.
- Be mindful of your visual health: invest in a large screen monitor if possible.
- Use your lunch break wisely as you would at the office, for a true break from your labour. Eating in front of your computer can become a bad habit!
- Obtain a quality office chair with lumbar support.
- Keep your personal phone in airplane mode to avoid distractions.
- If possible, have a computer for work and another for your personal life. Keep your work laptop in its designated "workspace" , so you don't see work emails at 10 P.M.
- Try to stick to a work schedule, to avoid overwork.
- Don't isolate yourself; have in-person conversations with colleagues or friends on a regular basis.
- If your boss holds a coffee break via Zoom, go for it! It's an important way to get to know your colleagues, and your boss.
- Talk to your peers about topics other than work, as you would in the office. Life goes on, and we are social creatures.
- Coordinate both your personal and your work life – make time for your family and friends. They are more important than ever!

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Author information

Laura Prezado has a bachelor's degree in biotechnology and a master's degree in biomedical medicine. She worked in the neurodegenerative field while doing her master's thesis and now works in the microbiology and chemistry field in a biochemical company.

Ana Fernandes is a former hospital pharmacy technician who decided it was about time for a career change. She is now a home-based clinical research associate. She has also studied Pharmaceutical Law and clinical trials monitoring.

For employers:

- Don't expect employees to work more than typical because of the "privilege" of working at home.
- Take the lead in establishing a daily schedule to avoid feelings of exploitation and exhaustion. Establish fixed working hour and mandatory breaks (for example, a lunch hour) to promote a healthy work environment.
- Maintain a record of your employees' work hours, and make sure that they are not overwhelmed and overworked.
- Supply your employees with the proper tools for remote work, be they computers, the proper online platforms, and/or a printer if needed.
- When possible, provide your employee with a budget to create a home office.
- Schedule one-on-one, weekly meetings with your team members to gauge the challenges/difficulties they may be having.
- During the week, arrange remote coffee breaks, get to know your team, and provide them space to know each other.
- Keep up to date on how to create a better environment for your workers – read articles and other sources of information.
- Support your employees and hear their needs.
- Be aware of any abuse that may take place via online forms of conversation, from WhatsApp to Google Meets, Microsoft teams, and Zoom.
- Don't forget about professional development: provide activities like work training or online presentations on different topics.
- If you see that your employee is struggling while working from home, if possible, provide them the opportunity to work from a co-workspace, with all the amenities.
- Don't text or send emails to your employees after working hours – they might feel obliged to respond.
- Listen to your employees' needs, but please, don't forget your own. Being an employer is challenging and stressful.

The September 2023 edition

Automation/Software

Streamlined complex medical report writing supported by artificial intelligence/machine learning is making its way into clinical regulatory writing. The medical writing automation's goal is to speed up and ease clinical development processes by reducing the time and cost involved in creating and keeping regulatory documents up to date. This issue will examine current issues, challenges, and opportunities towards human guided medical writing automation systems.

Guest Editors: Shiri Diskin and Daniela Kamir

News from the EMA

SECTION EDITOR

Section Editor:
Anuradha Alahari
Anuradha.Alahari@parexel.com

EMA contact:
Monika Benstetter
press@ema.europa.eu

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.

Facilitating global access to diabetes treatments for non-EU patients

April 22, 2022

E MA human medicines committee (CHMP) has given a recommendation for two diabetes mellitus treatments, Actrapid and Insulatard, for use outside the European Union (EU).

EMA is committed to supporting global regulatory capacity building and contributing to the protection and promotion of public health beyond the EU by assessing medicines for countries with limited regulatory resources. The two diabetes medicines were submitted to EMA under a regulatory procedure (Article 58 of Regulation (EC) No 726/2004) known as EU Medicines for all (EU-M4All).

This allows the Agency to assess the quality, safety and efficacy of medicines that address unmet medical needs or are of major public health interest for use outside the EU and give an opinion on their benefit-risk balance, taking into account the context of their use in target populations and any specific requirement in certain low- and middle-income countries outside the EU. Medicines submitted under this programme are assessed by EMA in collaboration with experts from the World Health Organisation (WHO) and the target countries. Any medicine assessed under this procedure must meet the same standards as medicines intended for EU citizens.

Actrapid and Insulatard are human insulins that have been centrally authorised in the EU since 2002. According to the EU marketing authorisation, unopened insulin products must be stored in a refrigerator (2–8°C). These strict storage conditions are difficult to adhere to when temperature conditions are challenging and access to refrigeration is limited, for example in countries experiencing conflict or a humanitarian emergency situation. This adds an extra burden to the care of diabetes patients who live under these conditions.

The company applied for an assessment of these two medicines with changed storage time, to include storage without refrigeration when used in countries outside the EU. Following the evaluation of stability data submitted by the company in support of their request, the CHMP concluded to allow storing the two insulin products at temperatures up to 30°C for a maximum of four weeks before they are taken into use or carried as a spare. This positive opinion by the CHMP paves the way towards increased access to treatment for diabetes patients worldwide.

Diabetes is a chronic disease in which the body does not produce enough insulin to control the blood glucose (type-1 diabetes) or when the body is unable to use insulin effectively (type-2 diabetes). Insulin is a hormone that regulates blood sugar. Raised blood sugar is a common effect of uncontrolled diabetes and over time leads to serious damage to many of the body's systems, causing blindness, kidney failure, heart attacks, stroke and lower limb amputation. Left untreated, type-1 diabetes can be a life-threatening condition. According to the WHO, in 2019 diabetes was the ninth leading cause of death with an estimated 1.5 million deaths directly caused by this disease. Prevalence has been rising more rapidly in low- and middle-income countries than in high-income countries.

Actrapid and Insulatard are the thirteenth and fourteenth medicines to receive an EMA recommendation under EU Medicines for all (EU-M4All). Experts from the WHO and regulators from Bangladesh, India, Iraq and Zambia were invited to follow the evaluation as observers. This helps to ensure that specific disease expertise and local knowledge are taken into account.

National regulators can use the CHMP's scientific assessment to decide on the use of these medicines in their countries.

Synchron Research Service: suspension of medicines over flawed studies

May 20, 2022

E MA's CHMP has recommended the suspension of the marketing authorisations of several generic medicines tested by Synchron Research Services, a contract research organisation (CRO) located in Ahmedabad, India.

The recommendation comes after irregularities were found in how the CRO carried out bioequivalence studies, which raised serious concerns about the company's quality management system and the reliability of data from that site. Bioequivalence studies are conducted to show that a generic medicine releases the same amount of active substance in the body as the reference medicine.

The CHMP looked at all medicines tested by Synchron Research Services on behalf of EU companies and found that for the majority (around 100 medicines) no adequate bioequivalence data were available from other sources. The Committee recommended that

these medicines be suspended. To lift the suspension, companies relying on data from Synchron Research Services must provide alternative data demonstrating bioequivalence. For a small number of authorised generic medicines (around 20), adequate bioequivalence data were available from other sources, and these medicines are allowed to remain on the EU market.

With just a couple of exceptions for which data from other sources are available, the majority of medicines that were being evaluated for authorisation on the basis of data from Synchron Research Services will not be granted authorisation in the EU. The list of concerned medicines can be found on the EMA website.

Some of the medicines that have been recommended for suspension may be of critical importance (e.g., due to lack of available alternatives) in a given EU Member State. Therefore, national authorities can temporarily

postpone the suspension in the interest of patients. Member States should also decide whether recalls of the affected medicines are needed in their territories.

EMA and national authorities will continue working closely together to ensure that studies on EU medicines are carried out to the highest standards and that companies comply with all aspects of good clinical practice (GCP). If companies do not meet required standards, authorities will take whatever measures necessary to ensure the integrity of data used to approve EU medicines.

The CHMP's recommendation will now be sent to the European Commission which will issue a legally binding decision in due course.

Information for patients and healthcare professionals:

- Several generic medicines have been suspended from the EU market because the company that tested them is considered unreliable.
- There is no evidence of harm or lack of effectiveness with any of the affected medicines. However, the medicines have been suspended until supporting data from more reliable sources are available.
- Several alternative medicines are available. Patients taking the affected medicines can contact their doctor or pharmacist for more information.
- National authorities in the EU will consider how critical individual medicines are in their countries and make final decisions on whether to suspend or allow them to remain available while new data are generated.

The CHMP review covered generic medicines authorised or being evaluated via national procedures on the basis of studies conducted by Synchron Research Services on behalf of marketing authorisation holders. The medicines were authorised or being evaluated for approval in several EU Member States.

The review was initiated at the request of national medicines regulatory authorities in several EU countries (Belgium, Denmark, Finland, the Netherlands and Sweden), under Article 31 of Directive 2001/83/EC. The CHMP opinion will now be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

First therapy to treat rare genetic nervous system disorder, AADC enzyme deficiency

May 20, 2022

EMA has recommended granting a marketing authorisation in the EU for Upstaza (eladocagene exuparvovec; from PTC Therapeutics International Limited), a therapy for the treatment of adult and paediatric patients with severe aromatic L-amino acid decarboxylase (AADC) deficiency with a genetically confirmed diagnosis.

AADC deficiency is an ultra-rare, inherited genetic disease which typically manifests within the first year of life. It is caused by changes in the gene that produces the AADC enzyme which is needed to produce certain substances vital for the normal functioning of the brain and nerves, including dopamine and serotonin. These substances are used by cells in the brain and the nervous system to send signals and are crucial for the development of motor functions.

Patients with AADC typically experience developmental delays, weak muscle tone, and inability to control the movement of the limbs. AADC deficiency is a long-term, debilitating, and life-threatening condition because it can lead to multiple organ failure. Patients also experience intellectual disability, show irritability, and are at risk of death in the first decade of life.

According to recent estimates, this condition affects 1 in 118,000 people in the EU. Currently, there are no approved therapies for the treatment of AADC deficiency. Patients are offered supportive treatments to manage the symptoms without addressing the underlying cause of the disease. Therefore, there is an unmet medical need for these patients.

Upstaza consists of a modified virus (adeno-associated viral vector) that contains a functional version of the AADC gene. When given to the patient by infusion into the brain, it is expected that the virus will carry the AADC gene into nerve cells enabling them to produce the missing enzyme. This in turn is expected to enable the cells to produce the substances they need to function properly (such as dopamine and serotonin), thus improving symptoms of the condition. The virus used in this medicine does not cause disease in humans.

EMA's recommendation is based on the results of three trials including 28 children between the ages of 18 months and 8 years and 6 months with severe AADC deficiency confirmed by a genetic diagnosis. All trials were conducted with an unblinded single arm and historic control data from published studies was used as a comparator.

The main favourable effects attained by the participants were head control and the ability to sit unassisted. An ad-hoc expert group was consulted to discuss the clinical relevance of the motor benefits of treatment and concluded that efficacy had been demonstrated and is clinically meaningful.

The most commonly reported side effects were raised body temperature (pyrexia) and involuntary, erratic movements (dyskinesia). The majority of side effects reported were mild or moderate.

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 Upstaza outweighed the possible risks in patients with AADC deficiency.

Upstaza was designated as an orphan medicinal product for the treatment of AADC deficiency on November 18, 2016. The applicant for Upstaza received scientific advice from the Agency at various stages prior to submission of a marketing authorisation application.

The CHMP, EMA's human medicines committee, agreed with the CAT's assessment and positive opinion, and recommended approval of this medicine under exceptional circumstances.

A marketing authorisation under exceptional circumstances allows patients access to medicines that cannot be approved using a standard authorisation route as comprehensive data cannot be obtained under normal conditions of use, either because there are only very few patients with the disease, the collection of complete information on the efficacy and safety of the medicine would be unethical, or there are gaps in the scientific knowledge. These medicines are subject to specific post-authorisation obligations and monitoring.

The CHMP requested the applicant to submit data to further characterise the long-term efficacy and safety of patients enrolled in the clinical trials, on the basis of a 10-year follow-up, and a registry-based safety study on patients treated globally with the medicine. The studies will be conducted according to agreed protocols.

The opinion adopted by the CHMP is an intermediary step on Upstaza's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on the 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/use of this medicine in the context of the national health system of that country.

EMA guidance supports development of new antibiotics

May 24, 2022

As part of its efforts to support a global approach to the development of new antimicrobial medicines, EMA has published the final revised guideline on the evaluation of human medicines for the treatment of bacterial infections.

Antimicrobial resistance (AMR), which is the ability of microorganisms to resist antimicrobial treatments, especially antibiotics, has a direct impact on the health of people and animals and carries a heavy economic burden worldwide. In the EU alone, it is responsible for an estimated 33,000 deaths per year. It is also estimated that AMR costs the EU €1.5 billion per year in healthcare costs and productivity losses.

EMA plays an important role in the fight against AMR by guiding and supporting the development of new medicines and treatment approaches, especially for patients with infections caused by multidrug-resistant bacteria, who currently have very few therapeutic options.

As AMR is a global threat, regulators in the EU, the United States and Japan have agreed to align as much as possible their respective data requirements so that medicine developers can design clinical trials that meet the evidence needs of multiple regulatory agencies. The revised document reflects the outcome of these discussions, and also includes:

- clarifications on recommended clinical development programmes for antimicrobials intended to address an unmet need;
- guidance on clinical trials to support treatment of uncomplicated urinary tract infections and uncomplicated gonorrhoea;
- updated guidance on displaying micro-biological and clinical efficacy data in the summary of product characteristics.

The revised guideline is published together with an addendum aiming to steer clinical development programmes required to support the authorisation of medicines for treatment of bacterial infections in children.

For the treatment of some infections, efficacy results can be extrapolated in certain children age groups by looking at efficacy data from adults. The addendum mentions that companies developing new antibiotics need to develop an extrapolation concept and provide details about it in an extrapolation plan.

For some infections that occur only or mostly in children below a certain age, extrapolating efficacy data from adults is not possible. The addendum includes guidance on trials that may be conducted in these exceptional cases.

The revised guideline was under public consultation for 6 months in 2019. The final document with all the updates implemented was adopted by EMA's CHMP at its May 2022 meeting.

Big Data strategy for veterinary medicines in the EU

June 13, 2022

EMA and the Heads of Medicines Agencies (HMA) have adopted a Veterinary Big Data strategy to 2027 outlining their vision for fostering data-driven, digital innovations in the veterinary medicines' domain in the EU.

Building upon key objectives of the recently implemented Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6), the strategy aims to converge traditional regulatory practice with innovative digital solutions. The strategy proposes to identify relevant use cases, existing and additional data sources, critical infrastructure, and methods to enable an environment that encourages innovation in the development of new veterinary medicines for the benefit of animal and human health and welfare.

As part of the implementation of the veterinary legislation, EMA and the whole EU veterinary medicines regulatory network have made significant investments to implement new IT systems that generate and centrally collect increased amounts of data. The strategy sets up a framework for managing and using these data to support key regulatory activities. This will enhance consistency, transparency, and responsiveness across the network by providing accurate and reliable information to promote public and animal health.

The Veterinary Big Data strategy proposes implementation in phases:

- Up to 2023: strengthen collection of key data

First gene therapy to treat severe haemophilia A

June 06, 2022

E MA has recommended granting a conditional marketing authorisation in the EU for Roctavian (from BioMarin International Limited) for the treatment of severe haemophilia A in adults who do not have factor VIII inhibitors (auto-antibodies produced by the immune system which make factor VIII medicines less effective) and no antibodies to adeno-associated virus serotype 5 (AAV5).

Patients with haemophilia A cannot produce factor VIII (an essential protein required for blood to clot and stop bleeding); they are more prone to bleeding and have prolonged bleeding, e.g. after injury or surgery. Haemophilia A is a rare debilitating disease affecting approximately 0.7 in 10,000 people in the EU. It is life long and may be life-threatening when bleeding occurs in the brain, the spinal cord or the gut.

Medicines currently authorised for treating haemophilia A mostly contain factor VIII, to replace the missing protein. Available treatments require one or more injections per week or per month and are lifelong. Therefore, there is an unmet medical need for new therapeutic approaches that might free patients from frequent injections.

