ETHICS OF RESEARCH PUBLISHING

Confidentiality and the ethics of medical ethics

W A Rogers, H Draper

In this paper we consider the use of cases in medical ethics research and teaching. To date, there has been little discussion about the consent or confidentiality requirements that ought to govern the use of cases in these areas. This is in marked contrast to the requirements for consent to publish cases in clinical journals, or to use personal information in research. There are a number of reasons why it might be difficult to obtain consent to use cases in ethics. Many cases concern people who are incompetent, and thus unable to give consent. Often the material is of a sensitive nature, it is not clear who should give consent, or the ethicist has no access to those involved. We argue that the use of cases in ethics research and teaching can be justified by appeal to the public interest argument, and suggest a number of areas for discussion and clarification.

THE CURRENT SITUATION

We checked the information for authors on the websites of several medical ethics journals and found no instructions regarding consent from patients as a prerequisite to the publication of case studies. This is in contrast to many mainstream medical journals which now require the written consent of patients before accepting case studies for publication. (See table 1)

We reviewed all issues of the JME published between 1982 and February 2002, focusing on two particular series of articles: “At the coal face” and “Case conference”, both of which tend to discuss case material. We excluded those articles that did not discuss personal information, and where an article used more than one case, each case was documented separately. We wanted to know, rough and readily, how often consent was obtained and/or documented, whether the case was anonymised, and what kind of barriers to consent were present, such as the patient being incompetent or deceased, or the case involving more than one person. The results are shown in table 2.

ANONYMISING ETHICS CASES

The prevailing, albeit largely unspoken convention is for ethicists automatically to anonymise case material in recognition of the importance of medical confidentiality, although this was documented in only four out of 31 cases reviewed above (see table 2). But there are problems with this practice. Personal details are often central to the ethical issues of the case. The patient’s age, ethnicity, family background, gender, and occupation may all be as important as their specific medical details. For example, our thoughts about paternalism and autonomy in a specific case may well be influenced by information about the gender, ethnicity, and occupations of those involved. The importance of these contextual details means they cannot easily be removed from the case or changed in any substantial way in order to protect the identity of the patient. If they were, the case might simply no longer be noteworthy. In some cases, it may be possible to change details, but it is not clear how many details need to be changed to preserve anonymity. The current view of some medical editors is that it is impossible to guarantee anonymity simply by making some changes to the details of the case, and there have been instances of patients recognising themselves and complaining.

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Table 1 Major journals and their requirements for consent and/or anonymisation

<table>
<thead>
<tr>
<th>Journal title</th>
<th>Instructions to authors re consent*</th>
<th>Instructions to authors re anonymisation*</th>
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<tbody>
<tr>
<td>Ethics Journals</td>
<td></td>
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<tr>
<td>Bioethics</td>
<td>No instructions</td>
<td>No instructions</td>
</tr>
<tr>
<td>Hastings Center Report</td>
<td>No instructions</td>
<td>No instructions</td>
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<tr>
<td>Journal of Clinical Ethics</td>
<td>No instructions</td>
<td>No instructions</td>
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<tr>
<td>Journal of Medical Ethics</td>
<td>No instructions</td>
<td>No instructions</td>
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<tr>
<td>Kennedy Institute of Ethics Journal</td>
<td>No instructions</td>
<td>No instructions</td>
</tr>
<tr>
<td>General Medical Journals</td>
<td>No instructions for case studies.</td>
<td>No instructions</td>
</tr>
<tr>
<td>Archives of Internal Medicine</td>
<td>Written consent required for clinical images.</td>
<td>Anonymise by assigning numbers or fictional names to patients.</td>
</tr>
<tr>
<td>BMJ</td>
<td>Written consent required if “any chance patient may be identified”. Patient to view manuscript prior to publication.</td>
<td>Withhold names, patient details not to be changed to try to disguise them. Patients to understand that complete anonymity cannot be guaranteed.</td>
</tr>
<tr>
<td>JAMA</td>
<td>Written consent required from patients who can be identified in written descriptions, photographs, or pedigrees. Patient to view manuscript prior to publication.</td>
<td>No instructions</td>
</tr>
<tr>
<td>The Lancet</td>
<td>Written consent required for all case studies. Patient to view manuscript prior to publication.</td>
<td>Withhold names. Patients to understand that complete anonymity cannot be guaranteed.</td>
</tr>
<tr>
<td>New England Journal of Medicine</td>
<td>No instructions but links to website of International Committee of Medical Journal Editors displaying the Uniform Requirements for Manuscripts Submitted to Biomedical Journals.</td>
<td>See box 1</td>
</tr>
</tbody>
</table>

*Information obtained from the “Instructions for authors” section on the website of each journal.

