Medical Communications and Writing for Patients

Editorial

Dear all,

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

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

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

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

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

Bestest,
Lisa

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

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

Writing for "true" consent

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

Lay summary

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

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

Other plain-language sections of the Research Application Form

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

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

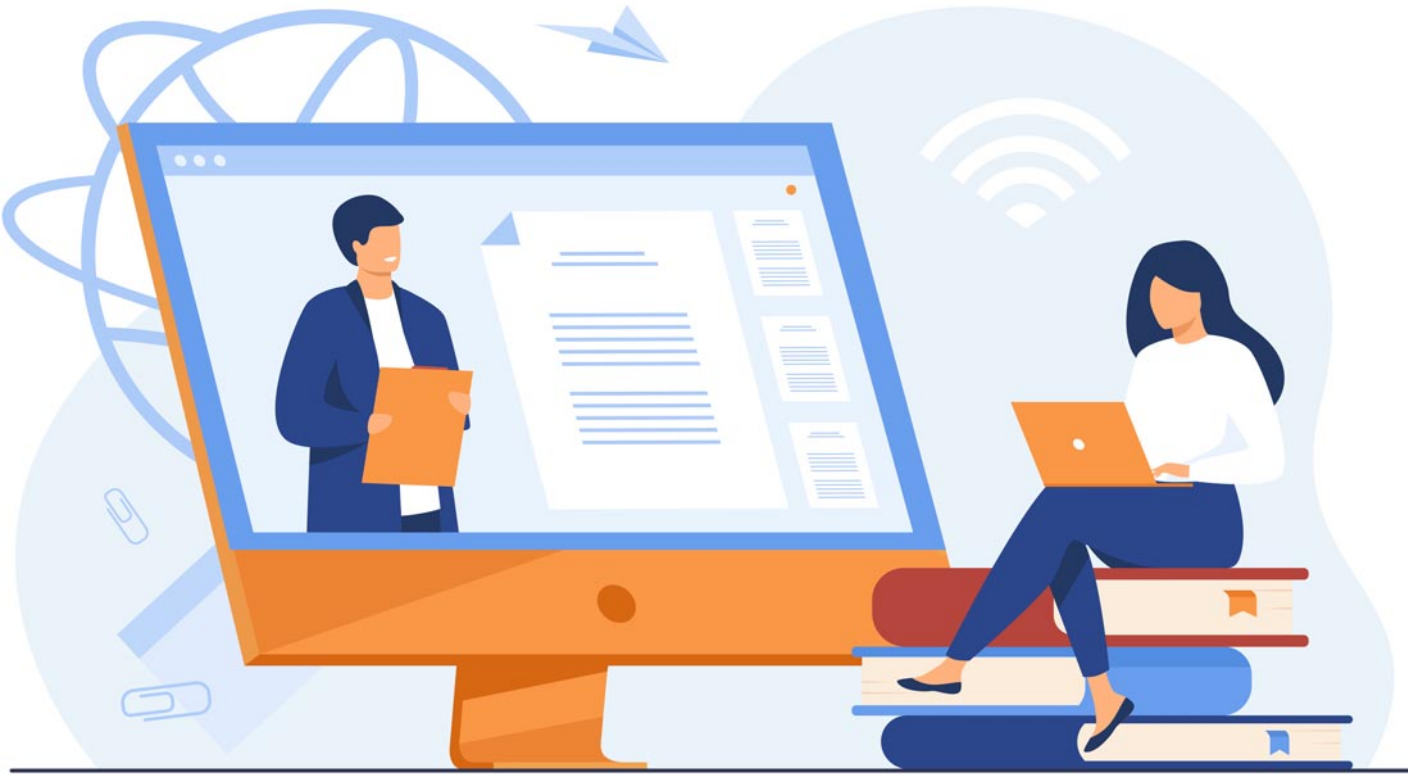
- What will be gained by answering the research question?
- Has similar research on this topic been done before? If so, why do we need an additional study? What is being done that has not been done before?

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

- The null and any alternative hypotheses and why such an alternative hypothesis was chosen
- Scientific and practical justification for the study design and methodology. If patient groups, carers, service users, or members of the public were involved in decisions on study design, explain how their inputs were incorporated into the final design. Ms Rapley highlighted that RECs give importance to suggestions generated from Patient and Public Involvement (PPI) projects in clinical studies
- Justification for including control arms to a trial, particularly for use of a placebo arm
- Procedures to detect and compensate for any possible "researcher effects" and "researcher bias"
- Sampling: how participants will be identified, approached, and sampled; calculations of study power and sample size
- Broad timetable for the stages of the research, such as preparation, convening meetings or conducting interviews, interpreting and analysing findings, preparing the final report
- Site(s) for interviews
- Plans for interim analyses or reports