Roctavian is the first gene therapy to treat haemophilia A. The active substance in Roctavian, valoctocogene roxaparvovec, is based on a virus (adeno-associated virus or AAV) which has been modified to not cause disease in humans. The virus contains the gene for factor VIII; once given to a patient as a one-off infusion, it is expected to carry the factor VIII gene into the liver cells, enabling them to produce the missing factor VIII. This helps the blood to clot more easily and prevents bleeding or reduces bleeding episodes. It is yet unknown how long the treatment effect from this single infusion will last in an individual patient. A sustained positive treatment effect of up to two years following a single infusion has been reported in approximately one hundred patients in the main study and up to five years in a few patients in a supportive trial conducted by the applicant. Longer-term follow-up tests may be required to verify a continued safe and effective response to the medicine.

EMA's recommendation is based on the results of a Phase 3 single arm (main study), non-randomised study in 134 male patients with haemophilia A without a history of factor VIII inhibitor and without detectable pre-existing antibodies to AAV5. Two years after the administration, efficacy data showed that the therapy significantly increased factor VIII activity levels in the majority of patients. Bleeding rates were reduced by 85% and most patients (128) no longer needed factor VIII replacement therapy.

Hepatotoxicity (liver damage), a common side effect due to immune reaction induced by these AAV-based gene therapies and characterised so far by an increase in the levels of a liver enzyme called alanine aminotransferase (ALT), has been reported with Roctavian. The condition can be treated successfully with corticosteroids. Other common side effects include headache, joint pain, and nausea.

Patients treated with Roctavian will be monitored for 15 years, to ensure the long-term

efficacy and safety of this gene therapy.

Roctavian 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.

In its overall assessment of the available data, the CAT, EMA's expert committee for cell- and gene-based medicines, found that the benefits of Roctavian outweighed the possible risks in patients with haemophilia A.

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 the CHMP is an intermediary step on Roctavian's path to patient access. The opinion will now be sent to the European Commission 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.

and identification of additional data sources to better support regulatory activities in subsequent implementation phases
- 2023-2025: integrate key data in targeted regulatory processes and start analytics solutions
- 2024-2027: connect data to power information sharing and dissemination and expand analytic capabilities. This phase will be aligned with the Big Data strategy for human medicines.

The new strategy impacts different business areas, such as pharmacovigilance, the fight against AMR, environmental risk assessment, regulatory submission, innovation of veterinary medicinal products development, and demonstration of efficacy/effectiveness.

A first Veterinary Big Data stakeholder forum bringing together regulators, the pharmaceutical industry, farm management system providers, academia, consumers and practitioners, took place in June 2021. A follow-up forum will be held on November 23, 2022.

EMA launches pilot project on analysis of raw data from clinical trials

July 12, 2022

E MA has launched a pilot project to assess whether the analysis of "raw data" from clinical trials by regulatory authorities improves the evaluation of marketing authorisation applications (MAAs) for new medicines as well as post-authorisation applications and to explore the practical aspects of the submission and analysis of such data.

Raw data constitutes individual patient data from clinical studies (including clinical trials as well as non-interventional studies) in electronic structured format that is directly accessible for analysis and visualisation. Examples of raw data include records of original observations and measurements of clinical study participants, such as clinical laboratory results, imaging data, and patient medical charts. Currently, the European medicines regulatory system does not routinely require the submission of raw data in the context of a marketing authorisation or post-authorisation application.

EMA's CHMP receives data submitted by the applicant or marketing authorisation holder (MAH) after statistical processing in aggregated format as clinical summaries, as well as in PDF listings. The CHMP scrutinises these summaries as part of the scientific evaluation of the benefits and risks of medicinal products. This process typically results in several rounds of questions in which the Committee may ask the applicants/MAHs for methodological clarifications, re-analysis of data, or additional data. However, according to EU regulation, the CHMP can request the applicant/MAH at any time to provide the raw data to perform further analyses to support the benefit risk assessment of medicines. Raw data have been requested by the CHMP on several occasions in the past when it was considered that it would be helpful in the evaluation of a medicinal product.

The pilot project is open to applicants or MAHs that are about to submit MAAs or post-authorisation applications. If selected, they will include raw data already as part of their submissions. More information on the pilot's objectives and on the terms of participation is available in the description of the pilot to industry on EMA website. The pilot is expected to last up to two years and will include approximately ten regulatory procedures submitted to EMA from September 2022. The pilot will fully comply with data protection legislation requirements.

Applicants and MAHs can contact EMA via rawdatapilot@ema.europa.eu to express their interest in participating in the pilot or to gather more information.

This pilot stems from one of the ten priority recommendations issued by the joint Big Data Task Force of EMA and the HMA in 2020 which highlighted the need to strengthen the network's capability to analyse data collected at individual patient level to better inform regulatory decision making. There are several potential benefits the analysis of raw data might bring including faster evaluation through fewer questions being put to applicants and a better definition of the target treatment population. Thus, raw data analysis may enabler faster and better access to new medicines for patients.

Upon the completion of the pilot, EMA will organise a workshop with relevant stakeholders to discuss the learnings and will also publish a summary report.

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)

The two most important keys on your keyboard

Towards better prevention of medicine shortages in the EU

July 15, 2022

European Medicines Agency (EMA) has published a guidance for patients' and healthcare professionals' organisations with key principles and examples of good practices to support them in preventing and managing shortages of human medicines.

Medicine shortages and reduced availability of medicines represent an increasing issue across the EU and the globe, and it has been amplified by the COVID-19 pandemic. It may have a significant impact on patient care by causing medicine rationing and delay of critical treatments. Due to medicine shortages, patients may need to use less effective alternatives and they could risk using medication incorrectly.

The causes of shortages can include manufacturing problems leading to delays or interruption in the production, shortages of raw materials, increased demand of medicines, distribution problems, labour disruptions, and natural disasters.

Patients and healthcare professionals are the main actors at the end of the supply chain, therefore their activities in preventing shortages are usually limited to managing the demand for medicines at risk of shortages. The EMA guidance also looks at measures that help to improve preparedness, planning and rationed use for medicines that are either in short supply or expected to be so in the near future.

Some of the key recommendations included in the EMA guidance apply only to patients' organisations, some only to healthcare professionals' organisations, and some to both. For example, both types of organisations are encouraged to:

- develop observatories in collaboration with national authorities to collect and analyse information from patients and healthcare professionals on shortages and their early signs;
- work with national authorities on criteria and ways to develop registries of essential and critical medicines;
- set up campaigns across the EU to raise awareness of shortages, where to find information on ongoing shortages, risks of stockpiling and safe use of alternative medicines.

The key recommendations have been prepared based on consultations with member organisations of the EMA Patients' and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Party (HCPWP). They draw on existing practices and initiatives in individual EU Member States where the recommendations have been implemented often in isolation, some of which are described in the annex of the guidance.

The full set of guidelines can be consulted in the good practice guidance, but also in an info-sheet developed by EMA for patients and healthcare professionals.

A collection of info-cards presents what patients can do when it comes to shortages of medicines.

Regulatory Matters

SECTION EDITORS

Zuo Yen Lee
zuoyen.lee@gmail.com

Clare Chang
clarechangphd@gmail.com

Editorial

The computer is the medical writer's best friend. As such, occupational hazards associated with this line of trade include back, neck, shoulder, and hand pain as a result of constrained postures from computer-based tasks. In line with the topic of the virtual workforce, we are pleased to have Ri Xu take us through her journey to understanding various muscle pains and her creative ways of working ergonomically to counter them.

Clare Chang and Zuo Yen Lee

Hand and back muscle pain and how to avoid them: A regulatory writer's story

Ri Xu
Freelance medical writer
ri.xu@xurimedical.com

Introduction

I am 33 years old and am prone to different kinds of muscle pain, not only while at work, but also while eating, driving, walking, and sleeping. As a regulatory writer, I experienced different muscle pain and tension and therefore set out to investigate pain management with multiple devices and creative ways to use them. This article is an anecdotal journey to discovering the causes of pain from medical writing and how they can be avoided. The recommended devices and principles of working can be useful for different medical writers.

Why medical writing causes muscle aches

I was a Clinical Evaluation Reports (CERs) writer supporting the regulatory compliance of medical devices for a year. CERs summarise clinical data from various data sources to assess the benefits vs. risks of a medical device. More than 70% of the work involves finding and placing relevant information into a template or a table. Sources of information include labelling documents, post-market surveillance reports, risk management documents, etc. Therefore, the physical work on the computer involves moving and clicking the mouse, and using a lot of hotkeys, such as Ctrl + F (search), Ctrl + C (copy), and Ctrl + V (pasting). At a fast pace, these activities may result in muscle pain in the hand.

Muscle pain analysis and discussions

Pain analysis is the crux to understanding why certain pain occurs and to find an ergonomic way of working moving forward.

General reasons for body aches

Generally, regardless of where the pain is (lower back, neck, hand, etc.), the reasons behind the pain (which may potentially become arthritis), are simple – overuse of muscles:

- Holding a posture or position for too long or moving incorrectly.[1] Human bodies are made to move and the movement has to be ergonomic.[2] Repetitive mouse movements and clicking can be painful for the hand, elbow, and shoulder. In my case, the pain was only relieved when I rested my right arm completely (e.g. when one is walking).[2] Even a partially relaxed position (e.g. resting hands on the table) caused a lot of pain. The problems of prolonging certain postures and moving incorrectly may be underrated and require further scientific studies since the current literature is limited.[1]
- Weight overloading, uneven weight loading, or uneven distribution of weight.[3] Bad postures can occur unintentionally when sitting on an uneven surface or walking on an uneven floor: the floor or seat is the cause of uneven weight distribution. Notably, weight overloading, uneven weight loading, or uneven distribution of weight are comon causes of arthritis during later stages of life.[4,5]

> Pain analysis is the crux to understanding why certain pain occurs and to find an ergonomic way of working moving forward.

For example, in my kung-fu class, my teacher asked me to hold the split stance: one foot forward and one foot back while moving a stick in one hand. While performing this movement, I felt pain in my hand and lower back. I could not even open and close my hand while holding the stick. My legs were uneven when I performed the split stance, which caused the lower back pain.

Hand pain
(including finger, wrist, and elbow pain)

While the use of the mouse and keyboard is straightforward, the causes of hand pain can be complex.

Operating the mouse

Based on my own observations, mouse movements can be categorised into three types: moving the cursor, clicking, and scrolling (see Creative office set-ups below.)

Weight bearing of the upper body

If one's upper body is leaning forward, then their wrist or arm is likely supporting part of their weight. I tried well-designed moveable elbow support but ended up transferring the pain into both my elbow and shoulder. Thus, leaning forward may contribute to wrist, elbow, and shoulder pain.

Holding the mouse

One of the main causes of pain can be holding the mouse for an extended period of time.

Moving the cursor

The cursor's movement is composed of two parts: long-distance movement and small adjustments. With long-distance cursor movement, the mouse/trackball only needs momentum to reach the destination area. After that, the cursor's movement is fine-tuned within that area. The most painful part is the small adjustment movement, where multiple muscles have to work together to ensure that the cursor is placed precisely. I've tried different types of mice: ergonomic left- and right-hand mice, trackball mice, trackpads, pen-shaped mice, etc. Regardless of the mouse type used, moving the cursor can be painful for very small adjustments. Consequently, I would not recommend a single mouse.

Additionally, I tried working with multiple mice, where I switched to another mouse when my hand pain became unbearable. However, the pain merely transferred from one muscle to another after the switch. Therefore, my suggestion for alleviating hand pain is to minimise moving the cursor using a mouse.

Clicks

Mouse clicking is not painful but having to hover one's fingers to be always ready for the clicks is painful (see suggestions in the Hand or finger hovering problem section below.)

Scrolling

Most devices on the market allow only up-and-down scrolling. However, there is a need for left and right scrolling as well.

Horizontal scrolling mice are very difficult to find because there are so few on the market. I also tried to add this function to my macro keyboards but was unsuccessful. Hence, there can be a potential market need for this function. Left and right scrolling devices, if available, may alleviate the pain stemming from the current click and drag function to scroll the horizontal bar.

Overall, from my pain analyses, I recommended limiting the usage of any mouse (including different shapes, types of mice, and trackpads) and especially avoid moving the cursor.

Operating the keyboard

A quick CER writer probably uses hotkeys quite frequently. Performing such movements frequently for eight hours a day may be painful, especially when hovering one's hands above the keyboard while anticipating the next hotkeys (See Hand or finger hovering problems). For this matter, I suggest using small macro keyboards (see the section below, Trial and error – Recommended devices).

Hand or finger hovering problem

How often does a writer need to click the mouse? Let's estimate one click every two to three seconds. Imagine that the left-click button was on a wall that is easily accessed by raising a hand. This movement would not be painful if the hand returned to a relaxed position after every click. However, if the hand were to hover near the button until the next click, the hand (or arm rather) would become very fatigued. Hand hovering is often subconscious and difficult to change. Hence, one may resolve hand pain by returning the hand to a comfortable resting position more frequently – after each action.[6] By doing so, the muscles get to relax for up to 50%

Figure 1. Creative office set-up: a mouse on both left and right sides of the chair

Creative office set-ups

After months of trial and error, I established my current office set-up, in an attempt to resolve the pain mentioned above. This setup is based on devices currently on the market.

To work while sitting in a chair with a slight backwards incline, I have two trackball mice, one to the left and one to the right of my chair (Figure 1). Trackball mice allow for moving the cursor by rolling the trackball. In front, I have small macro keypads and trackpads placed at comfortable positions (Figure 2). Trackpads require moving fingers on the pad.

While a touchscreen and macro keyboards avoid more than 70% of painful cursor movement, there are still situations when the mouse cannot be avoided.

To increase comfort, I try to relax my hands as frequently as possible by switching hands while operating the computer.

Here is how I operate the mice: I separate long-distance cursor movement, small cursor adjustments, and clicks. I perform the long-distance movement with my right hand on the trackpad and small adjustments with my left hand on the trackball mouse (Figure 1 and Figure 2). For clicks, I either use the trackball mice or the trackpad.
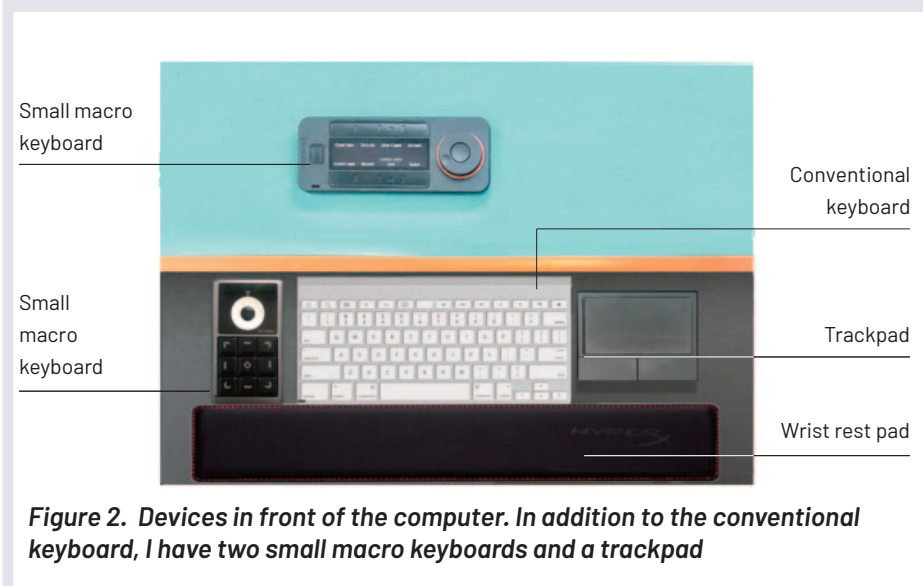

Figure 2. Devices in front of the computer. In addition to the conventional keyboard, I have two small macro keyboards and a trackpad

of the working time. Changing hands frequently can make this possible (see Creative office set-ups below.) This recommendation applies to all devices being operated, including touchscreens.