It seems likely that, despite our best intentions, it is possible that patients could be identified, either by themselves or by someone who knows them, through the cases that are used for teaching and publication.

**OBSTACLES TO GAINING CONSENT**

One obvious solution to this issue is for ethicists to gain the consent of patients before publishing any information about patients or using this information in teaching. But there are problems with this suggestion. The first and most urgent is that at least some of the patients featured in cases studies are not competent to give consent; eleven out of 31 in our series.

In our experience this is a problem that is already hindering the publication of valuable case studies in disability studies and psychiatry. It is hardly in the best interests of the patients concerned for this information to be published and in the case of incompetent adults, there is no one who can give consent on their behalf. Of course, in the case of children, parents can consent but to ask them to do so contravenes the ethical convention that consent should not be sought for non-urgent, irreversible interventions that could wait until the child was able to decide for him/herself at a later date. Since the publication of a case study is not in the medical best interests of the child concerned, and since once in the public domain the information cannot be recalled, it would seem most ethical to wait until the child reaches majority so as to permit her to consent for herself. By this time, however, the case study will be out of date. This is obviously a problem for paediatric medicine case studies and one that has not yet been addressed.

Competent patients may not wish to consent to publication of their cases, as by their very nature, cases of ethical interest tend to be about sensitive issues, about problems in the doctor/patient relationship, or about accidents or mishaps. It is hard to imagine, for example, how an ethicist could gain permission from a couple to write about misattributed paternity discovered accidentally through genetic testing when there is no consensus as to whether the couple themselves should be told of the finding.\(^1\) In addition, sometimes the issues raised by a case are not to do with that patient as such, but raise questions about the organisation of care, or relations between health care professionals. In this situation, the events surrounding the patient serve as a trigger to the wider issue, but the case is as much about other people as it is about the patient, making it difficult to identify who should be the person to give consent. Likewise, some cases involve many people to give consent. Interestingly, some cases involve many people to give consent.

<table>
<thead>
<tr>
<th>Consent in 31 cases published in the JME 1982–2002</th>
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<tbody>
<tr>
<td>Consent for publication</td>
</tr>
<tr>
<td>Documented that consent obtained</td>
</tr>
<tr>
<td>Documented that consent not obtained</td>
</tr>
<tr>
<td>No mention of consent</td>
</tr>
<tr>
<td>Patient apparently competent to give consent at some stage</td>
</tr>
<tr>
<td>Declaration that case anonymised (or similar)</td>
</tr>
<tr>
<td>Barriers to consent: competence</td>
</tr>
<tr>
<td>Patient not competent to give consent</td>
</tr>
<tr>
<td>Unable to clarify or competence disputed</td>
</tr>
<tr>
<td>Barriers to consent: deceased patient</td>
</tr>
<tr>
<td>Incompetent patient died as part of case</td>
</tr>
<tr>
<td>Competent patient died as part of case</td>
</tr>
<tr>
<td>Barriers to consent: more than one person involved in case</td>
</tr>
<tr>
<td>Case involved more than one person</td>
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</table>

Box 1 Protection of patients’ rights to privacy

Patients have a right to privacy that should not be infringed without informed consent. Identifying information should not be published in written descriptions, photographs, and 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 the patient be shown the manuscript to be published.

Identifying details should be omitted if they are not essential, but patient data should never be altered or falsified in an attempt to attain anonymity. Complete anonymity is difficult to achieve, and informed consent should be obtained if there is any doubt. 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.\(^2\)
different players and may disclose personal information about
the patient’s family, partner, or friends which they would rec-
ognise and which they might not be happy to have in the pub-
lic domain.

Another problem is that the ethicist does not necessarily
have access to the patients concerned in order to gain their
consent. Indeed, it is considered desirable for clinicians to
withhold the identity of patients when discussing them with
ethicists. For published case studies, the clinician could be
asked to approach the patient for permission, but in addition
to the problems already highlighted the patient may be dead,
or the case may have occurred in the distant past or in another
country.

The way that this request was worded would have
significant implications. The forms currently used by medical
journals such as the BMJ do not mention research, but are
simply requests for consent to publication. If, however, the use
of case studies is recognised as ethics research, ethicists would
need to be prepared to submit their proposals for research
using cases to ethics committees, and to develop appropriate
patient information materials and consent to research forms.

**POTENTIAL HARMs**

If a patient is recognised or recognises him or herself in a case
study, what are the harms that may occur? The main harm is
the experience of violation of privacy that comes from having
information that was given in confidence disclosed in the
public arena. However, it is not clear how this works in practice
if there has been some anonymisation so that an individual
may recognise that this case is like their case, without being
certain this is indeed their case. If the case is of a type that
may be common to several unconnected people, and there is noth-
ing to link it with a specific individual, then there may be no
breach of confidentiality in the sense of having the personal
details of the patient entering the public domain without con-
sent. People may think they recognise themselves or someone
they know, but it is not clear that the privacy objection holds
if no one realises, or can be certain, that the information is
about a specific person.

