

PATIENT ISSUES AND CONFIDENTIALITY

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WHY SHOULD THE PATIENT BE AN ISSUE IN PUBLICATION OF RESEARCH MATERIAL?

- ▶ Protect confidentiality and privacy- prevent revealing of identity; most journals are in the public domain
- ▶ Informed consent as a fundamental requirement irrespective of identity issue
- ▶ On the other hand the publication of case material is in the general interest of scientific advance, education and therefore patient care

**International committee of medical journal editors (ICJME); Uniform Requirements
for Manuscripts Submitted to Biomedical Journals:
Ethical Considerations in the Conduct and Reporting of Research: Privacy and
Confidentiality**

- ▶ Patients have a right to privacy that should not be violated without informed consent.
- ▶ Identifying information, including names, initials, or hospital numbers, should not be published in written descriptions, photographs, or pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication.
- ▶ Informed consent for this purpose requires that an identifiable patient be shown the manuscript to be published.
- ▶ Authors should disclose to these patients whether any potential identifiable material might be available via the Internet as well as in print after publication.

**International committee of medical journal editors (ICJME); Uniform Requirements
(cont)**

- ▶ **Nonessential identifying details should be omitted. Informed consent should be obtained if there is any doubt that anonymity can be maintained. For example, masking the eye region in photographs of patients is inadequate protection of anonymity.**
- ▶ **The requirement for informed consent should be included in the journal's Instructions for Authors. When informed consent has been obtained, it should be indicated in the published article.**
- ▶ **Patient consent should be written and archived with the journal, the authors, or both, as dictated by local regulations or laws.**

BMJ policy

- ▶ Publication of any personal information about a patient will normally require the consent of the patient. This will be so even if identifying details are removed.
- ▶ Personal information about a patient will not be published over the patient's refusal, except in the most exceptional circumstance of over-riding importance to public health.

► Publication without the consent of the patient will be permitted if all of the following conditions are met:

- The patient who is the focus of the article is untraceable without an unduly burdensome effort and it is also impossible or unreasonable to expect consent to be obtained from the patient or the patient's next of kin.
- The article contains a worthwhile clinical lesson or public health point which could not be as effectively made in any other way. (Worth while is intended to sit on a spectrum between “interesting,” which is the publication threshold with patient consent, and “over-riding public health importance,” which is the publication threshold over patient refusal.)

- **A reasonable person in the patient's position would not be expected to object to the publication of the case. (This requires an assessment of the intrusiveness of the disclosure and the potential that it has for causing the patient, or the patient's family, embarrassment or distress. Particular attention must be paid to differences of cultural and social attitudes. It must not be assumed that what is a matter of indifference in one society will have the same status in another.)**
- **The risk of identification of the patient is minimized by measures designed to prevent the identity of the patient being revealed either to others or to the patient himself or herself. (These measures will include anonymisation of the case or the author, or both. The publication without consent of photographs will require particularly scrupulous attention to anonymisation.)**

- ▶ Do we need a more liberal policy for India where getting consent (& tracing patients) is more difficult & we need more case studies being written up?
- ▶ Why not put the onus on the authors and journal to anonymise the patient rather than the patients informed consent?