Neck pain, shoulder pain, and lower extremity pain

The positions that can cause neck pain are listed below:

- Bending neck downwards. This often occurs when one is reading something below eye level.
- Facing forward with a hunched back and rounded shoulders. This often occurs when one needs to work in front of a computer but wants to relax the neck and shoulders. The posture may be assumed unintentionally and subconsciously.
- Tilting or turning the head to one side. This often occurs when the writer looks only at one side of the screen.

The ideal alignment of the neck assumes a slight lordotic curvature, which can be achieved by leaning backwards on a chair and staying centred.[7]

Lumbar (lower back) pain

One reason for lower back pain is an uneven weight load. Sometimes a chair is not flat and is lower in the middle and higher on the edges. In this case one needs to ensure that the chair is centred. It may be hard to notice when sitting a little bit off-centre and pain may occur.

Back support is also a necessity and most chairs do not have this. Immediately trying a commercial gaming chair or back support for office use can be costly and may not necessarily help. Every individual has a preference for the height and thickness of the cushion for back support, [2,8] so it is important to try out back support and make sure it is centered.

Trial and error - Recommended devices for pain relief

Based on trial and error and analyses above, the following equipment or settings can be helpful:

- Touchscreen. A touchscreen can minimise cursor movement.
- Small macro keyboards. Each hotkey (i.e., a combination of keys) can be easily programmed into one single key on a macro keyboard. Small macro keyboards can be easily placed anywhere and are very comfortable to use. As a result, the hand pain caused by hovering over keyboards can be avoided. Macro keyboards are very popular in the gaming and digital art industry. It was a lot

of fun to create my own "gaming keypads" for regulatory writing work.

- **Voice recognition** in Microsoft Word and Windows Operating System. In Word, voice recognition is very useful for drafting text. However, when it comes to copy-pasting work, macro keyboards are still faster.
- **Automation software**, such as Macros in Word and Excel. (Automation software can repeat certain sequences of keystrokes and mouse-clicks conducted on a computer.) So far, I have found Word Macros very efficient in cross-referencing and fixing broken links.
- **Monitor risers** that raise your computer screen to eye level, reducing neck strain.
- **"Lazy-man glasses"** for reading files on the table without bending the head. (These glasses have prisms that allow one to read files below without looking down.)
- **Customised lumbar support** pillows centred in the chair.

Conclusions and suggestions

Through trial and error, I performed pain analyses and proposed principles for pain management. Currently, there is limited literature supporting the point of view discussed in this article, which potentiates further research in office set-up design.[9,10]

Principles for pain management

The principles of pain management from my analyses are below:

- Relax the hand and arm more frequently regardless of which devices are being used. The muscles get to relax 50% of the time by changing hands frequently.
- Limit the usage of any mouse (including different shapes, types of mice, and touch-pads), especially in terms of moving the cursor.
- Limit neck bending.
- Lean back and centre oneself in the chair.

A contradiction of good posture vs. conventional office settings

- The preferred and more ergonomic posture for the human body while sitting is to lean backwards. However, conventional office settings typically involve forward-facing work. This might be the major reason why many people suffer from back pain and hand pain.[7] Non-conventional office settings can be created, where devices such as mice are not operated in front of the user, but to the side, which may be more comfortable and create less stress on arms, wrists, and hands. (See Figure 1).
- Prolonging certain postures, even the most relaxed postures, may also cause pain. A new device or set-up may relieve pain temporarily but not permanently.

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Disclosures and conflicts of interest

The author declares no conflicts of interest.

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Author information

Ri Xu, PhD, was a CER medical writer at Johnson & Johnson MedTech and is now a freelance medical writer specialising in Medical Communications. She obtained a PhD in Engineering Physics based at Polytechnique Montreal, Canada in 2020. She loves solving problems, experimenting with new devices, and innovation. You can view her profiles at https://www.linkedin.com/in/ri-xu/, and https://www.researchgate.net/profile/Ri-Xu

Medical Communications and Writing for Patients

SECTION EDITOR

Lisa Chamberlain James
lisa@trilogywriting.com

Dear all,

In this edition of *Medical Writing*, we have a report from the latest Meet & Share session from the MedComm Special Interest Group (SIG). EMWA's SIGs host Meet & Share sessions throughout the year, encouraging open and honest discussion between medical writers on a variety of topics (identified and advertised ahead of the session). EMWA is an incredible community with a lot of very experienced and talented medical writers who never cease to

amaze me with their generosity of time and advice, so I strongly encourage you to look out for the Meet & Share sessions and get involved!

The MedComm SIG's latest Meet & Share session looked at the issues surrounding the approaches to referencing in medical publications. The very informative report comes from the latest recipient of the Geoff Hall Scholarship Sampoorna Rappaz, who is already delving straight into EMWA life and getting involved with the SIGs.

I hope that you enjoy Sampoorna's article as much as I did, and in the meantime, stay safe and sane – enjoy the sunshine (if you have any!), and see you in the December issue!

Bestest,
Lisa

Clarifying referencing

Third Meet and Share session of the Medical Communications Special Interest Group

Sampoorna Rappaz
Freelance Medical Writer
sampoorna.satheesha@gmail.com

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In March 2022, Med Comms SIG held its third Meet and Share session, which dealt with the nuances of and practical approaches to referencing in medical publications. We regularly use author instructions and style guides that detail reference formatting, but there is a lot more to effective referencing than just making it look correct. A systematic review of studies on reference accuracy in biomedical literature (39 studies identified) estimated a median citation error rate of 36% (range, 4–67) and the median quotation error rate of 20% (range, 0–44).[1] Also, a study by senior editorial board members of *Deutsches Ärtzeblatt* showed that the referencing error rate in publications is about 20%, which the authors opine is a conservative estimate.[2] Recently, a study published in *JAMA Surgery* found that 9% of the citations in high-impact surgery articles were inaccurate.[3] Taken together, inaccurate referencing is a frustrating reality in medical publications.

While citation errors (incorrect authors' names, journal name, volume and page numbers, etc.) can make substantiation difficult, quotation errors (inaccurate representation of source study or author statements) can impede scientific progress itself, especially when such errors are unintentionally echoed in the

scientific discourses and publications that follow. Therefore, it is important for medical communicators – as purveyors of accurate and precise scientific information – to follow referencing best practices, which may not always be clearly defined. At the Meet and Share forum, participants were presented with various situations where there were no clear predefined citation or referencing guidelines and were asked to share their approach. A summary of the discussion is presented below.

Where and how to cite?
The participants were presented with the following hypothetical situation:
If you have a list or sub-claims within a sentence, do you split the citations or do you place them all together at the end of the sentence? For example:

> **Option 1:** "In other studies, death occurred in 5–10%(1-3), myocardial infarction in 2–5% (1,2,4), and revascularisation in 10–20% (2,3,5)."
>
> ***OR***
>
> **Option 2:** "In other studies, death occurred in 5–10%, myocardial infarction in 2–5%, and revascularisation in 10–20% (1-5)."

Response:
The group agreed that the first option is more

> *While citation errors can make substantiation difficult, quotation errors can impede scientific progress itself.*

accurate, precise, and makes recycling content easier. The second option is more useful when facing space or word count constraints. It was highlighted that the manuscript section would also need to be considered when thinking about this issue. For instance, in the discussion section, where arguments would need to be substantiated using accurate and precise referencing, the second option should not be used. Whereas, in the introduction section, the second option provides adequate information and could be used; however, the first option would still be the preferred format.

How to decide between primary and secondary references?
The participants were presented with the following hypothetical situation:
You want to cite a claim from a publication by XYZ et al. that says, "Statement a (1-3)." Which option is best?
Option 1: You cite all source references from the publication, but not the publication itself ("Statement a [1-3]").

OR

Option 2: You cite only the publication ("State-ment a [XYZ et al.]").

Response:

There was no clear preference for one option over the other. The consensus was that the primary sources (references 1-3 in the example above) should be checked for accuracy irrespective of the manner of citation. Option 2 would suffice if a systematic review or meta-analysis is the source of the claim. As part of this discussion, it was also noted that recent evidence should be given preference when choosing references, provided that it is well supported by data. However, older publications (>15 years) should not be mechanically discarded. Overall, scrutiny is key.

Are citations allowed in the results section?

The majority was against adding citations to the results section; however, it was pointed out that, while rare, such practice is possible. For instance, when the current manuscript contains 5-year data and the 1-year data have already been reported, one could add the sentence, "Data up to 1 year have been published previously (reference)" in the results section instead of the introduction or methods sections. This addition could help the readers who skip these preceding sections. This practice seems to be a matter of personal preference, and the majority recommended adding this information to the introduct-ion or methods sections. Also, at times, outliers can lead to new hypotheses, and citations may

need to be included in the results section to substantiate the reasoning behind the new explorations; this helps maintain a logical flow in the manuscript and strengthens the element of storytelling.

How many references are required per claim?

The group agreed that there is no "magic number" of references per claim, but it need not be restricted to just one. Having one reference to support a claim is necessary but it may not be sufficient unless we are restating a well-known fact. Even so, if it is a key point in the manuscript then more than one reference should be used. There may be a thin line between redundant and relevant references, so discretion is important. Also, it is now possible to include references in the supplementary information in some journals, so reference number constraints should no longer stop writers from being thorough.

How do we avoid citation manipulation?

The Committee on Publication Ethics (COPE) defines citation manipulation as, "… behaviours intended to inflate citation counts for personal gain, such as: excessive self-citation of an authors' own work, excessive citation to the journal publishing the citing article, and excessive citation between journals in a coordinated manner."[4]

The consensus was that the authors' previous publications and the journal editors' publications can be cited if these publications are equivalent

in terms of relevance and strength of evidence to other references. It was pointed out that publishers advise keeping self-citations to a minimum.

COPE provides more information and practical advice on this issue on its website.[5]

How do we cite information that is not available in a published and indexed scientific article format?

As it is not possible to publish all industry-developed documentation in full, such as regulatory files and product labels, uniform resource locators (URLs) to these sources have to be included in the reference list. However, it may happen that peer reviewers or journal editors disallow references to drug compendia, "data on file", etc. and insist upon indexed articles. Therefore, the publishing of even seemingly "minor" or "uninteresting" pieces of research is important, as this would make the information discoverable and citeable. Also, unlike the permanent digital object identifiers (DOIs) that may be assigned to journal articles, URLs are short-lived. A study found that about 20% (1 in 5) of all science, technology, and medicine articles published between 2009 and 2012 suffer from "reference rot", i.e. either the URLs in the reference list have ceased to exist or the originally referenced content in the URLs has changed, making substantiation impossible.[6] Medical communicators must do their best to not add to this growing problem.

While preprints were not discussed during this session, it is important to highlight here that

the updated International Committee of Medical Journal Editors (ICMJE) recommendations now include notes on referencing preprints.[7] Additional information and guidance on this matter can also be found in the AMWA-EMWA-ISMPP position statement[8] and the American Medical Association's editorial style manual.[9]

Overall, the key learnings were that professional medical communicators need to follow referencing best practice, i.e. ensure references are accurate, in-text citations are as precisely placed as possible, information sourced from the references is correctly represented, and the strongest and most relevant evidence is chosen. Referencing, when done well, makes substantiation easy and efficient. After all, precise and accurate referencing is crucial to maintaining the integrity of scientific communication.

Med Comms SIG thanks all participants for sharing their valuable input. All EMWA members are welcome to join the SIG's next forum.

Acknowledgements

Disclosures and conflicts of interest

The author declares no conflicts of interest.

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Author information
Sampoorna Rappaz, PhD, is a freelance medical writer and editor based in Switzerland. She is a supporting member of the Medical Communications SIG and the Communicating with the Public SIG. ORCiD: https://orcid.org/0000-0002-7330-7586 Google Scholar: https://scholar.google.com/ citations? user=E9nHlqkAAAAJ&hl=en

Veterinary Medical Writing

SECTION EDITOR

Louisa Marcombes
louisa@boudimedi.fr

An illustrated look at brachycephalic dogs

They say that a picture paints a thousand words, and for a medical writer, that sounds like a no-brainer for efficient working. Nevertheless, despite the relatively recent introduction of concepts such as infographics, graphical abstracts, and graphic medicine in the world of medical communications, the written word remains king. But if the fundamental goal of medical communications is to promote understanding of medical science in as many people as possible, whatever their background, is the visual content format underused?

Picture the scene. It's silly season, the office is empty (even "From the Horse's Mouth" is on holiday), and your MEW Vet Section editor has just finished reading the excellent "Comics aren't just for kids", a recent article in this publication by Era Mae Ferron.[1] And she is inspired! She has been toying with the idea of doing graphic-novel-style medical content for a while, and now she has learned that graphic medicine is a *thing!*

The following graphic medicine article, "Everything that medical writers need to know about brachycephalic dogs", is the result of that inspiration. It takes a hot topic from the veterinary world, brachycephalic dog welfare, and is based on my own experience as a veterinary surgeon working with these lovely animals. Whilst creating this article, I reflected on the applications of graphic medicine, or perhaps more accurately "graphic pathography"[2] in medical communications and formulated some thoughts: does this article have more (or less) impact in this form than if the same information had been given in a 1500-word article? And, correspondingly, does this result in improved retention of the key message? Green and Myers[2] have identified patient care, medical education, and the social critique of the medical profession as areas in human medicine where the graphic medicine format can be applied to enhance teaching and patient care. Are there similar applications for veterinary medicine or for medical writing? Or could its use be expanded, for example, to a graphic format of the summary of product characteristics of pharmaceuticals? Finally, and deftly sidestepping the learning style controversy of educational theory, is the benefit (or otherwise) of graphical medicine appreciated by all members of the audience, or will text (or even audio) always be preferred by some?

These are all questions I invite the reader to mull over when viewing this article. Graphic medicine has the potential to enhance understanding of medical information and a growing evidence base will inform medical communication professionals how it is best applied. However, what I can say for sure having completed this project, creating the picture probably takes as long as writing those thousand words.

Louisa Marcombes
louisa@boudimedi.fr

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EMWA Autumn Conference
November 3–5, 2022
Riga, Latvia

Save the date!

Everything
THAT MEDICAL WRITERS NEED TO KNOW ABOUT
Brachycephalic Dogs
~AN ANIMAL WELFARE COMMUNICATION~

TEXT AND GRAPHICS: LOUISA MARCOMBES
FREELANCE MEDICAL WRITER

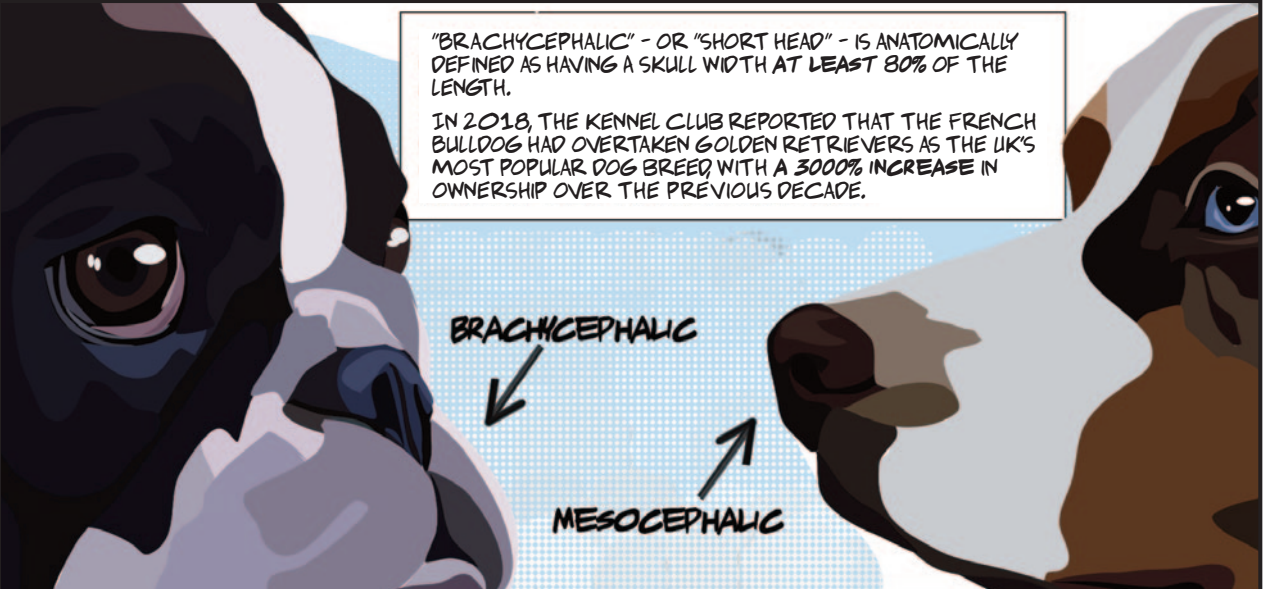"BRACHYCEPHALIC" – OR "SHORT HEAD" – IS ANATOMICALLY DEFINED AS HAVING A SKULL WIDTH **AT LEAST 80%** OF THE LENGTH.

