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COMMITTEE ON PUBLICATION ETHICS

Journals' Best Practices for Ensuring Consent for Publishing Medical Case Reports

Promoting integrity in research publication

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Journals' Best Practices for Ensuring Consent for Publishing Medical Case Reports: guidance from COPE

Introduction

The publication of case reports is a common practice in medical journals, and increasingly in basic science journals when an article illustrates a specific scientific point (e.g., a genetic phenotype). There is no doubt that case reports are valuable in the academic literature. However, they pose a specific ethical challenge for journals because, by their very nature, individuals in reports are highly identifiable. Hence, journals must ensure that proper consent for publication has been obtained and that the individual(s) who is being reported on is aware of the possible consequences of that reporting.

Because no single form can serve the purposes of all journals, here we lay out the principles that a consent form should generally include and list examples of forms currently in use, so that editors can develop forms that suit their journals' purposes.

Reference
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General principles

- Publication consent forms should be required for any case report in which an individual or a group of individuals can be identified. This requirement also applies when a report involves deceased persons. Examples of identifying information are descriptions of individual case histories, photos, x-rays, or genetic pedigrees. A list of 23 potential identifiers has been published in BioMed Central's Trials.

- Journals should not themselves collect the signed consent forms, because the receipt and storage of confidential patient information could subject them to cumbersome security requirements and potential legal liability under applicable privacy or patient information laws, such as the Health Insurance Portability and Accountability Act of 1996 in the USA.

    » Journals should make a blank copy of the form available on their website and require authors to attest that it, or a form that includes all the elements of the form, has been signed by the patient or a proxy.

    » If the patient or proxy has signed a form that differs from the form adopted by a journal, a blank copy of the form should be provided to the journal so that they can ascertain whether all the required elements were included.

    » Authors should also attest that the original of the signed form is held by the treating institution.

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Information to be collected in publication consent forms

1. Publication consent forms should include a place for the name of the patient and the name of the individual signing, or otherwise marking, the form.

    - If the patient is not the signer, the relationship of the signer (i.e., the proxy) to the patient must be stated.

    - If one person is signing for a family or other group, that person should attest that all relevant members of the family or group have been informed.

    - If proxy consent is obtained, the form should include a statement to indicate that the individual or group do not have legal, mental, or physical capacity to consent and the reason why. Examples include underage children, persons with cognitive or intellectual disabilities, or deceased persons. In such cases, it is especially important to consider that children, for example may not understand the future consequences of publication.

    - In some instances, it may be appropriate for institutions to require approval for a case study to be published. Institutions should be encouraged to make their requirements clear to their staff and have a policy or procedure for consenting patients/consumers/proxies for case studies to be published, including who should obtain that consent.

2. The form should include a place for the name, signature, and contact information of the person who has explained and administered the form to the patient or proxy.

    - This will usually be the individual reporting the case, but might be another individual, for example, curators of disease registries.
    - This person must have the authority to obtain consent (e.g., be the senior clinician responsible for the patient's care or their delegate).
    - Special consideration will be needed if, as occasionally happens, the patient who is reported on is also a co-author of the case report.

3. Forms should indicate that signing the consent form does not remove the patient's rights to privacy. However, wording should make it clear that, even with the best efforts of medical staff at confidentiality, and even with the journal's best practices in place, the journal cannot guarantee anonymity. There is a risk that the patient may be identified by someone, somewhere, once the case report is published. This is especially true if the case is published freely online.

4. Forms should indicate that the patient has been informed that he or she may revoke consent at any time before publication, but once the information has been published, revocation of the consent is no longer possible.

5. Forms should make it clear what current and further uses might be made of the published case report, including as applicable publication in print or online and whether freely available or by subscription, in audio or video recordings and presentations, webinars, etc.

6. Indication of the patient's or proxy's agreement to publication should be included. Forms should indicate whether or not the patient or proxy 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.

7. It should normally be clearly stated that patients cannot expect to derive any financial benefit from publication of the case. Alternatively, if there is some financial benefit to the patient, that should be clearly stated on the form.

8. The publication consent form should be available in multiple languages, as relevant, so the one appropriate to the location of the study can readily be used.

Examples of forms for consent to publication of cases and relevant guidance

1. PLOS Journals: http://journals.plos.org/plosone/s/file?id=8ce6/plos-consent-form-english.pdf

2. BMJ Journals: http://journals.bmj.com/site/authors/patientconsent/consentenglish.pdf

3. Journal of Medical Case Reports and BMC Journals: http://resource-cms.springer.com/springer-cms/rest/v1/ content/6621850/data/v1/Consent-Form-PDF http://www.biomedcentral.com/getpublished/editorial-policies#consent+for+publication.

4. Medwave (Spanish): http://www.medwave.cl/medios/Editorial/Formularios/Autores/FCIP-2015.doc

5. Wiley ethics guidelines: http://exchanges.wiley.com/ethicsguidelines

Definitions

- ***Consent***: Unlike consent to a medical procedure or enrolment in a trial, consent to publishing a case report addresses, specifically, the publication of the case and the possibility that the individual described in it could be identified.
- ***Privacy***: A common principle or statutory right that extends to patients or study participants. Individuals have the right to control the extent to which personal (including medical) information is revealed, and to whom. A few exceptions may exist, such as in cases of potential harm to the patient himself or herself or to the community, or in criminal cases. A person's right to privacy may be protected, but that person may still be identifiable from a case report, even with application of best practices.
- ***Confidentiality***: An ethical duty for researchers or medical staff to protect information entrusted to them by a patient or study participant. This principle allows patients or study participants to reveal information to researchers or medical staff that they otherwise would not want to disclose.
- ***Anonymity***: In the context of case reports, details are eliminated that might make it possible for others or the patient him- or herself to identify the patient. However, in practice anonymity cannot be guaranteed. Depending on the case itself (especially for unusual cases), it may not be possible to fully anonymize patient information and it is possible that someone, somewhere will see the report and be able to identify the individual(s) being described.

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More resources:

Plaza J, Fischbach R. Privacy and Confidentiality, Current Issues in Research and Ethics (CIRE) online learning http://ccnmtl.columbia.edu/projects/cire/pac/foundation/

World Medical Association Declaration of Helsinki: http://www.wma.net/en/30publications/10policies/b3/

FindLaw Australia. Health Records: Confidentiality, privacy and access: http://www.findlaw.com.au/articles/4556/health-records-confidentiality-privacy-and-access.aspx

Provenance

VB wrote the first draft and revised these guidelines in response to comments. The education committee and other council members at COPE provided comments on a number of revisions and we also incorporated feedback received in response to a public call for comments.