The importance of consent in case reports

Ross J. Thomson 1,2* and C. Fielder Camm 3.

1Department of Cardiology, Royal Free London NHS Foundation Trust, UK; 2William Harvey Research Institute, Queen Mary, University of London, UK; and 3Department of Cardiology, Royal Berkshire Hospital, UK

Case reports provide important learning opportunities but risk breaching patient confidentiality

Confidentiality is one of the fundamental tenets of modern medical ethics.1 Patients expect that information they share with their healthcare providers will remain confidential. Such trust allows open and honest reporting of symptoms and medical history, which is crucial to developing the correct diagnosis and initiating appropriate treatment. As clinicians, we have an ethical and professional responsibility to safeguard confidential information shared by patients, supplemented in almost all jurisdictions by legal obligations.

It is clear, however, that reporting and discussion of an individual patient case is an important part of medical education and scientific research.2 Case reports help learners to translate theory into practice, and to learn how to apply guidelines and evidence-based recommendations in real-world scenarios. They are also vital in identifying novel diseases, new manifestations of existing illnesses, and potential treatment strategies. The ongoing COVID-19 pandemic has underscored the potential value of case reports in this regard, with well over 4000 published to date.3

Informed patient consent to publish

How, then, do we balance the rights of our patients to confidentiality and the benefits to medicine and society at large that come from sharing their stories? The Committee on Publication Ethics4 and the International Committee of Medical Journal Editors5 have issued guidelines on the publication of case reports. These state that, with limited exceptions, consent from the patient should be obtained prior to publication of a case report. When obtaining informed consent authors must advise their patients not only that their case will be placed in the public domain but that despite every effort at anonymisation there exists a possibility that they may be identified, and that their consent is irrevocable after (but not before) publication. As part of the consent process, the patient should have the opportunity to read the manuscript and view any images accompanying it.

European Heart Journal—Case Reports strongly believes in the ethical requirement for patients to consent to the publication of their cases. As such, it is expected that written informed consent will be obtained by authors from patients prior to submission of the case report. In this respect, we are in line with a number of other case report journals.6,7

European Heart Journal—Case Reports provides a consent form that authors can use to record that they have gained the patient’s permission to publish their case, and this should be completed prior to submission. We do not collect this form—to do so would involve the patient being identified to the Journal’s editors—but ask the authors to retain it in accordance with their institution’s procedures. We also allow authors to use their institution’s consent form, although we ask them to submit a blank copy so that we can ensure the consent it obtains is adequate.

Why ‘anonymisation’ of a case report is insufficient

It is clear that ‘anonymisation’ is not a substitute for informed consent—by their very nature case reports often describe novel or rare presentations, and removal of an individual’s name and other classic ‘identifiers’ is not sufficient to prevent them from being recognized. A case report that contains sufficient information for a patient to recognise themselves is, in our opinion, not truly anonymised. Attempts to completely anonymise a case are likely to render it less useful from an educational perspective. That said, authors should try to anonymise their case as far as practicable, taking particular care to ensure that names and other identifiers are not included in the text or...
images. Consent to publish does not obviate the requirement to minimise the risk of the patient being identified.

**What if written consent cannot be obtained?**

In unusual circumstances, it may not be possible to obtain written consent, for example in the current COVID-19 pandemic where there have been restrictions on face-to-face clinic appointments. In these situations, witnessed verbal consent, for example, with two independent clinicians participating in a conference call with the patient, may be sufficient.

**What if the patient cannot consent to publication of the case report?**

There are a range of situations where a patient may not be able to give consent for publication of a case report. As such, an individual approach must be taken when dealing with such cases. The Journal has developed a flow-chart and ‘lack of consent’ form that authors can complete and submit to the editorial office to allow their individual circumstances to be considered. This should be undertaken prior to submission of the manuscript.

Where the patient is a child, consent should be obtained from their parent or guardian. However, if they are old enough to understand the situation, the child’s agreement should also be sought even if they are unable to give legal consent in the authors’ jurisdiction. If the patient is deceased, we ask for consent from their closest relative.

In situations where the patient and/or their relatives are uncontactable despite the authors’ best efforts then the Journal’s editorial board will consider the situation on a case-by-case basis. Additionally, there may rarely be legal issues that prevent consent being sought.8

However, publication of such cases by the journal is very much considered the exception rather than the norm.

**Ethics committee approval**

In situations where patient consent to publish has not been obtained, approval of a local ethics committee may be a factor in favour of publication. However, approval of a local ethics committee does not necessarily guarantee that European Heart Journal—Case Reports will allow publication of a case report without consent. In particular, approval from an ethics committee should not overcome a patient’s refusal to provide consent.

Importantly, we see a clear distinction between consideration and approval by an ethics committee and a statement from an institutional review board (IRB) saying that a case report does not require their approval because it is not considered research. The latter does not constitute evidence in favour of publication without consent. Many IRBs state that they do not consider case reports to constitute research,9 and in some jurisdictions case reports do not fall within the legal definition of medical research.10 While this is true, it does not alter the ethical standard for informed patient consent being required for publication of case reports.

In summary, patient consent is the key to the ethical publication of case reports and a central component to the publication in this Journal. Anonymisation of a case report is not sufficient to eliminate the need for consent, and the practicalities of consent can be complex. While European Heart Journal—Case Reports is mindful of the potential difficulties of consenting patients for publication, any publication without consent must balance the wider benefit to medical learning with the clear and present risk of identification of the patient without their knowledge, agreement, or understanding.

**Conflict of interest:** none declared.

**References**

1. Herring J. Medsoc Law and Ethics. Oxford, UK: Oxford University Press, 2018.
2. Vandenbroucke JP. In defense of case reports and case series. Ann Intern Med 2001;134:330.
3. National Library of Medicine, National Institutes of Health. LitCovid [Internet]. 2020 https://www.ncbi.nlm.nih.gov/research/coronavirus/docs/Arts/filters=topics. Case%20Report (29 December 2020).
4. Riley DS, Barber MS, Kienle GS, Aronson J, von Schoen-Angerer T, Tugwell P et al. CARE 2013 explanations and elaborations: reporting guidelines for case reports. J Clin Epidemiol 2017;89:218–235.
5. International Committee of Medical Journal Editors Recommendations [Internet]. 2019. http://www.icmje.org/recommendations/ (29 December 2020).
6. BMJ Case Reports - Instructions for Authors [Internet]. n.d. https://casereports.bmj.com/pages/authors/#consent (29 December 2020).
7. Oxford Medical Case Reports - Instructions for Authors [Internet]. n.d. https://academic.oup.com/omcr/pages/Policies (29 December 2020).
8. Dahiya G, McQuade D, Alpert C. Myocardial bridging in the era of a drug epidemic: a case report addressing the need to revisit donor organ assessment. Eur Heart J - Case Rep 2019;3:1–4.
9. Johns Hopkins - Institutional Review Board [Internet]. 2006. https://www.hopkinmedicine.org/institutional_review_board/guidelines/policies/guidelines/case_report.html (29 December 2020).
10. Health Research Authority. UK Policy Framework for Health and Social Care Research [Internet]. 2020. https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/ (4 November 2020).