IN 2018, THE KENNEL CLUB REPORTED THAT THE FRENCH BULLDOG HAD OVERTAKEN GOLDEN RETRIEVERS AS THE UK'S MOST POPULAR DOG BREED, WITH **A 3000% INCREASE** IN OWNERSHIP OVER THE PREVIOUS DECADE.

BRACHYCEPHALIC

MESOCEPHALIC

THIS EXPLOSION IN THE POPULARITY OF BRACHYCEPHALIC DOGS IN MANY COUNTRIES HAS **CAUSED ALARM** AMONGST VETERINARIANS.

BRACHYCEPHALY IN VETERINARY PATIENTS, AS WITH HUMANS, PREDISPOSES INDIVIDUALS TO A RANGE OF DISEASES THAT CAN **SEVERELY IMPACT** THE ANIMAL'S QUALITY OF LIFE.

NEVERTHELESS, AS WELL AS DOGS, BRACHYCEPHALY IS **DELIBERATELY BRED** FOR IN NUMEROUS DOMESTIC SPECIES...

SUCH AS RABBITS...

... CATS...

...AND EVEN HORSES.

24 DOG BREEDS ARE DEFINED AS BRACHYCEPHALIC, EIGHT OF WHICH ARE AMONGST THE 31 MOST POPULAR BREEDS IN THE US.[2]

PUG

ENGLISH BULLDOG

FRENCH BULLDOG AKA "FRENCHIE"

THE FACTORS DRIVING THIS RISE IN POPULARITY ARE WELL DESCRIBED...

BRACHYCEPHALIC DOGS HAVE BEEN OVER-REPRESENTED IN MARKETING NOT ONLY FOR ANIMAL PRODUCTS...

Pseudo-Away

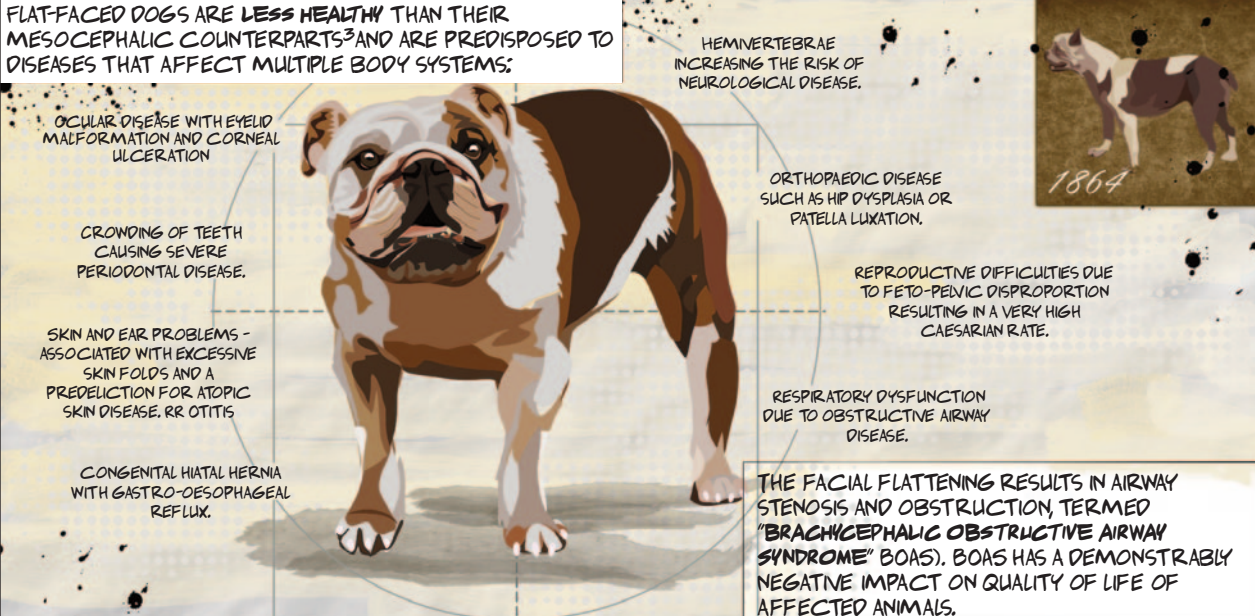...BUT ALSO FOR PRODUCTS TOTALLY UNRELATED TO THE PET INDUSTRY, SUCH AS MOBILE PHONES AND SOFAS.

Sofa Sale Now On

FURTHERMORE, THE PHOTOGENIC NATURE OF BRACHYCEPHALIC DOGS, ALONG WITH THE CHARACTERISTIC CHARISMA OF THESE BREEDS MEANS THEY ARE POPULAR SUBJECTS FOR THE SOCIAL MEDIA POSTS OF CELEBRITIES AND INFLUENCERS.

AND THE MORE EXTREME THE BRACHYCEPHALIC PHENOTYPE, THE GREATER THE SOCIAL MEDIA APPEAL.

FLAT-FACED DOGS ARE LESS HEALTHY THAN THEIR MESOCEPHALIC COUNTERPARTS[3] AND ARE PREDISPOSED TO DISEASES THAT AFFECT MULTIPLE BODY SYSTEMS:

OCULAR DISEASE WITH EYELID MALFORMATION AND CORNEAL ULCERATION

CROWDING OF TEETH CAUSING SEVERE PERIODONTAL DISEASE.

SKIN AND EAR PROBLEMS – ASSOCIATED WITH EXCESSIVE SKIN FOLDS AND A PREDELICTION FOR ATOPIC SKIN DISEASE. RR OTITIS

CONGENITAL HIATAL HERNIA WITH GASTRO-OESOPHAGEAL REFLUX.

HEMIVERTEBRAE INCREASING THE RISK OF NEUROLOGICAL DISEASE.

1864

ORTHOPAEDIC DISEASE SUCH AS HIP DYSPLASIA OR PATELLA LUXATION.

REPRODUCTIVE DIFFICULTIES DUE TO FETO-PELVIC DISPROPORTION RESULTING IN A VERY HIGH CAESARIAN RATE.

RESPIRATORY DYSFUNCTION DUE TO OBSTRUCTIVE AIRWAY DISEASE.

THE FACIAL FLATTENING RESULTS IN AIRWAY STENOSIS AND OBSTRUCTION, TERMED "BRACHYCEPHALIC OBSTRUCTIVE AIRWAY SYNDROME" BOAS). BOAS HAS A DEMONSTRABLY NEGATIVE IMPACT ON QUALITY OF LIFE OF AFFECTED ANIMALS.
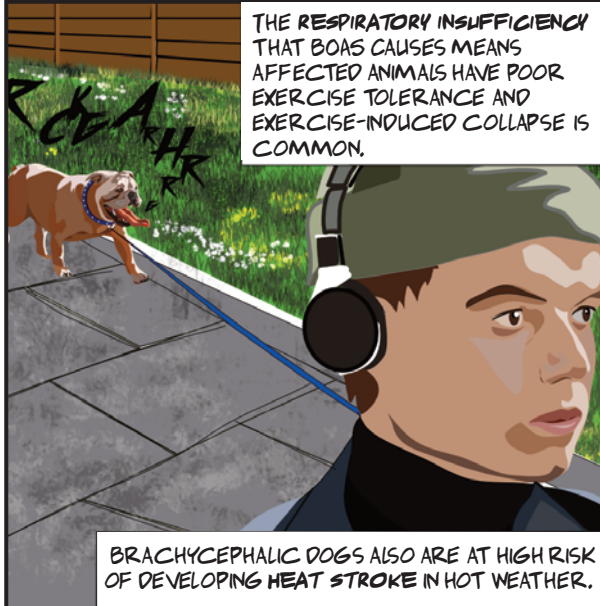
THE FOLLOWING ANATOMICAL CHANGES ARE SEEN IN DOGS WITH BOAS: NARROWED NOSTRILS, ELONGATED SOFT PALATE, OVERSIZED TONGUE, AND HYPOPLASTIC LARYNX AND TRACHEA.

HRAG HRARRG CLHRAGRAAACH

AS A RESULT, THE RESPIRATORY FUNCTION IN AFFECTED DOGS CAN BE SEVERELY COMPROMISED AND IS OFTEN SIGNALLED BY A CHARACTERISTIC STERTOROUS BREATHING.

THE RESPIRATORY INSUFFICIENCY THAT BOAS CAUSES MEANS AFFECTED ANIMALS HAVE POOR EXERCISE TOLERANCE AND EXERCISE-INDUCED COLLAPSE IS COMMON.

BRACHYCEPHALIC DOGS ALSO ARE AT HIGH RISK OF DEVELOPING HEAT STROKE IN HOT WEATHER.
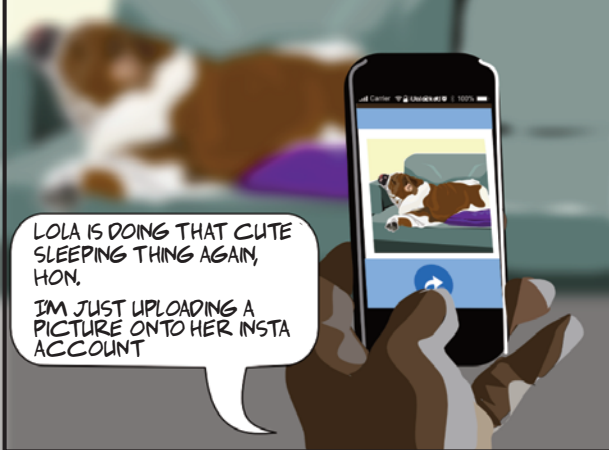
SNORE ... GNAAAGKH ...

EVEN SLEEP DOES NOT BRING RESPITE FROM BREATHING DIFFICULTIES BECAUSE BOAS MAKES IT CHALLENGING TO MAINTAIN **OPEN AIRWAYS DURING SLEEP**.

MANY DOGS HAVE CHRONICALLY POOR SLEEP QUALITY AS A RESULT AND WILL OFTEN ADOPT UNORTHODOX SLEEPING POSITIONS TO **IMPROVE AIRWAY PATENCY**.

IRONICALLY, THESE ABNORMAL BEHAVIOURS ARE APPEALING TO WELL-MEANING OWNERS WHO OFTEN POST THEM ON SOCIAL MEDIA.

THE **CLINICAL SIGNS** OF BOAS THEMSELVES CAN BE A FACTOR IN THE POPULARITY OF BRACHYCEPHALIC DOGS.

LOLA IS DOING THAT CUTE SLEEPING THING AGAIN, HON.

I'M JUST UPLOADING A PICTURE ONTO HER INSTA ACCOUNT

MEANWHILE AT THE VET'S ...

GRRHHH°K GRRUGHROOOKAH

OK, WHOS NEXT?

OTIS. IN FOR VOMITING UP BILE.

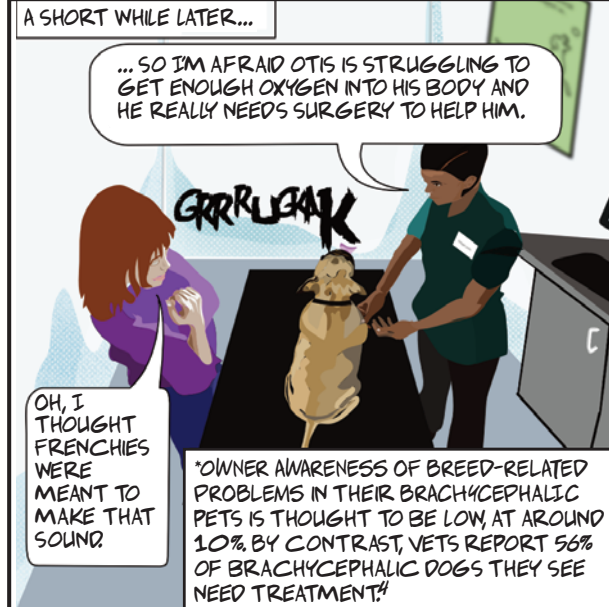I SUPPOSE THERE ARE NO PRIZES FOR GUESSING WHAT TYPE OF DOG OTIS IS.

A SHORT WHILE LATER...

... SO I'M AFRAID OTIS IS STRUGGLING TO GET ENOUGH OXYGEN INTO HIS BODY AND HE REALLY NEEDS SURGERY TO HELP HIM.

GRRRUGAK

OH, I THOUGHT FRENCHIES WERE MEANT TO MAKE THAT SOUND.

*OWNER AWARENESS OF BREED-RELATED PROBLEMS IN THEIR BRACHYCEPHALIC PETS IS THOUGHT TO BE LOW, AT AROUND 10%. BY CONTRAST, VETS REPORT 56% OF BRACHYCEPHALIC DOGS THEY SEE NEED TREATMENT.[4]

CORRECTIVE SURGERY FOR BOAS INVOLVES SEVERAL INTERVENTIONS :
• **WIDENING** OF STENOTIC NARES (A)
• **PALATOPLASTY** OF THE ELONGATED SOFT PALATE (B)
• LARYNGEAL **VENTRICULECTOMY** (C)
• TONSILLECTOMY

BOAS SURGERY CARRIES A RISK OF **MAJOR COMPLICATIONS**.

POSTOPERATIVE **DYSPNOEA** SECONDARY TO TISSUE SWELLING AND **ASPIRATION PNEUMONIA** ARE COMMONLY REPORTED.[5]

(A) BEFORE / AFTER

(B) HARD PALATE / SOFT PALATE / TONGUE / EPIGLOTTIS

(C) HARD PALATE / SOFT PALATE / EVERTED LARYNGEAL VENTRICLES / EPIGLOTTIS / TONGUE
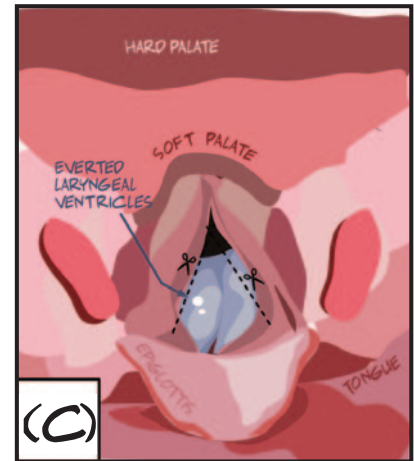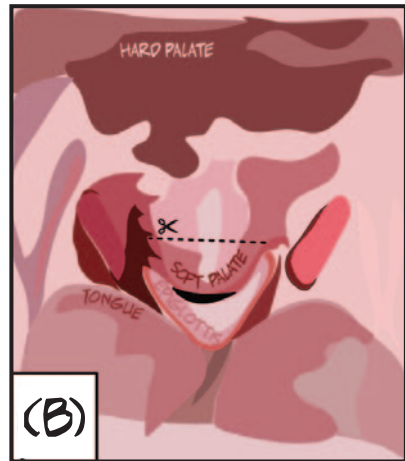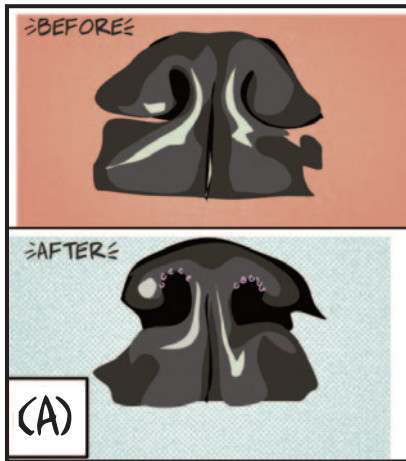
MANY VETS WHO REGULARLY ANAESTHETISE COMPANION ANIMALS ANECDOTALLY REPORT THAT BRACHYCEPHALIC DOGS TAKE **LONGER** THAN MOST OTHER PATIENTS TO RECOVER FROM GENERAL ANAESTHESIA, IRRESPECTIVE OF THE SURGICAL PROCEDURE THAT THEY HAVE UNDERGONE

A COMMONLY HELD BELIEF AMONGST VETERINARIANS IS THAT THIS IS BECAUSE THE ENDOTRACHEAL TUBE ALLOWS THE DOG TO **BREATHE PROPERLY**, POSSIBLY FOR THE FIRST TIME IN ITS LIFE.