There are, however, difficulties with this reasoning. The first
is that the biggest indicator that a case is about a particular
individual is the geographical location of the author and their
name. Anonymous authorship is unlikely to be attractive to
many authors, as they belong to a system that largely
measures the value of academics (and their institutions) by
publication output. Second, what makes at least some of the
cases so useful is that they are novel, and therefore the infor-
mation might only match one individual.

Perhaps more importantly, there are dangers if we think
that the only harm from a breach of confidentiality is experience
of violation of the privacy of specific individuals, as on this line
of reasoning, no harm would be done if the person never
found out, either through chance or because they are not
capable of knowing. This would offer no protection to the
person if no one realises, or can be certain, that the information is
about a specific person. Given

**PUBLIC INTEREST ARGUMENT**

Given the problems with guaranteeing anonymity, and the
difficulties of obtaining consent, is it possible to justify the
publication of patient information without consent, or even
given the poor history of the media in fostering balanced debate
about ethical issues, it may be fair to claim that analysis and
discussion by ethicists and others in academic journals is the
best way for this to proceed, or at least that this makes an
important contribution to public debate. History suggests the
public interest is not served when ethical matters are
discussed by unidentified individuals behind closed doors, as,
for example, happened with early decisions about transplant
recipients. There has been intense public interest in ethical
issues in the UK; it was the public’s reaction to the
development of in vitro fertilisation (IVF) infertility treatment
that sparked off sufficient concern to result in the Warnock
committee’s investigation and the subsequent Human Fertilisa-
tion and Embryo Act 1990. This suggests there is a significant
public interest in being made aware of and informed about
ethical issues in health care.

This line of reasoning is similar to that used to justify the
use of patient data in epidemiological research, when the ben-
etis to society of the research are considered to outweigh the
harms of using anonymised data without consent. This is a
very grey area, however, as there is no consensus as to what is
in the public interest. Approval from an ethics committee can
provide some reassurance, but this does not protect research-
ers from either professional or legal sanctions. Ultimately it is
the courts that have the power to determine what is in the
public interest.

The second justification for using case studies in research
and teaching is that it is in the public interest to have medical
practitioners who have received good training in ethical prac-
tice, and that this is best achieved by the use of case studies.
Certainly the current consensus in medical ethics education is
that case studies are invaluable, and the use of cases is not
confined to teaching ethics. There is an expectation that
medical students are legitimate recipients of health informa-
tion and that they are bound by the standards of medical
confidentiality. There does not seem to be any important
difference between using cases for teaching ethics and using
them for teaching communication skills or general practice or
any other medical subject.

In summary, it seems that the use of cases in medical edu-
cation is largely unproblematic and that any regulation of use
should apply equally to the use of cases in all branches of
clinical teaching. The disparity occurs in research, where cases
are the raw data for ethics research, but at present are not
subject to the same consent requirements as other forms of
research data collection, analysis, and publication.

**WHAT SHOULD WE DO?**

If we accept that it is difficult to anonymise ethics cases, and if
we accept that this is a breach of confidentiality, and if we fur-
ther accept that it is not possible to obtain patient consent in
many cases, then we are faced with some stark choices. We
either have to abandon all unauthorised use of cases in teach-
ning and research, or we have to accept that it is in the public
interest for these activities to proceed, but that it is time to
clarify some issues and raise the standards. These are some of
the specific issues that we believe should be considered.

What kind of standards should obtain for publication of
case studies?

The ideal standard would be for patients to give written con-
sent for the use of their information. This would allow full
discussion of all relevant material in a transparent manner. We
recognise that this is not possible in many cases, but where
consent has been given, this should be clearly stated.

If it is not possible to obtain consent (and who should judge
this is another question), we can perhaps look to some of the
discussions about the use of information without consent in
other contexts. Even strong proponents of informed consent
such as Doyal set out conditions in which it might be
acceptable to use information without consent, and one of these conditions is that for practical reasons, consent is hard to obtain. This is not writing with ethics research in mind, but she argues that exploitation is unlikely if there are no harms to the patient involved, where the concept of harm is understood in a fairly robust way. Exploitation is hard to define or measure, but certainly cases may be written up in either a more or a less respectful way. If cases are used to try to further our understanding of ethical issues and, through this, to support high standards of ethical practice, then this does not seem to be exploitative. If cases are used for their shock horror value to increase the standing of the ethicist in the eyes of medical students, this may well be exploitative. If cases are used to engage in intellectually stimulating but essentially solipsistic arguments, then perhaps it is better to use thought experiments rather than cases about real people.

