Case Reports in Women's Health 27 (2020) e00204

Contents lists available at ScienceDirect

Case Reports in Women's Health

journal homepage: www.elsevier.com/locate/crwh

Invited Editorial

Writing case reports, consent for publication and General Data Protection Regulation (GDPR)

Case reports represent a timely way for advancing medical scientific knowledge of rare medical conditions. They allow presentation of diagnostic challenges and novel treatments in unusual situations. They inform and increase the knowledge base to deliver individualised healthcare and provide a valuable educational resource. Case reports need to respect patient privacy and unnecessary detail in the manuscript and anything in images that could lead to identification of the patient needs to be removed [1,2]. Consent for publication of the report and associated images is therefore an essential requirement as, by their nature, clinical details and images can be traced to individuals even though identifiers are removed.

Those obtaining consent should be suitably qualified and authorised to do so by their institution. They should provide all relevant information and use plain language about the publication of patients' data in case reports and risks of identification even though names are not published [3]. Consent forms should specify whether or not the patient or their legal representative has seen the final version of the case report to be published (including pictures). If a final version has not been shown, it must be clear what the patient or proxy has seen and that he or she has agreed to publication without having seen the final version of the article [4,5]. Patients or their legal representatives should not feel rushed into giving consent. For example, consent for publication should be obtained after rather than before surgery, as there could be concerns about the validity of consent obtained in a preoperative or emergency setting. Furthermore, since almost all academic journals are available online and many of them have some form of open access or permissive creative commons licences, it has become particularly important to inform patients that once published it is impossible to guarantee complete removal of reports and images from freely available databases even when an article is removed [3,6,7].

Consent from the patient should preferably be written. However, if consent cannot be expressed in writing, but the patient has mental capacity, non-written consent must be formally documented and witnessed, in accordance with local legislation and institution practice. A legal representative may provide consent if patients lack mental capacity, are under the legal age to provide consent, or are deceased. The legal age for providing consent varies between countries. If they can be obtained, the views of those under the legal age (minors) regarding publication should be respected. Similarly, patients with fluctuating or deteriorating conditions may be able to give consent during a remission or in the early stages of the disease, but at a later stage it may be uncertain whether they continue to do so. Thus, the reason for a legal representative signing a consent form should be provided.

In cases where patients lack mental capacity, are untraceable, deceased or there is no legal representative and publication of the case report is in the public interest, approval should be provided in accordance with local legislation. This may involve institutional authorities such as a hospital board and an ethics committee. These exceptional circumstances should be documented.

Documentation of consent must be retained by the author, the institution and patients or their legal representatives. Copies of the consents or evidence that such consents have been obtained should not be provided to journals unless specifically requested in exceptional circumstances (for example if a legal issue arises). Duration of retention by the institution now needs to take into account investigations into data fabrication which may occur many decades after publication. [8,9]

The importance of consent strengthened with the requirements set out in the 2018 European Union General Data Protection Regulation (GDPR) [10]. In processing personal data for research purposes, GDPR emphasises the respect for the principles of lawfulness, fairness and transparency (GDPR, Article 5.) [10]. Additionally, for processing health-related data for research purposes (as in case reports), GDPR requires that appropriate safeguards are put in place for the protection of personal data (GDPR, Article 9.) [10]. These safeguards include utilising the principle of data minimisation, pseudonymisation and anonymisation of data, as well as already existing good research practices such as obtaining ethical approval for clinical trials [10,11]. The principles of lawfulness and fairness require that data processing has its lawful basis and that participants know how their data are being processed, as well as ensuring that processing is aligned with their expectations. Emphasis is also put on transparency [12,13].

Following these principles, and because of the nature of case reports, measures to mitigate risk of identification should be explained [14]. This is particularly important for open-access publishing, where articles are readily available to a vast number of people rather than to a relatively small number of journal subscribers [15]. This is related also to the type of license under which content is published, such as Creative Commons, [16] which allows re-use for non-commercial purposes. However, other rights such as publicity, privacy, or moral rights may limit how the material is used [16].

In conclusion it is essential that consent for publication from either patients, legal representatives or relevant authorities is documented in case reports.

https://doi.org/10.1016/j.crwh.2020.e00204

Contributors

Marija Roguljić contributed to the writing, reviewing and editing of the manuscript.

Rea Ščepanović contributed to the writing, reviewing and editing of the manuscript.

Margaret Rees was responsible for the conceptualization of the editorial and contributed to the writing, reviewing and editing of the manuscript.