COME ON, LITTLE GUY. ITS ALL OVER, YOU CAN WAKE UP NOW!

ZZZZZZZZZZZZZZZZZZZZZZZZZZZ

BRACHYCEPHALY IN DOGS PREDISPOSES THE ANIMAL TO SEVERE CLINICAL DISEASE WHICH HAS SIGNIFICANT IMPACT ON ITS QUALITY OF LIFE. SO UNIQUE ARE THE HEALTH PROBLEMS THESE BREEDS FACE, FRENCH BULLDOGS ARE **NO LONGER CONSIDERED A "TYPICAL DOG"** HEALTH-WISE. [6]

THE VETERINARY PROFESSION IS LEADING THE DRIVE TO REVERSE THIS TREND THROUGH **AWARENESS AND EDUCATION INITIATIVES** AIMED AT VETERINARY PROFESSIONALS, OWNERS, BREEDERS, POLICY-MAKERS, MARKETING PROFESSIONALS AND INFLUENTIAL CELEBRITIES.

HOW CAN **MEDICAL WRITERS** HELP TO IMPROVE THE WELFARE OF BRACHYCEPHALIC BREEDS?

1. ASK YOURSELF IS AN IMAGE OF A BRACHYCEPHALIC DOG **ESSENTIAL** FOR THE CONTENT OF YOUR PROJECT.

IF THE ANSWER IS "NO", THEN OPT TO USE AN IMAGE OF A DOG WITH A **NORMAL CRANIOFACIAL MORPHOLOGY**.

2. IF YOUR PROJECT ABSOLUTELY REQUIRES AN IMAGE OF A BRACHYCEPHALIC BREED, THEN CONSIDER USING A SUBJECT WHICH HAS BEEN **BRED RESPONSIBLY**.

IN DECEMBER 2021, THE KENNEL CLUB IN THE UK REVISED THEIR BREEDING GUIDELINES FOR FRENCH BULLDOGS TO PRODUCE PUPPIES WITH **ELONGATED MUZZLES AND OPEN NOSTRILS**.

THE ONLY ACCEPTABLE RATIONALE FOR USING IMAGES OF EXTREME BRACHYCEPHALY IS TO **ILLUSTRATE** THE CLINICAL IMPACT OF BOAS AND OTHER BREED-ASSOCIATED DISEASE.

FLARED NARES

ELONGATED MUZZLE

3. **ENGAGE** WITH ORGANISATIONS WHICH ARE WORKING TO RAISE AWARENESS ABOUT THE WELFARE OF BRACHYCEPHALIC DOGS. CURRENT CAMPAIGNS CAN BE FOUND HERE:

HTTPS://WWW.FECAVA.ORG/POLICIES-ACTIONS/HEALTHY-BREEDING-3/

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THE END

Teaching Medical Writing

The flipped classroom: A new perspective

Claire Gudex
cgudex@health.sdu.dk

M edical writers who teach academic writing or offer educational workshops might find that a flipped classroom approach offers new perspectives and innovative strategies for enhancing their students' learning.

The intention of the flipped classroom approach is to free up face-to-face class time for creative, interactive, and higher-order learning activities that can give learners greater understanding and retention of concepts.[1,2] In the flipped classroom, participants engage with online material *before* receiving instruction in it in the physical classroom. It is thus a type of asynchronous education. Typical activities in the flipped classroom are pre-recorded videos and quizzes, but discussions, debates, simulations, and peer feedback can also be used.

A meta-analysis published in 2018 found that a flipped classroom approach significantly improved student learning compared to a traditional classroom approach in the general education of medical, pharmacy, and nursing students.[3] The 28 studies (18 from the US and the others from China, Taiwan, Australia, Canada, and Saudi Arabia) involved 2295 students exposed to a flipped classroom and 2420 students exposed to a traditional classroom. Student learning was measured through posttests and exams.

Similarly favourable results for a flipped classroom were reported in a US study of college students on an advanced writing course comprising eight lessons on language structure and the writing process.[4] The students participated in traditional teaching or a flipped classroom with pre-class videos and quizzes, and learning was assessed through pre- and post-tests.

Medical writers can benefit from these experiences of using a flipped classroom approach in medical education. The main lessons learned are summarised below.

Pre-recorded videos in the flipped classroom

Many students prefer pre-recorded videos to traditional classroom learning because they feel more motivated and engaged.[3-6] Other benefits of using pre-recorded videos in the flipped classroom include:

a. Unrestricted access to the video lectures before class allows students to learn at their

own pace, and they can watch a video multiple times to better understand the topic.[1,3]

b. The freeing up of time in the physical class enables interactive and collaborative activities in the physical classroom, as in the following examples:

- In the advanced writing course reported by Pavanelli,[4] students watched online instructional video lessons on different aspects of language before the class and completed their homework and assignments inside the class, where they worked with the instructor and their peers to share their understanding of the video lessons and received instant feedback on their writing.
- Saba Ayon[6] used videos, PowerPoint presentations, and handouts in a course on how to write different forms of correspondence and scientific texts for engineering, business administration, and graphic design students at a Lebanese university. Face-to-face class time was used for group work and discussions, students' questions, and feedback.
- In a course on English reading and writing for Chinese college students, Zhang[5] created a flipped classroom of videos covering key vocabulary, reading comprehension, text analysis, and writing skills. The face-to-face sessions were devoted to peer interaction activities (group discussion or project) and teacher-student feedback.

c. With a flipped classroom approach, the teacher's role changes from an instructor to a facilitator who is able to check the student's understanding, facilitate learning, and encourage deeper exploration of the topic.[5]

Using pre-recorded videos in the flipped classroom can also have drawbacks, however:

a. Students may be dissatisfied with the amount of pre-class work they are expected to do in the flipped classroom.[2,3,6] Therefore, the total length of all combined video segments is recommended to be maximum 20 minutes.[3]

b. Although students watch the pre-recorded video tutorials, they may not interact with the content and thus not engage as active learners.[7]

c. If some students do not watch the pre-class videos, they cannot work effectively with their teammates in class, putting extra pressure on the teacher and other students.[2]

d. Engin & Donanci[1] found that despite positive feedback on the pre-class videos, most students preferred to have both the video input and an overview from the teacher in the following class so that they could ask questions if they did not understand the input. These authors now include a question-answer session at the start of the face-to-face session.

Quizzes in the flipped classroom

In their meta-analysis, Hew and Lo found learning benefits from short educational quizzes before the start of a face-to-face class.[3] This finding was supported by Lee,[2] who combined flipped classroom and team-based learning in an English composition course. The quizzes were developed by the instructors beforehand and were used to assess student learning of the pre-class learning materials. Several findings emerged from these studies:

1. The quizzes helped students recall prior knowledge. Consulting prior knowledge helps learners make better sense of new information by connecting it to something they already know.[8]

2. Pre-class quizzes allow the instructor to identify misunderstandings or difficulties and to take remedial action in class, including altering the content of the class (often called "just-in-time teaching", JITT).

3. Quizzes can motivate students to use the pre-class material. In the advanced writing course reported by Pavanelli,[4] students watched pre-class videos and submitted online quiz answers to ensure they came prepared for class. The questions were reviewed at the start of class, and students then worked collaboratively with the instructor and their peers to share their understanding of the video lessons. Saba Ayon[6] also gave her student pre-class tasks such as short-answer questions and multiple-choice quizzes, and students who failed to submit their answers were considered absent on that day.

The importance of planning

As in all courses, the objectives of the flipped classroom must be determined before the activities are designed. The increased student participation and dialogue may lead to more effective learning, but instructors may not be able to cover as much material as they have in the past, so they may need to review the learning outcomes of the course.

Creating appropriate learning and assessment activities for the flipped classroom can increase the instructor's workload. Time and effort are required to think about the aim and design of the activities and to then prepare both the pre-class and in-class activities.[6] On the plus side, the pre-class activities can often be reused in the next course with less effort.

Students might resist changing from a lecture approach to a flipped classroom because being passive in a lecture may be easier and less intimidating than being actively involved in a class. Instructors using a flipped classroom need to ensure student understanding of the approach by explaining its rationale and potential benefits.[3] Instructors should state their expectations for the students' input and the amount of time students will need to invest in order to be ready for the class activity.

Wide range of possibilities for flipped classroom activities

Hew and Lo[3] note that video lectures can use different styles such as recorded classroom lectures, freehand writing videos as used by the Khan Academy (www.khanacademy.org), or PowerPoint presentations with the instructor talking or with 2 to 3 people in conversation. Other possibilities are screencasts (recording of a computer screen, usually accompanied by audio narration or captioning) and podcasts (audio files that can be downloaded and listened to) or reusing online content such as websites and videos. Video content should be concise (e.g. maximum 10 to 15-minute segments) and can

include guiding questions to help students recognise key messages in the pre-class activity.

Fassihi created a flipped classroom design for an English as a Second Language (ESL) course in academic writing.[9] She recreated her original face-to-face course as a series of homework and class assignments that mixed videos (created on her own laptop) with assessments, exercises, and online feedback sessions. Instead of reading and annotating her students' essays, she used a screen capture tool to record herself as she reviewed the essays and provided verbal feedback. Students received a 3- to 4-minute video in which they could watch her screen as she read through the essay, offering constructive criticism. This was more efficient feedback for both instructor and student as the corrections were faster and easier to explain verbally than as written comments.

The Flipped Learning Network

(www.flippedlearning.org)
The Flipped Learning Network (FLN), a non-profit online community for educators interested in flipped learning practices, notes that a flipped classroom does not necessarily lead to *flipped learning* unless four 'pillars' are incorporated:[10]

1. *A flexible environment* to ensure different learning modes to meet different learners' needs, including a flexible timeline for students to learn at their own pace and flexible spaces that allow students to choose the place and time to learn.
2. *Fostering a learning culture* that moves from a teacher-centred approach towards a student-centred approach and helps students to construct their own learning.
3. *Intentional content* with clear identification of

the materials to be taught in class and those to be explored by the student at home so that classroom time is maximized and used for active learning strategies.

4. *The professional educator* who facilitates student learning and can plan and assess learning activities and act as mentor and problem solver.

Summary

The flipped classroom approach appears to have considerable potential for effective learning and could be highly relevant in medical writing courses and EMWA's educational training. It allows more class time to be spent on applying key concepts in collaborative and interactive ways and can increase student motivation and engagement in learning. If you are looking for a new approach to your teaching, you might like to experiment with a flipped classroom and explore how preparatory online activities could enhance your students' learning experience.

> The flipped classroom approach appears to have considerable potential for effective learning and could be highly relevant in medical writing courses and EMWA's educational training.

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My First Medical Writing

SECTION EDITOR

Evguenia Alechine
ealechine@gmail.com

Editorial

As always, this section brings you the best of EMWA's rising stars. This time, I had the pleasure to work with Sofia Urner on her article about the scientific pros and cons of coffee.

Sofia obtained a PhD in biology and has extensive experience in biomedical research, mainly in cardiovascular biology and diabetic complications. During her career as a scientist, she has worked in different countries (Germany, USA, Australia), authored several scientific publications, and successfully applied for grants.

Following her passion for medical communications, she is now a freelance scientific and medical writer.

Grab your favourite cup of coffee and enjoy the read!

Evguenia

Good or bad – how does coffee influence our health?

Sofia Urner
info@sofia-urner.com
Düsseldorf, Germany

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First thing in the morning. Every day. Usually black but sometimes with milk. This is how I drink my coffee. And I love it. It is not only because of the taste and the energy kick but also because of the time I dedicate to myself and my coffee. I am sure coffee drinkers know exactly what I mean. But what is the actual magic of coffee? And how does coffee affect our health? Let's have a look at what science is saying.

The magic of coffee

Coffee is one of the most consumed drinks worldwide. It is obtained by brewing roasted seeds of the plant genus *Coffea*. The two most popular and commonly used species for coffee production are *Coffea arabica* (Arabica coffee) and *Coffea canephora* (Robusta coffee). The actual coffee beans are the seeds located in the red berries of the coffee plant. It takes 7 to 11 months for the berries to ripen before the coffee beans can be harvested, dried, and processed into coffee.

Coffee contains more than 1000 chemical substances, including various bioactive components with beneficial effects at the cellular and physiological levels. These include, but are not limited to, stimulatory, antioxidant, and anti-inflammatory effects.[1-3]

The most famous and probably the most studied ingredient in coffee is the alkaloid caffeine. The plant uses caffeine as a toxic defence strategy against pests like insects. Luckily, caffeine does not have the same effect on humans, so we can fully enjoy its positive properties. The most prevalent effect of caffeine relates to its structural similarity with the endogenous molecule adenosine. Adenosine acts by binding to specific adenosine receptors in the brain. These receptors slow down neural activity and make us feel tired and sleepy. Caffeine acts as an antagonist of adenosine receptors, which means it can bind to them with a similar affinity, blocking their signalling and promoting alertness and wakefulness.[2] Thus, the energising effect of coffee is indeed related to caffeine.

These effects occur shortly after the consumption of coffee. Generally, caffeine is absorbed by our stomach and small intestine within 30-45 minutes, and its blood concentration peaks shortly after. It is then metabolised in the liver by the cytochrome P450 oxidase enzyme system, which breaks it down to paraxanthine (84%), theobromine (12%), and theophylline (4%). These caffeine metabolites also directly impact physiological processes, such as stimulating fat metabolism, increasing urine volume, and relaxing smooth muscles.[1] In healthy adults, the half-life time of caffeine, which is the time it takes to reduce its plasma concentration by 50%, is approximately three to four hours, but can vary widely. For example, under specific hormonal influences like pregnancy, caffeine has a half-life time of nine to 11 hours.[1,2] This highlights the variety of immediate and delayed effects coffee has on our body, from boosting energy levels within minutes to longer-term metabolic adaptations lasting several hours.

Although it sometimes seems that caffeine alone is the star of coffee, other bioactive substances also significantly contribute to its magic. These include other alkaloids (like trigonelline), polyphenols (like chlorogenic acid), or diterpenes (like cafestol and kahweol). These substances provide antioxidant, anticancerogenic, and anti-inflammatory properties. They are neuroprotective, contribute to antidiabetic effects, and are antimicrobial.[3] Furthermore, coffee is rich in vitamin B3, magnesium, and potassium, thus delivering precious micronutrients to the body.[2]

Coffee dogmas

Different dogmas about coffee contribute to the debate on whether coffee is harmful to our health or not. But are these dogmas based on scientific facts? Let's have a look at two common ones:

Does coffee raise blood pressure?

Hypertension, or increased blood pressure,

> Coffee contains more than 1000 chemical substances, including various bioactive components with beneficial effects at the cellular and physiological levels.

affects more than 30% of adults and is a risk factor for severe health complications, such as heart attack, stroke, or kidney failure.[4] The bioactive components in coffee directly or indirectly affect blood pressure regulation. Caffeine alone influences blood pressure via several mechanisms. It stimulates the narrowing of blood vessels, activates the sympathetic nervous system, and controls the water and electrolyte levels in the body.[5] Due to these mechanisms, blood pressure increases shortly after caffeine consumption. However, coffee also contains substances with blood-pressure-lowering effects, such as chlorogenic acid or trigonelline, which may compensate for the pro-hypertensive actions of caffeine.[6] Several studies have tried to clarify whether a direct correlation exists between coffee consumption and blood pressure. Although the conclusions on the effects of drinking up to three cups of coffee per day are conflicting, with studies showing beneficial, neutral, or negative outcomes,[7-9] drinking more than three cups of coffee daily is mainly associated with a reduced risk of hypertension.[7,10,11] This suggests even protective effects on cardiovascular health. However, it should be highlighted that these effects have been observed in habitual coffee consumers, while non-regular coffee drinkers are more likely to have increased blood pressure after drinking coffee.[6] A possible explanation for this is that habitual coffee drinkers become tolerant to caffeine, thus diminishing its effects on blood pressure. Also, regular coffee consumption has been shown to positively change the gut microbiota, such as by increasing *Bacteroides*, associated with lower blood pressure.[6,12] In general, several factors influence the risk of hypertension, and coffee consumption is only one of many variables, such as age, lifestyle, and genetics.