With regard to the public interest argument, many of our landmark ethics cases do come before the courts and so enter the public arena. There are, however, cases that do not come to the courts that are of great public interest, and we feel that it is important to be able to write about and discuss the issues raised by these cases. Again, it is not easy to define exactly what constitutes a landmark case, but the use of experienced referees and editors will help to identify novel issues and weed out repetition.

Where it is possible to anonymise cases, this of course should be done. The name and, where possible, the age of the patient involved should always be changed. Beyond this, it is difficult to be prescriptive. Perhaps we need to adopt a stylized presentation format in which readers and students are always invited to “Imagine a case . . .”. This might require the use of “fictionalising editors” to edit cases to the required format. We need to distinguish carefully between the information that is necessary to understanding the case, and the information that adds colour but is not strictly necessary. It is important to recognise that any account of a case may make people aware of more of the facts than they were previously, for example, if a person recognises that a case is about her neighbour, the published account may give her more information than she originally had.

Sometimes it is not clear whether anonymisation has occurred (table 2). We think that for journal publication, anonymisation should be documented, but should this include the nature of the anonymisation? This might have advantages, but could also be potentially more identifying if the patient involved realises that s/he differs from the case only in respect of those features that have been changed.

**What kind of standards should obtain for the use of case studies in teaching?**

For teaching, the same kind of standards should apply as for teaching in other branches of medicine. Students need to understand that ethics cases are subject to exactly the same confidentiality requirements as other clinical material. Ethicists should set high standards in their use of cases, using only as much material as is necessary and avoiding any kind of sensationalism.

**Should ethics research fall under the same regulatory framework as other research using patient data?**

This is a tricky area; the nature of ethics research does not seem to be always well understood outside ethics circles. Research based on case studies occupies an uneasy ground between empirical and theoretical research; on the one hand it is obviously different from a qualitative study or an intervention trial, but on the other hand, it does use real patient data. If we accept that there are harms to patients from non-intervention research such that these require ethical scrutiny by a research ethics committee, perhaps we should have the same standards for ethics research. This does seem, however, to be overkill and it is unlikely that ethics committees would welcome the further workload. Also it is not just medical ethics that is struggling with current standards for confidentiality in research. We have already alluded to the problems of presenting case based material about incompetent adults in disability studies and psychiatry; publication of family pedigrees in genetics research also raises some of these issues. Emerging very strict data protection legislation is causing problems for researchers who work with medical records, or with epidemiological data and tissue banks where there is no expectation that identifiable patient information will be reported. Perhaps debate about ethics research should form part of the larger debate about developing workable standards for confidentiality in research.

**Who is professionally responsible for breaches of confidentiality?**

Doctors and other health care workers have an almost absolute obligation to protect patient confidentiality.21,22 Ethicists on the other hand, do not have any obvious professional obligations to patients. The nature of the relationship between an ethicist and the patient about whom they are consulted is undefined, and it is likely that in countries without a recognised/formal system of clinical ethicists, most patients are unaware that their doctor has consulted an ethicist about them. Despite this lack of formal clarity, most ethicists would consider themselves bound by accepted standards of confidentiality, at least in relation to the health care of specific patients. In the UK the General Medical Council (GMC) states that anyone receiving personal information in order to provide care is bound by a legal duty of confidence, irrespective of their contractual or professional obligations, and it seems reasonable to consider that this should apply to ethicists in their capacity of advising about specific patients.21 The use of this data for any other purposes, such as teaching or research, will breach confidentiality unless the patient has given consent, or the data is anonymised.23

Ethicists who are not also practising health care professionals are unlikely to have professional indemnity. Patients may well seek redress from any treating health care practitioner who breaches confidentiality by disclosing information to the ethicist, unless this disclosure was authorised. Patients may also seek redress from journals publishing identifiable material. At the very least, ethicists should discuss the matter with their source clinicians before using a case for teaching or research, firstly to ensure that the pertinent details are correct, and secondly to secure their assistance in anonymising. In terms of the accuracy of the facts, there is also the problem of libel if a patient/worker is presented in a light that s/he considers unfavourable and which is based on a reported impression of the facts.

**CONCLUSION**

We believe that ethics research and ethics teaching which use cases are valuable activities. To date there has been very little discussion about the ways in which these activities may breach patient confidentiality. As a professional group, we need to debate the issues raised in this paper, and to develop practical standards for publication. The irony will not be lost on our colleagues in medical publishing if it is cases in ethics journals that are found to breach confidentiality. Ethics research does raise its own issues with regard to the
difficulties of anonymisation, but shares common ground with other types of research in terms of struggling to comply with the current standards. We all need to work towards standards that protect patients while allowing teaching and research that are very much in the public interest.

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