Conflict of interest

The authors declare they have no conflict of interest regarding the publication of this editorial.

Funding

No funding from an external source supported the publication of this editorial.

Provenance and peer review

This editorial was not externally peer reviewed.

Acknowledgement

The authors would like to thank Dr Elizabeth Wager, Department of Research in Biomedicine and Health, School of Medicine, University of Split, Croatia, for her helpful comments.

References

[1] CARE Case Report Guidelines, http://www.care-statement.org/ (Accessed 6 April 2020).
[2] Elsevier The Do's and Don'ts of Writing and Publishing Case Reports, https://www.elsevier.com/connect/authors-update/the-dos-and-donts-of-writing-and-publishing-case-reports (Accessed 6 April 2020).
[3] L. Skyes, A. Harryyparsad, W. Evans, Dental images: ensuring the understanding, acceptance and consent of and by patients to all possible usages, S Afr Dent J. 72 (7) (2017) 336–338.
[4] M. Rees, S.L. Corson, Publication of medical case reports and consent, Case Rep Womens Health. 15 (2017 Jul 26) A1–A2, https://doi.org/10.1016/j.crwh.2017.07.002.
[5] V. Barbour, on behalf of COPE Council Journals' Best Practices for Ensuring Consent for Publishing Medical Case Reports: guidance from COPE, www.publicationethics.org December 2016 (Accessed 6 April 2020).
[6] Marija Roguljić, Elizabeth Wager, Consent for publishing patient photographs, Case Rep Womens Health 2020 April, p. 26 , e00194.
[7] Z. Marshall, F. Brunger, V. Velch, Asghari, C. Kaposy, Open availability of patient medical photographs in google images search results: cross-sectional study of transgender research, J Med Internet Res. 20 (2) (2018) e70.
[8] A. Grey, M. Bolland, G. Gamble, A. Avenell, Quality of reports of investigations of research integrity by academic institutions, Res Integr Peer Rev. 4 (2019 Feb 19) 3, https://doi.org/10.1186/s41073-019-0062-x.
[9] King"s College London enquiry into publications authored by Professor Hans Eysenck with Professor Ronald Grossarth-Maticek, https://www.kcl.ac.uk/news/statements/docs/hans-eysenck-enquiry-final-may-2019.pdf May 2019 (Accessed 6 April 2020).
[10] EU General Data Protection Regulation (GDPR), Available from, https://gdpr.eu/tag/gdpr/ (Accessed 6 April 2020).
[11] UK Research and Innovation (UKRI), GDPR and Research – An Overview for Researchers. Available from, https://www.ukri.org/files/about/policy/ukri-gdpr-faqs-pdf/ (Accessed 6 April 2020).
[12] Health Research Authority (HRA), , GDPR: Technical guidance; Transparency. 2018. Available from: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-detailed-guidance/transparency/ (Accessed 6 April 2020).
[13] C.F. Mondschein, C. Monda, The EU's General Data Protection Regulation (GDPR) in a Research Context, in: P. Kubben, M. Dumontier, A. Dekker (Eds.), Fundamentals of Clinical Data Science [Internet], Springer, Cham (CH) 2018 Dec 22, p. 2019 , Chapter 5. Available from: https://www.ncbi.nlm.nih.gov/books/NBK543521/.
[14] M. Cornock, How the writers of case reports need to consider and address consent and the general data protection regulation (GDPR), Case Rep Womens Health. 19 (2018)e00060.
[15] Medical Research Council (MRC) Regulatory Support Centre, GDPR: Answers to some frequently asked questions (FAQs) – What does GDPR mean for open data? Available from, http://www.highlights.rsc.mrc.ac.uk/GDPR/open_data.html 2019 (Accessed 6 April 2020).
[16] Creative Commons, Creative Commons Licences, Available from: https://creativecommons.org/use-remix/cc-licenses/ (Accessed 6 April 2020).

Marija Roguljić
Department of Oral Medicine and Periodontology, Study Programme of Dental Medicine, School of Medicine, University of Split, Šoltanska 2, 21000 Split, Croatia
Corresponding author.
E-mail address: marija.roguljic@mefst.hr

Rea Ščepanović
Department of Research in Biomedicine and Health, School of Medicine, University of Split, Šoltanska 2, 21000 Split, Croatia

Margaret Rees
Women's Centre, John Radcliffe Hospital, Oxford OX3 9DU, UK