Advice for drafting an effective research application form

- **Meet reviewers' expectations.** Reviewers should be able to easily ascertain whether the research is useful, whether the study can answer the research question, the current state of the field, and whether the participant inclusion and exclusion criteria are justified and as inclusive as possible. These and other aspects of the study that are scrutinised by RECs are presented in the report of part 1 of the Meet & Share series.[1]
- **Ensure that the language is easily understood by a general audience.** Remember that a third of the REC membership comprises members of the public (i.e. not registered healthcare professionals or professionally involved in clinical research). Language-related issues are the most common issues faced by RECs. Ms Rapley had the following suggestions to improve the understandability of a lay summary:
  - Test it out on a non-specialist who is not intimately involved in the research. This could also be part of the PPI aspect of the study.
  - Use readability scores. The scores calculated using the Microsoft Word® Editor function (Flesch Reading Ease and Flesch-Kincaid Grade Level) are good enough to get a rough estimate of the language level. There are also plenty of web-based applications that can be used to analyse readability.
  - Use plain-English guides and glossaries. The National Institute of Health Research (NIHR) plain English summaries guide, published in April 2021, is useful for writing and reviewing lay summaries.[3] Use plain-language substitutes for technical language and acronyms. These can be found in plain language glossaries such as the



Multi-Regional Clinical Trials (MRCT) Center Clinical Research Glossary.[4]

- Use generative AI tools, such as ChatGPT (https://openai.com/chatgpt), to evaluate and rewrite text in plain English. Ms Rapley has found ChatGPT's outputs to be "not too bad"; she suggests using them as a good starting point.

- **Use visuals to make processes and information clearer**, such as flow charts, diagrams, tables, etc. Information in section A13 is especially hard to grasp when presented just verbally and should be accompanied by well-designed visual elements.

- **Do not simply reproduce or refer to the protocol**, especially when answering sections A12 (scientific justification) and A13 (study design and methodology). Ms Rapley requested all medical writers who work on ethics submissions to highlight this advice in their organisation's standard operating procedure (SOP) document. The text from the protocol will not be appropriate for the REC membership, making it not fit-for-purpose and copy-pasting also signals to the membership a lack of empathy and diligence, which may alter their perception of the study.

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

Do not simply reproduce or refer to the protocol.

What is the consequence of submitting an ethics application that is not easily understood by the lay reviewers and members of public? The REC will point out the problem and have more questions and requests, which means it will take longer for the study to be approved. Ms Rapley pointed out that while RECs do not have the power to request a resubmission of the application form (although they wish they could), they can keep asking questions until they get what they want. In her experience as a REC member, she has reviewed applications that have been rejected due to ethical concerns arising from poor language. Dr Gertel, who in part 1 of the series had discussed the composition and functions of Institutional Review Boards (IRBs) in the US,[1] added that IRBs do have the power to label an application as unacceptable and request a rewrite and resubmission. He finds this to be very useful when IRBs review decentralised clinical trials (DCTs), where screenshots of interfaces are provided for assessment; these interfaces need to be understandable as the participant is isolated and has no access to immediate support.

Participant-facing documents

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

RECs check for the following features when reviewing these documents:

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

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

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

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

New guidance and standards for ethics submissions in the UK

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

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

The Design and Review Principles are as follows:

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

The Participant Information Quality Standards are as follows:

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

Writing in plain language – a worthy challenge

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

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

The principles of health literacy

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

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

Development of the MRCT glossary

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

Such a resource would have the following benefits:

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

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

In closing...

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

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Disclosures and conflicts of interest

The author declares no conflicts of interest.

References

1. Rappaz S. Meet and Share session on protecting the public from undue harm during research studies: A report. Med Writ. 2023;32(4):74–7. doi:10.56012/qxky3990
2. Integrated Research Application System (IRAS). A step by step guide to using IRAS to apply to conduct research in or through the NHS/HSC. Version 2.0. 28 June 2018 [cited 2024 Jan 26]. Available from: https://www.myresearchproject.org.uk/help/contents/StepByStep_v2-0_20180628.pdf
3. National Institute of Health and Care Research (NIHR). Plain English summaries. Version 1.0. April 2021 [cited 2024 Jan 26]. Available from: https://www.nihr.ac.uk/documents/plain-english-summaries/27363
4. Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center). Clinical Research Glossary. Available from: https://mrctcenter.org/clinical-research-glossary/
5. Health Research Authority. Participant information design and review principles. 21 August 2023 [cited 2024 Jan 26]. Available from: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/participant-information-design-and-review-principles/
6. Health Research Authority. Participant information quality standards. 27 November 2023 [cited 2024 Jan 26]. Available from: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/participant-information-quality-standards/
7. US Department of Health and Human Services, Office of Disease Prevention and Health Promotion. National Action Plan to Improve Health Literacy. 2010. Available from: https://health.gov/our-work/national-health-initiatives/health-literacy/national-action-plan-improve-health-literacy
8. Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center). Plain Language [cited 2024 Jan 26]. Available from: https://mrctcenter.org/health-literacy/tools/overview/plain-language/
9. Kassis SB, Bahador B, Gawrylewski H, et al. Promoting equity in understanding: A cross-organisational plain language glossary for clinical research. Med Writ. 2020;29(4):10–15.

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