Does coffee consumption lead to irregular heartbeat?

Caffeine can affect the heartbeat by increasing catecholamine (adrenaline and noradrenaline) levels in the blood, leading to an increased heart rate.[13] Therefore, caffeine has a reputation for stimulating irregular heartbeat, also called arrhythmia. However, a meta-analysis of several studies failed to find an association between coffee consumption and an increased risk of arrhythmia.[14] Furthermore, studies show that habitual drinking of one to three cups of coffee daily can even reduce the risk of arrhythmia, with each additional cup further lowering the risk.[15-17]

The facts – coffee and mortality

Because coffee has such a wide range of physiological effects, both negative and positive impacts of coffee on health can be found if looking at specific health aspects. For example, coffee has been associated with increased blood cholesterol levels, lower bone density, or increased risk of spontaneous abortion in pregnant women.[1] On the other hand, coffee has also been shown to decrease the risk of Parkinson's and Alzheimer's disease, prevent certain cancers, or reduce the risk of developing type 2 diabetes mellitus.[1] Therefore, a more holistic approach may be required to answer the complex question of whether coffee is harming or improving our health in the long term.

In this regard, many extensive studies have analysed the association between coffee consumption and mortality, considering and adjusting for relevant lifestyle factors, such as smoking, physical activity, or alcohol consumption, and primarily suggest positive effects of coffee. A recent study with over 460,000 UK Biobank participants and a follow-up time of approximately 11 years showed that consuming half to three cups of coffee per day lowers the risk of all-cause mortality, death due to cardiovascular events, and incident stroke events.[18] Another study, including over 520,000 participants from 10 European countries with a mean follow-up time of approximately 16 years, concluded that consuming three or more cups of coffee daily is associated with lower all-cause mortality.[19] These positive effects of coffee consumption on

mortality have been confirmed in another recent study including around 170,000 Korean individuals over a follow-up time of approximately nine years.[20] Strikingly, drinking decaffeinated coffee has similar health benefits, suggesting that the positive effects of coffee are not exclusively due to caffeine.[18]

Long live the coffee drinker!

Let's get back to our initial question – is coffee good or bad for our health? According to recent research, coffee consumption seems mainly beneficial. In individuals without underlying health conditions, the complex health-supporting properties of coffee likely outweigh potential health risks. Knowing this, we can enjoy our daily coffee – or two. However, as with everything in life, it is probably all about balance in the end.

Sofia Urner

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Gained in Translation

Editorial

We recently had the pleasure of welcoming Raymond Manzor, a very enthusiastic new member to our team of writers for the section Gained in Translation.

That was a great opportunity to discuss our working methods as medical translators.

Raymond decided to have an in-depth look into his day-to-day work and to explain it in his article. As he rightly writes, medical translation is not magic, but rather a skillful mix of searching for information, evaluating its relevance and constantly questioning the quality of the documentary sources.

Thus, having a medical background as a medical translator can be an advantage, but is not an essential criterion. However, it is essential for a medical translator to master the three tactics Raymond outlines in his article: proximity, comparison, and reliability.

Aurelie Gobet

But don't you need a medical background to do that?

This is a frequent question medical translators get asked. And it is not an easy one to answer, especially if the person asking it has a medical background.

It is also a legitimate question. With many medical texts, years of research may be on the line or a patient's health may be at risk. Can someone with a background in literature and languages be trusted to translate such vital documents?

The short answer is yes, they can. This article will explain how.

Before we begin, a note to the reader. As I translate from French to English, I will illustrate my points using French terms such as "traitement de première intention". I will not necessarily explain the terms, however. I want the reader to follow the thought processes of the translator as we move from an unfamiliar term in French to an English translation.

Additionally, by "medical background" I mean anyone who has trained or worked in any field relating to healthcare, medicine, pharmacology, or clinical research. I do not have a medical background.

It's not magic

So how can a medical translator know that they have the right translation without a medical background? Well, we might mention a thrill of certainty, a tingling in the tummy, or a humming in the ears.

But these do not sound very scientific, do they? We need something more concrete than tinglings and hummings. Tempting as it is to explain translation as some mystical intuition, the reality is quite prosaic. It is training and experience that lead to accurate translations,

because we are taught to do our research properly. Between the advice of our experienced tutors and the merciless critiquing of our peers, we quickly develop research tactics to head off objections to our translations. Three of those tactics are proximity, comparison, and reliability.

Proximity

One tactic we employ when we encounter an unfamiliar term is to scan nearby words for clues about the immediate and wider context of the term we are stuck on. As an example, say we are translating an article about non-small cell lung cancer (NSCLC), but we are unsure how to translate "traitement de première intention" into English. If we search around the problematic term, we might notice "pembrolizumab". "Traitement" might be "treatment" or "therapy". These two words give us hints regarding the immediate context. We also know that the document is about NSCLC. This is our wider context. So, we type "pembrolizumab", "treatment", and "NSCLC" into a search engine and start reading. Our eyes might be drawn to the words "first line": "first" looks like a good fit for "première"; and "first line" keeps appearing next to "pembrolizumab" and "treatment".

If the translator notices a tingling in the tummy, we are on the right track. But tinglings are of limited use. We need proof. We need to challenge our intuition.

And we do that by comparing it.

Raymond Manzor
raymondmanzor@gmail.com

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Comparison

We double-check our intuition about "first line" by exploring it in settings other than NSCLC. We open a new tab and type "first-line treatment" in quotation marks on its own. The search should yield a host of websites with definitions of the expression, for instance the NCI Dictionary of Cancer Terms. Now that we have a definition, we compare it against that of the original "première intention" on French oncology websites to see if they match.

And we can go further. If the English definition refers to "second line" and "third line", we triple-check our term by testing "traitement de *deuxième* intention" and "traitement de *troisième* intention" in the French literature as well. If the French term continues to mirror the English, and it does, our certainty grows.

Still, we might push our research even further. And to do so, we return to the tactic of proximity. Rather than just scanning the words around "first line", we might cast about for other clues in nearby sentences or even in the next paragraph. For example, if the French author is writing about NSCLC and pembrolizumab, they may mention a dosage regimen: say, 200 mg every

> One tactic we employ when we encounter an unfamiliar term is to scan nearby words for clues about the immediate and wider context of the term we are stuck on.

Figure 1. The three tactics of proximity, comparison, and reliability and their interplay as we research a medical translation

3 weeks as a 30-minute intravenous infusion. We return to the English literature on pembrolizumab as first-line treatment for NSCLC, except this time we put "200 mg" in quotation marks. Lo and behold, we find the same dosage mentioned in English sources.

We might be content to stop our research here. But there is one element that we have not considered yet, but that we prize above all others.

Reliability

As medical translators, we learn early in our careers to vet our sources.[1] When we research a term like "first line", do we leap at the first result to pop up in Google? Absolutely not. The information must be reliable, so we vet the source. It is beyond the scope of this article to discuss everything we look at while vetting our sources. For now, let's focus on four elements.

The first is the domain extension. If translating into English for example, ".uk", ".au", ".ie", or ".nz" can probably be trusted. And ".edu" and ".ac.uk" are even better. Conversely, ".fr" or other domain extensions for French-speaking websites are a definite red flag if we want to be sure of a term in medical English.

The second element is the publisher. If it is *The BMJ*, the *New England Journal of Medicine*, or a professional organisation, then we keep reading. If it is a medical journal or a professional organisation from a non-English-speaking country, however, we might think twice before trusting their English – even if the science is impeccable!

Once we trust the domain extension and the publisher, the third element to consider is the author. Are they an expert? Are they a native English speaker? We might look at the author's title, affiliation, and name (though this last can be treacherously misleading).

And now that we are sure of the domain extension, publisher, and author, we look at the fourth and final element, the writing: is the text well presented? Are the sentences concise and well structured? Only then do we consider a text a reliable source for checking our word in authoritative medical English.

If "première intention" and "first line" repeatedly appear next to pembrolizumab for NSCLC, if the definitions of "traitement de première intention" and "first-line treatment" match in the two languages, and if the sources for "first line" are written by native English experts on English-language websites, we can safely translate "première intention" as "first line".

And if this level of research seems extravagant for such a basic word as "first line", bear in mind that the whole process that we have just discussed took no more than five minutes when I first came across "traitement de première intention" in one of my earliest medical translations. Explaining all the thoughts that went through my head, on the other hand, takes a little longer.

A drop in the ocean

And that is only one term. Sentence after sentence, paragraph after paragraph, reference after reference, we read, search, compare, and evaluate information and sources. If we turn a Rubik's Cube this way and that and consider it

Advantages of a medical background:

☑ Less research and more time for the writing

☑ Understanding the wider context and better translation decisions

☑ Career advancement

Figure 2. The advantages of having a medical background as a medical translator.

from every angle, eventually – at least in theory – we solve the puzzle. It is the same with translating a text. As we work through it, we begin to understand what makes sense and what does not.

Slowly over the weeks, months, years, and decades, we develop strategies for finding solutions, checking them, and confirming them.

However, the crucial word is *translate*. We do not have a doctor's knowledge or skills. We cannot diagnose an arrhythmia, design a trial, or read a radiograph. Simply put, we cannot do a doctor's job. But then, we are not paid to treat patients.

So, is a medical background superfluous?

Certainly not. Having a medical background helps medical translators. Subject matter expertise means less time researching unfamiliar terms and concepts, and more time focusing on word choice and phrasing. The result is frequently a better translation.

A medical background also ensures a broader knowledge of the subject being discussed. It makes it easier to grasp the wider context of the text and gauge the reliability of sources. Again, this leads to a faster, accurate translation and fewer mistakes.

Finally, having an MD or similar after our name can open doors to career advancement that would otherwise be closed. Regardless of whether such training is truly needed by medical translators, many recruiters and clients want proof of subject matter expertise. For this reason alone, a medical background is worth having. Not only does it help translators hone their craft, but it enhances their legitimacy in the eyes of recruiters and clients.

Then a medical background is a must?

On the face of it, it certainly is a considerable advantage and can improve the quality of translations.

But this only holds true to a point. There are

> However, the crucial word is translate. We do not have a doctor's knowledge or skills. We cannot diagnose an arrhythmia, design a trial, or read a radiograph. Simply put, we cannot do a doctor's job.

dangers in entering the translation field with a medical background. Such translators may know as much about the subject of the text they are translating as the author. As we said, this knowledge speeds up research and frees up more time to concentrate on the writing. But if the translator feels comfortable with the subject matter, will they give careful thought to every word and phrase they commit to paper, as a trained, experienced translator would, or might they just assume that they have the answers already? This will depend on their experience not in the medical world, but in translation. The more they translate, the more they will know to check, double-check, and triple-check every word. For instance, if translating "numération sanguine complète" into UK English, will they assume that "complete blood count" is correct because it is more familiar, or will they explore UK-based websites

and notice "full blood count"?

Another danger to having a medical background is that it may be difficult to put the reader first. After all, the curse of knowledge is very real.[1] For anyone unfamiliar with this concept, it is a cognitive bias in which a person assumes that what they know, everyone knows. Indeed, it is a mistake any translator can make. Yet we write and translate for the reader, not for ourselves. Sometimes, a pinch of ignorance helps us see the text from the reader's perspective. Even among specialists, not every reader has the same knowledge. They may be younger or older than the author, have more or less experience, or practise in a different specialty.

What is more, a medical background does not imply medical omniscience. To take an example from my personal experience, I once went to a general practitioner early in my career for help with a translation relating to cardiology. I wanted to know if my translation made sense. The general practitioner told me that it did, but only "If you're used to this kind of thing". When I asked what he meant, he told me that the translation read like the work of a cardiologist, but that he could not understand the meaning.

Therefore, if years of training and experience as a general practitioner do not suffice to decipher a text about cardiology, where does that leave us? It is rare, though possible, to have a background in cardiology and only translate texts about that field. For most translators, however, they will be asked to translate on a myriad of topics from different specialties. The only way to prepare, then, is to read journals, attend webinars and conferences, and interact with specialists. Yet ultimately, no one can know everything ahead of time. We only realise what knowledge we need when we open the text. The only common thread, sometimes, is that every text is a translation.

Horses for courses

As we have seen, there is no great mystery about it: medical translators are trained to research their work carefully. Over time, we develop tactics, ways of fine-tuning our research. Three of these tactics are proximity, comparison, and reliability. We learn to triple-check every word. And if we are unsure, we ask.

There is no doubt that having a medical background may give a medical translator an edge over their peers. It speeds up the research phase, which means more time to concentrate on the writing. But those with a medical background must wield their knowledge carefully. They cannot know everything. And they must still know and apply the basic principles of translation: check everything and put the reader first.

In the end, we are not diagnosing a patient or developing a medicine. Our job is to translate; our knowledge and skills as translators must come first.

Acknowledgements

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The author declares no conflicts of interest.

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Author information

On obtaining his MA in Translation in 2012, **Raymond Manzor** swore never to work in medical translation. Fate had other ideas, however, and he soon specialised in translating manuscripts from French to English. He now edits and writes as well and has a special interest in disease prevention and health promotion.

The Crofter: Sustainable Communications

SECTION EDITOR

Kimi Uegaki
kimi@iwrite.nu

Editorial

Greetings from the croft! When I was growing up, my mother regularly reminded us about taking care of our health as it is our most important possession. I have to admit that during my teens and 20s, when I felt invincible, I would respond with a "Yeah, Mom" and roll my eyes. Then life happened, and I came to appreciate her words more and more on a personal and professional level. Learning how to optimise my health and make the right choices for myself so that I can be a productive individual for as long as possible has been a lifelong quest, and has become especially important as a freelance medical writer working from home. So you can imagine how happy I was when – in my late 40s – I met Mariella Franker, a scientific writer turned natural productivity coach for introverts. Our conversations have been filled with "aha" moments for me and I'm very thankful for Mariella's contribution to this issue of the Crofter in which she shares her perspective and practical tips for sustaining our productivity.

Wishing you happy reading and many "aha" moments.

Best,
Kimi

Sustainable productivity: A new approach to work-life balance and helpful practices for introverts

Mariella Franker
www.thefrankermessage.com

Freelance medical writers are well accustomed to the virtual workplace, often doing their work remotely and connecting with their clients through technology rather than in person.

Remote work offers some valuable advantages compared to working in the office, for example, increased flexibility and not being bound for set working hours or a fixed work location. Working remotely provides many options to create a highly personalised version of work-life balance.

However, if you don't pay attention, the boundaries between your personal life and your work life can become obscured, and you find yourself working all the time, spending less time with your loved ones, and not getting enough rest or caring for your health. In short: you are further away from the lifestyle you may aspire to. The answer to this is to focus on sustainable productivity from an individual standpoint and to pay attention to your specific needs. Specifically for introverts, I've included three helpful practices to stay mindful about your needs on a day-to-day basis.

What is sustainable productivity?

The Leadership circle from Clearwater Consulting, a consulting company specialised in effective leadership programmes, defines sustainable productivity as how well a leader balances human and technical resources to sustain long-term high performance.[1] A recent article by MIT Sloan School of Management explains that sustainable productivity focuses on employee engagement and well-being in addition to more traditional metrics such as sales, inventory, and revenue.[2]

These definitions are seen from an organisation-wide standpoint and can also be transferred to individuals by asking questions like this: What's needed in my life to balance my health and well-being with long-term high performance?

Well-being is the missing link in sustainable productivity for remote workers

Health and well-being aren't the first things that come to mind when we think of being productive or having an impact with our work. In the aftermath of the recent crisis (and possibly recession still to come), many of us are being stretched to the limit. Mental health issues, such as post-traumatic stress disorder and burn out, have increased during the pandemic, most notably among healthcare workers[3] and remote workers.[4,5]

Remote work by its very nature requires careful attention to find a healthy balance. Our personal life and our work life aren't separated by a commute to the office or by office closing hours. It is our responsibility to set these boundaries and to actively work on a healthy work-life balance.

> What's needed in my life to balance my well-being with long-term high performance?

Busy does not equal productive

One of the common misconceptions is that when we're busy, we're automatically productive. Phrases like "get things done", "just do it", and "non-stop hustle", which are eagerly thrown around in the productivity and motivation area, reinforce this belief.

However, busy does not equal productive. Busy means being engaged in activity, i.e., any activity. We can keep ourselves endlessly busy with unimportant tasks, like checking email, sitting in lengthy meetings, and browsing on social media, that don't bring us any closer to our goals – or our desired lifestyle for that matter. Being busy instead of productive doesn't help us to make real progress and we end up feeling overwhelmed, stressed, and dissatisfied with our work.

Productivity, on the other hand, is marked by abundant production or achievement. Being productive isn't about engaging in any activity but it's about doing those few things that have the most impact. When you engage in activities that have a big impact on your overall goal, you quickly make progress, and you can push that

goal much further than you could have otherwise. It also reduces overwhelm and stress and you have a bigger sense of achievement because you can see that you're making progress. Sustainable productivity balances the impact of your work with your ability to sustain that impact over time, which is where our well-being comes into play.

Well-being on a day-to-day basis

While in the past taking care of our well-being was reserved for yearly vacations, lockdowns and travel restrictions have taught us that we need to adequately take care of ourselves on a day-to-day basis.

This is especially challenging in modern society where our attention is constantly pulled into different directions. Multi-tasking,[6] increased sedentary time,[7] and, more recently, zoom fatigue[8] are health-related issues that have increased among remote workers in recent years. The demands of doing remote work without a set structure and our desire to live a flexible lifestyle require a new, individual approach to sustainable productivity.

> Productivity is about doing those few things that have the most impact

Three helpful practices for sustainable productivity

Creating an individual approach to sustainable productivity doesn't necessarily require dramatic shifts, like switching fields or finding a new job. Small changes on a day-to-day basis have a big impact and can create a much more satisfying work-life balance. Here are three helpful practices that you could introduce into your life right now.

1 **The start of your day is for you**

How often do you start the day rushed? Perhaps you go straight from the frenzy of the school run to your desk and quickly get to work on your next assignment. Or perhaps there are already hundreds of to-dos bouncing around in your head the moment you wake up. With so many things on our plate and so many things that are pulling at our attention, it's not surprising that we feel rushed and "already behind" from the moment we wake up. However, how we start our day can set the tone for the rest of our day.
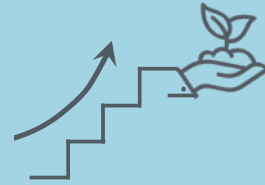
The greatest practice to go from rushed and stressed to calm and capable is to give yourself permission to prioritise your own goals and to give them a place of honour in your day. That place of honour could be right at the start of your day, to make sure that they don't get bumped to the end of the list (again) and to set the tone for your day.

Figure 1. Infographic: An individual approach to sustainable productivity.

A sustainable productivity approach will be important for remote workers to adapt to the recent and future changes of the remote workforce. Here, I summarise what productivity is and what it is not and I include 3 helpful daily practices for sustainable productivity on an individual level.

An individual approach to
sustainable productivity

WHAT SUSTAINABLE PRODUCTIVITY IS NOT

✗ working all the time
✗ spending less time with loved ones
✗ constantly feeling busy
✗ your health and well-being come last
✗ work comes first and the rest of your life slots in

WHAT SUSTAINABLE PRODUCTIVITY IS

✓ healthy work-life balance
✓ productive instead of busy
✓ doing the few things that have the most impact
✓ prioritising your health and well-being
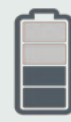✓ your work supports your desired lifestyle

3 HELPFUL DAILY PRACTICES

1. Start your day with inspiration and joy
2. Make space for your natural working process
3. Rest before your energy is depleted

Mariella Franker

process is different, but one is not more valuable than the other. By making space for yours, you're supporting your unique strengths and bringing unique value to the people around you.

3 Rest before your energy is depleted

If the pandemic has taught us anything, it is to not wait for the yearly vacation or until we have a big chunk of time to take a rest. Sustainable productivity is equal parts working and resting. Small snippets of daily self-care are very effective to achieve a healthy work-life balance. For introverts especially, resting plenty and often is a key element of sustainable productivity. Because of the way introverts process the world around them, they can easily become overstimulated and are prone to energy fatigue. Replenishing this energy is essential to their well-being and to work at their best.

Resting includes getting enough sleep and getting "quiet time" during the day. Quiet time allows introverts to go through their natural self-reflection process. This is important for problem solving and deciding which next steps to take. When introverts don't get enough quiet time many of them experience anxiety and stress and their inner critic becomes very dominant, further hampering their progress.

Creating opportunities for quiet time doesn't have to be difficult and you can start with something as simple as taking a 5-minute break after a zoom meeting. Keep a list of shorter and longer activities that help you to relax and to recharge your energy and plug them in whenever you feel fatigue setting in. This will ensure that you get enough rest and quiet time during the day and that you don't deplete your energy.

Adapting to today's – and tomorrow's – virtual workforce

Although the remote workforce isn't new, the pandemic has accelerated technological advances

It can take as little as ten minutes a day to make this change. Look for things that inspire you and that bring you joy. This could be anything from a short meditation, to watching an inspiring video, to taking a short walk. Giving yourself permission to prioritise your own needs and wishes is the basis for sustainable productivity: doing those few things that have the most impact while caring for your well-being.

2 Make space for your natural working process

Your natural working process connects to the way that you naturally solve problems and how you work at your best. Everyone's natural working process is a little bit different and what you need to work at your best is unique. When we look at the general personality traits of introverts and extroverts, we can already see a few differences.

For example, most extroverts formulate their thoughts and ideas while speaking and will engage in conversation quite early in the exploration process (the classical brainstorm technique). Introverts, on the other hand, explore and formulate their thoughts and ideas through an extensive self-reflection process and it's only after that process that most introverts will engage in conversation.

Western society generally adheres to a more extroverted standard and qualities like decisiveness, quick action, and charming talkers are admired. As a result, many introverts feel pressure to adopt these qualities at the expense of their natural process. However, the closer you stay to your natural working process, the easier it is to have a big impact with your work without feeling overwhelmed or forcing yourself to be someone you're not. Everyone's natural working

and has shifted our approach to work-life balance. With the many benefits that remote work offers, there are also challenges. A new, individual approach to sustainable productivity requires day-to-day attention to our well-being. Remember to:

- Start each day with inspiration and joy.
- Make space for your natural work process.
- Rest before your energy is depleted.

This will help you to stay productive in a sustainable way and to adapt to the changing circumstances in today's – and tomorrow's – virtual workforce.

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Author information

Mariella Franker, PhD, is a certified Natural Advantage® Productivity Coach. A former scientist and scientific writer, she now helps introverts discover their unique strengths and to be productive in a way that feels natural to them. She is co-founder of the Science and Medical Writer's Network in the Benelux, Associate Coach at De Succesvolle Introvert, and Founder and CEO of The Franker Message. Mariella can be reached at www.thefrankermessage.com.

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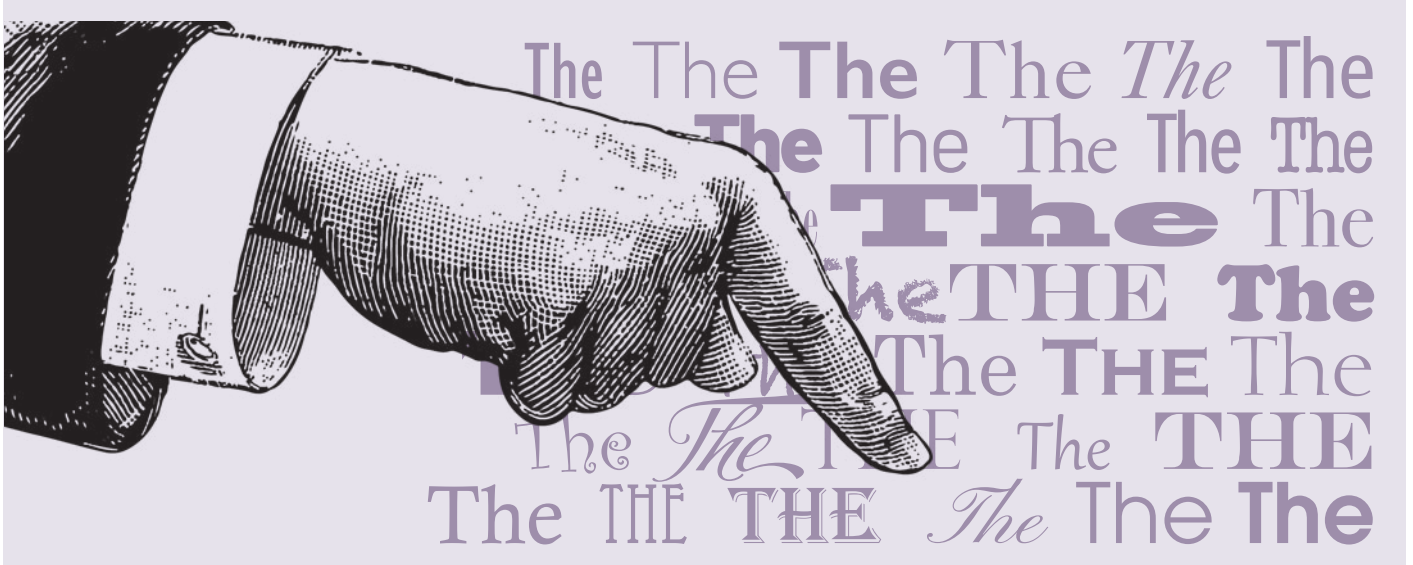# Riga, Latvia

Good Writing Practice

SECTION EDITORS

Wendy Kingdom
info@wendykingdom.com

Amy Whereat
amy.whereat@speakthespeech.fr

Syntactic grammar distraction usage or misusage:

Definite article

Introduction

Just like the indefinite article, usage of the definite article *the* is intrinsic to the language. Thus, most English-as-a-first-language authors intuitively collocate *the* with a collocatable noun by "what sounds right". In contrast, English-as-a-second language authors cannot rely on intuition, especially those authors whose first language lacks articles. However, eventual acclimation to English by English-as-a-second language authors results in an increased reliance on intuition. Until then, there are some syntactic situations which function as guidelines for *the* usage or misusage.

Usage guidelines

Inherent uniqueness

Example 1: Widely known noun
(Material and Methods section)
Haemoglobin was precipitated.

Revision
***The** haemoglobin was precipitated.*

Notes
Other examples are **the** sun, **the** hypothesis.

Example 2: Pre-mentioned noun
(Results section: results statement)
Phagocytosis by dermal fibroblasts was increased.

Revision
*Phagocytosis by **the** dermal fibroblasts was increased.*

Notes
The revision appeared in the Results section subsequent to mentioning the specific fibroblasts in the Materials and Methods section.

Grammatical uniqueness

Example 3: Subject of a sentence
(Material and Methods section)
Protein concentration of the lysate was measured.

Revision
***The** protein concentration of the lysate was measured.*

Notes
Subsequent sentences in the paragraph would be focused on the lysate *protein concentration*.

Michael Lewis Schneir, PhD
Professor, Biomedical Sciences
Ostrow School of Dentistry of University of
Southern California, Los Angeles, CA
schneir@usc.edu

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Example 4: Proper noun pre-modification
(Material and Methods section)
The lysate protein concentration was measured by Bradford assay.

Revision
*The lysate protein concentration was measured by **the** Bradford assay.*

Notes
The assay is specified by its name, "Bradford".

Example 5: Adjectival pre-modification
(Material and Methods section)
The radioactivity was calculated for collagenase-solubilised fraction.

Revision

The radioactivity was calculated for **the** collagenase-solubilised fraction.

Notes

The premodifier *collagenase-solubilised* specifies the noun *fraction*.

Example 6: Adjectival post-modification

(Introduction section: hypothesis)
The zinc-binding ligand may be related to ligand reported to bind calcium.

Revision

The zinc-binding ligand may be related to **the** ligand reported to bind calcium.

Notes

The post-modifier *reported to bind* specifies the noun *ligand*.

Misusage guidelines

Example 1: Redundancy

(Results section: observation)
When <u>the</u> phagocytosis by <u>the</u> dermal fibroblasts was increased by latex bead addition, <u>the</u> intracellular degradation of <u>the</u> recently synthesised collagen increased.

Revision

When phagocytosis by dermal fibroblasts was increased by latex bead addition, intracellular degradation of **the** recently synthesised collagen increased.

Notes

Adding an essential *the*, as justified in the previous examples, has its limitations: redundancy and over-emphasis. Each of the underlined *the*'s in the example is grammatically correct, because the determiner-marked nouns were probably mentioned in previous sections of the journal article. However, they can be deleted, because their cumulative effect is distracting. The decision of which noun to mark with a definite article may depend on emphasis as shown, where the last noun phrase is intended to be the focus of the paragraph.

In the interim, listening to an oral self-expression of a sentence often can test whether *the* before the noun is necessary – the ear (not the eye) is often a better test of direct article necessity, because most people converse much more than they write.

Another test of *the* necessity is one-by-one removal. Beginning at the start of a sentence, test whether reading without the first *the* affects clarity, and then repeat testing the remaining *thes*. By applying this oral testing, a hierarchy of *the* necessity can be developed.

Example 2: Over-emphasis

(Results section: data location)
<u>The</u> comparison of the algorithms is shown in Table 1.

Revision

A comparison of the algorithms is shown in Table 1.

Notes

The connotes that no other means of comparison is possible.

Summary

The indicated guidelines were identified to justify usage and misusage of the determiner *the*. Summary of guidelines for definite article usage and misusage:

Usage	Misusage
Inherent uniqueness	
1. Widely known noun	1. Redundancy
2. Pre-mentioned noun	2. Over-emphasis
Grammatical uniqueness	
3. Sentence subject	
4. Proper noun pre-modification	
5. Adjectival pre-modification	
6. Adjectival post-modification	

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Getting Your Foot in the Door

SECTION EDITOR

Ivana Turek
ivana.turek@gmail.com

Editorial

There are many paths to becoming a medical writer. Here, Sophie Ash shares her story on how she succeeded in going from scrubbing toilets to mastering medical writing and finding new, flexible ways of work. Her story encourages us to take a chance and not to give up, even if it is hard to see where the road is leading us.

Ivana

From burned-out nanny to six-figure business owner: Sophie's road to success

Sophie Ash
Prospology
sophie@prospology.com

doi: 10.56012/SGHH5682

I'd like to preface this story by pointing out that recognising my own accomplishments has never been easy for me. But, of all the personal and professional development I've done, telling my story is perhaps the thing that has propelled my businesses forward the most. So, if you take anything at all from reading this, let it be that storytelling, networking, and personal branding are incredibly powerful assets that you can use to your advantage, if you're willing to be vulnerable.

Powerful words

The story begins in mid-2017. I had just gotten home from a full day's work as a nanny and housekeeper and was exhausted. But I had friends coming over for drinks and dancing and, honestly, that was the only thing keeping me going at the time. A couple of hours into the festivities, I popped out onto the balcony to interrupt a conversation or two (it was my duty as a host, after all). I wasn't prepared for just how life-changing that particular conversation would be. It went something like this:

Stanley: "Sophie – James and I have been talking about you."

James: "Yeah, we've got your whole life planned out for you."

Me: "Erm… What do you mean?"

Stanley: "We've decided you need to get into PR. I have a friend who works at a PR agency. Do you want an introduction?"

Stop at nothing

Everything changed in that moment. I had 13 virtual coffee chats that following week, in between scrubbing toilets and making packed lunches. It started with Stanley's friend and,

before I knew it, I was addicted! Each contact put me in touch with someone else they knew in the field and it kept going – like a game of dominos but with people-shaped tiles. Every night, on the tube home, I'd re-listen to recordings and meticulously scribble my biggest takeaways. Then, I'd get right back out there the next day and do it all over again. It didn't matter whether I was rushing back from a dance studio, scheduling a play date, or cubing a watermelon – my attention was on my future career. I wanted to be a writer and I was willing to do whatever it took to make that happen.

Goodbye, old me

From PR, to communications, to healthcare communications, to medical communications, I was gaining more clarity every day around what I wanted to do with my life. "Stanley was right – I *am* supposed to be a writer!" I thought. The more people I talked to, the more confident I felt that I actually had what it took to succeed. With my undergraduate degree in Nutrition, I already had a strong medical education and plenty of clinical expertise that I could bring to the table. And, I'd delivered countless workshops for patients and healthcare professionals. So, if anyone could become a medical writer, it was me! I was going to get out of my crappy job, out of my apartment (which sucked up all of my salary anyway), and into a new reality where I was the boss of my time and loved my work. Within a month, I had quit my job, given my landlord 4 weeks notice, and started preparing to move in with my boyfriend and his family so I could start

> I wanted to be a writer and was willing to do whatever it took to make that happen.

my dream life. It was terrifying and invigorating. I loved it!

Hello, pharma

Just four days after leaving my apartment, I had my first interview as a medical copywriter in pharma. I interviewed for full-time work, but I knew deep down that I wanted to freelance. I went through several rounds of interrogation before hearing a verdict. When the team told me they'd start me off on a freelancing contract to see how things went, I was ecstatic. "This is my big break!" I rejoiced. Everything was working out exactly as planned. Just one month after my last day as a nanny and housekeeper, I walked into the largest advertising agency in the city with a three-week Senior Medical Copywriter contract, a company laptop, and an Art Director partner waiting for me. It was a steep learning curve but exactly what I needed. I'd written for a health sciences company when I was a student, and for my own blog for a while, but there was a whole new language to familiarise myself with, even though the writing itself was pretty easy to pick up. I felt challenged for the first time in years and it was invigorating. When I wasn't asking my partner to explain what was going on, or conceptualising new campaigns, I was chatting to as many people as I

could get my hands on. Everyone was incredibly smart and talented. I knew I wouldn't be there long so squeezed every last drop of value from that employee database while I still had access. People are the key to everything.

Living the dream

Six months later, I had worked with a total of 35 freelance medical writing clients and counting. As anticipated, my three-week in-house contract gave me the insight, connections, and confidence I needed to branch out on my own, and failure was not an option for me. I learned how to build a website, crafted a story that showcased my expertise, and started pitching to companies who might need my help. The first few calls and meetings didn't go anywhere, as I didn't have a portfolio yet and no-one took me seriously. But, it didn't take long before a few companies were willing to give me a chance, and I soon had an array of samples to show prospective clients. I learned the ropes mostly through paying close attention during client briefs, asking more experienced writers questions, and getting feedback on my work in any way I could. Word spread fast that I'm a great writer (talent speaks for itself, but it's also nice when people talk favourably about you!). After 6 months, I didn't need to market my services anymore and was well on my way to owning a six-figure business. My rates were higher than most experienced medical writers in my newly curated network, but it didn't matter. I was thriving and everyone wanted to be a part of it. I was living the dream.

Expansion mode

In November 2019, I attended my first ever AMWA conference (I'm a dual British-Canadian citizen with many US clients). I was burning out like no tomorrow and making $120k+ per year, so I flew into San Diego with the intention of learning how to hire subcontractors in my business. That I did (when I wasn't trying axe throwing or exploring an art museum). Entering into 2020, I had a small team of freelance medical writers, with varying levels of experience, who could take on all of my excess work. This allowed me to focus on sales, marketing, and client relationship management instead of all the nitty gritty of producing deliverables. I was ready for my next challenge.

> Storytelling and personal branding are incredibly powerful assets that you can use to your advantage.

Howdy, partner!

Skipping ahead to August 2020, business hadn't died down at all, despite being 6 months into a global pandemic. I was struggling to find any form of work-life balance and needed more help. I reached a breaking point and decided I was either going to a) start scaling things back, or b) bring in a business partner and grow even more. I chose the latter. I gave 50% ownership to my now partner, Sam Sibalis, who was fresh out of business school looking for an exciting opportunity. We expanded our team and tripled our revenue in our first year as an official medcomms agency: A perfect example of how it helps to remain open-minded whenever you're in need of a change.

A self-made guru

Nowadays, I spend most of my time coaching budding freelance medical writers who want to enter the field – most from a pharmacy, clinical, or research background – while my team takes care of the agency side of things. I travel often. I work whenever and wherever I want. I constantly invest in my personal and professional development. And I tell my story, often. One of my favourite things to do is to chat to new people on LinkedIn (if you haven't already started building a personal brand, do it!). Every day, I'm grateful to have such a flexible lifestyle that operates 100% on my own terms. No more toilet scrubbing (I have a cleaner!). No more human taxi service (I got a brand new Mercedes-Benz this year, just for fun). No more living on someone else's terms. I'm a writer and bad-ass entrepreneur and I'm here to stay.

Dare to dream

No matter how far you've come, there's always so much more to learn. And, as you've seen in my story, it's never too late to turn your life around. My advice is to embrace change, be curious, and remain open to any and all opportunities that come your way. Only you know what's best for you. Don't ever let anyone tell you you can't do something just because they don't understand. It's ok to be a visionary. Not everyone will understand and that's ok. If it feels right, go all in and give it everything you've got. I've seen and helped so many individuals transform their lives through freelance medical writing. You don't need to have run a business before in order to succeed. You don't need an advanced degree or a background in marketing. You don't need to already have the right connections. You just need to be intentional and tactful, and seek support from those around you who know their stuff. I believe in you!

Disclaimers

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

Disclosures and conflicts of interest

Sophie's company, Prospology, offers business and marketing coaching services to individuals who are new to freelance medical writing.

Author information

Sophie Ash is a former dietitian who emigrated from the UK to Canada, where she built a six-figure freelance medical writing business with no PhD, formal training, or direct industry experience. Now, she coaches individuals on the business and marketing aspects of freelance medical writing to help them thrive too. You can find her at https://linkedin.com/in/sophieash

Out On Our Own

SECTION EDITOR

Laura A. Kehoe
laura.a.kehoe@gmail.com

Editorial

Another story, another inspiring journey into freelance medical writing. Clotilde Jumelle took a leap of faith and went straight from postdoc to freelancing and has never looked back. In this issue, she tells us about the decisions she's made to get where she is and offers several strategies for other aspiring freelancers who are searching for their first clients and contracts.

If I've learnt anything over all these years of freelancing and chairing the EMWA freelance business group, is that freelancers are extremely motivated and determined people, with a huge amount of resilience. There are many ups and downs, set-backs, and skills to learn (such as accounting and IT). However, if you can manage all that and more, the pleasure of choosing your projects, working directly with clients, and getting their projects realised out-weighs those difficulties.

Clotilde is one of those freelancers. Her pragmatic approach into freelancing and her passion for what she does shines through here, and I'm sure reading her article will encourage other people to step into the freelance world. Even if you're an experienced freelancer, I hope these types of stories stimulate you and make you reflect on your unique freelance journey. Happy reading!

Laura A. Kehoe

A journey from postdoc to happy freelance writer

A s a PhD candidate or a postdoc, your advisors expect you to dedicate your life to research. It is extremely rewarding, and I have no regrets that I followed this path. Nevertheless, after 8 years of working in research labs, I ended up feeling irritated, over-worked, and unfulfilled. The fact is, I love working as much as I love not working.

Growing up, I was never able to clearly picture how my professional life would unfold – there were so many options out there! – but I was hard working and very keen to get started in higher education, pursue a PhD, and get my first experience as a postdoc in the field of ophthalmology. Then, I had the chance to go to the US as a postdoc at Harvard Medical School to continue my ophthalmology research. Born and raised in France, this opportunity to work in one of the most prestigious universities in the world sounded like a dream come true. But after 2 years, a large chunk of which occurred during the COVID-19 pandemic, I realized that working in a research lab under these conditions was not for me. From that moment, I came back to France, and I started looking for the "Holy Grail" of a healthy work/life balance. Writing papers

> Writing papers had always been my favourite part of being a postdoc because it means the completion of months/years of experimentations that are now ready to share the scientific and medical community. Therefore, freelancing in medical writing appeared to me a perfect job.

had always been my favourite part of being a researcher, because it means the completion of months or years of experiments that are now ready to be shared with the scientific and medical community. Therefore, freelancing in medical writing appeared to be a perfect job. And I was right, today I am more than happy to be "out on my own" because it completely fits the lifestyle to which I aspired. Needless to say, like any other job, there are down sides of self-employment, and I wouldn't recommend it to everybody. Going from postdoc to freelancer can be challenging for your bank balance at the beginning but can also be very profitable in a relatively short time span.

Advantages and limitations of freelancing after a postdoc

My postdoc experience gave me several skills which ended up being particularly useful when freelancing as a medical writer. First, we are trained to understand, analyse, and summarise all types of data. Moreover, we are used to preparing slides for presentations to scientists and lay audiences, and manuscripts for peer-reviewed publications. Therefore, we are

Clotilde Jumelle
Freelance Medical Writer
Kea Scientific, France
clotilde.jumelle@keascientific.com

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particularly well adapted to provide this type of service to the clients and luckily for us, there are a lot of needs in this field. However, it can be complicated when trying to diversify the type of work we do. For example, writing regulatory affairs documents represents another type of work, which is particularly sought after, and would require a specific training course for freelancers coming directly from postdoc.

Getting started as a freelancer

Without previous experience working with or for medical writing agencies, it can be hard to know where and how to start, and there is a lot to learn at the beginning. Contacting other freelancers, who had to go through this as well, is definitively the best way to gather advice on how to start. I got the contact details of a few freelancers by word-of-mouth. They were all very kind and helpful and I really feel they are there as a supportive community if I have any questions. They can help to answer the large variety of questions we might have when we start: What are the different statuses for self-employment and which one to choose, how to create a website, the networks/groups to join (it was a freelancer who

To find clients, it is crucial to be resourceful, and to have more than one string to your bow in order to ensure a stable income and lifestyle, and thus decrease any negative stresses.

recommended joining EMWA!), and how to prepare a quote or an invoice.

Different strategies to find clients

Finding clients is by far the most challenging part of the journey for any freelance newbie, especially when you come from a very different environment, like research labs. Sometimes, it feels like we beg for work; it is often demoralising when we get no response, and we are always wondering if we will eventually find a client. During this phase, it is important to persevere and remain hopeful. Various strategies can be used to find potential clients. Here are three which I used to build my client portfolio in only a few months.

1 The first strategy is a passive strategy – word-of-mouth. Using our network

Most importantly, freelancing gives me the chance to control both the quantity and quality of my work in order to optimise the balance between work and personal life while being profitable.

represents a straightforward, easy, and fast way to spread the word and find clients. In our previous positions, including postdoc experience, we may have had the opportunity to meet or work in collaboration with people that can become potential clients or at least spread the word for us. The advantage is that they already know us, and our skills, and therefore, they are more likely to trust us, give us work, and recommend us to their network. However, our connections may not be sufficient to provide us the amount of work we are looking for, and more active strategies may be needed.

2 The second strategy is to find potential clients using professional network such as LinkedIn. This strategy can be particularly laborious, but targeting clients directly gives you the best chances to find

someone who actually needs your services. The search tool can help you to target individuals working in a specific medical field or in a position that would require your services (i.e. medical affairs, clinical projects etc.). I spent literally the first 2 months of this endeavour sending teaser emails to the individuals I targeted. The emails were relatively short and contained my background, the types of service I could provide, as well as a link to my website where they could find more information. It is using this strategy that I found my very first and regular client, for whom I continue to work today.

3 The third strategy is to apply for full-time positions for medical writers listed by MedComms agencies. Even if this may sound contradictory with the idea of freelancing, these job offers indicate to us the companies that are currently and actively looking for the services we can offer. I applied to a few of these positions and around one-third of them accepted me as a freelancer. The biggest advantage to work for

MedComms agencies is that it will usually provide a regular work schedule, and constant workflow, which gives us some stability. Moreover, there is the distinct advantage of working for and with a knowledgeable team that we can learn from. Therefore, we do not feel alone in our work and do not have direct responsibilities with regards to the clients. However, although the stability is welcome, these agencies usually have short turnaround times and strict deadlines, giving us less freedom, therefore, a lot of adaptation is required to work with them in the long run.

To find clients, it is crucial to be resourceful, and to have more than one string to your bow in order to ensure a stable income and lifestyle, and thus decrease any negative stresses. I find it particularly beneficial to work both directly with clients and for agencies, since it gives me the perfect balance between freedom and team working.

Conclusion

Being a freelance writer can be stressful and as we frequently work by ourselves, can make us feel lonely. However, much of the stress can be prevented by having enough experience with science and writing in general, letting us feel comfortable in the field of scientific and medical writing. It also requires soft skills suitable for freelancing such as being proactive, resourceful, and well organised, allowing us to search out and find clients and also respect their deadlines. Working with MedComms agencies can also provide the opportunity to work in a team and prevent loneliness, which is even more important after the shutdowns and distance-working of the COVID-19 pandemic.

Some people have also asked me if it is boring to do medical writing, after leaving a very active lab with frequent "eureka" moments. The answer is clearly, not at all! Every day is different: a different client, different project, different medical field. Most importantly, freelancing gives me the chance to control both the quantity and quality of my work in order to optimise the balance between work and personal life while being profitable.

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The author declares no conflicts of interest.

Author information

After working for 8 years as a researcher in the ophthalmology field, **Clotilde Jumelle, PhD**, is currently a freelance medical writer for Kea Scientific.

Healthy home office

Writing mode   *On-call mode*

Miyuki Tauchi miyukitauchi@yahoo.co.jp

Upcoming issues of **Medical Writing**

December 2022:

Open science and open pharma

Open access ensures that the highest quality, peer-reviewed evidence is available to anyone who needs it, anywhere in the world. This issue will focus on how open access and plain language summaries improve transparency, advance medical science and ultimately improve patient care. Focus will also be given to how Open Pharma, a group of pharmaceutical companies and other research funders, alongside healthcare professionals, regulators, patients, publishers and other stakeholders in healthcare, are driving this goal.

Guest Editors: Martin Delahunty, Tanya Stezhka, and Chris Winchester

June 2023:

Freelancing

Freelancing is becoming an increasingly popular option for medical writers and communicators, but it's not as straightforward as finding a few clients and getting paid. There's so much more involved. Freelancers are mini business owners and to be successful, you need a plethora of skills, be self-motivated, driven, and adaptable and take the highs with the lows. In this issue, the authors will discuss what options are out there for freelancers, how to get started, and all the challenges that you may come across. Freelancing can be a lucrative business but addressing all the factors is key to being successful.

Guest Editors: Laura Kehoe and Satyen Shenoy
The deadline for feature articles is March 1, 2023.

March 2023:

Clinical trials

Medical writers and communicators are involved in clinical trials, from writing the trial protocol to reporting and publishing the trial results. This issue will focus on our roles, responsibilities, the documents we create, and our audience. Furthermore, we will also cover the regulations and best working practices governing documentations for clinical trials.

Guest Editors: Raquel Billiones and Ivana Turek
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September 2023:

Automation/Software

Streamlined complex medical report writing supported by artificial intelligence/machine learning is making its way into clinical regulatory writing. The medical writing automation's goal is to speed up and ease clinical development processes by reducing the time and cost involved in creating and keeping regulatory documents up to date. This issue will examine current issues, challenges, and opportunities towards human guided medical writing automation systems.

Guest Editors: Shiri Diskin and Daniela Kamir
The deadline for feature articles is June 1, 2023.

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