



PUBLICATION ETHICS FOR SURGEONS

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"Publication ethics describes the framework of good conduct and professional courtesies by which we protect the quality and trustworthiness of the publishing process, and the practices which lead to published work. Academic publishing depends, to a great extent, on trust. Editors trust peer reviewers to provide fair assessments, authors trust editors to select appropriate peer reviewers, and readers put their trust in the peer-review process. Academic publishing also occurs in an environment of powerful intellectual, financial, and sometimes political interests that may collide or compete. Good decisions and strong editorial processes designed to manage these interests will foster a sustainable and efficient publishing system, which will benefit academic societies, journal editors, authors, research funders, readers, and publishers. Good publication practices do not develop by chance, and will become established only if they are actively promoted."

Blackwells Publication Ethics Guide

Trust lies at the heart of everything that we do as surgeons. It defines our relationship and reputation with our patients. The publication of our clinical and academic endeavours is an important process in advancing reputations and careers. In this article on Ethics, and in a subsequent article on Malpractice, I will consider a range of matters relating to clinical and scientific publication which arise from the practical experience of editorship of a surgical journal of which aspiring surgical authors and writers should be aware.

Publication Ethics impinges upon many important aspects of the framework in which we conduct our personal and public lives. It covers actions that we take to promote ourselves, our work and our institutions through the act of publication. Publication Malpractice is the ugly sister of Publication Ethics. It describes those processes and behaviours which, inadvertently or wilfully, undermine the integrity and utility of the medical and scientific literature, and of those who publish in it. The Editorship of an international surgical journal throws open the doors upon some dark and murky behaviours that do no credit to some members of the profession, and upon other questionable practices that undermine the quality of the international literature.

Good ethical practice is, ultimately, an individual and collective state of mind, arising out of the public spirited desire of individuals, groups, institutions and professions to respect, protect and strengthen the rights of individuals, subject to considerations of the greater collective good; and to make the world and human society a better living space.

Ethical considerations and behaviour are, thus, critical to daily clinical practice and to clinical research, and to writing for medical publications. General medical ethics and publication ethics are closely entwined, because the publication process is the end point of the expression and description of clinical work. The responsibility is always

primarily upon authors and researchers to ensure best ethical practice, and it is not the responsibility of journals to detect deliberate fraud. However, journals, publishers, editors and reviewers can do much to promote the principles and processes of ethical publication.

Ethical rules and standards of general and specific behaviour are largely implicit. They exist to ensure that no unnecessary harm is done to the physical and mental health of patients in the course of clinical practice, nor, by extension, to animals in the course of clinical research. Medical practitioners, and surgeons in particular, have very special privileges endowed by the state and by the law in respect of the physical and personal proximity that they are allowed to individual patients, and in the conduct of investigations, procedures and treatments which invariably have a greater or lesser capacity for harm, even when used in seemingly safe and appropriate circumstances. They also have extraordinary powers of influence over sane, healthy and responsible individuals.

Formal Medical Ethical codes thus exist to ensure that the implicit trust which patients place in medical practitioners is not abused, and that doctors, and other health professionals, maintain the highest professional standards in their daily work. Ethical codes are particularly important in the protection of children; of those with mental disability; and in those societies where certain groups of individuals lack the freedom of choice enjoyed by others under the law or through social custom and practice. In these circumstances, there is a strong moral obligation upon the doctor to promote and protect individual rights, as for example, those of women in some communities; of prisoners; and of the socially disadvantaged by virtue of economic, religious or caste issues.

Unfortunately, growing political distrust of the medical profession, fuelled in part by very bad apples such as Dr Harold Shipman and in part by media coverage of events such as the Alder Hey paediatric pathology and the Bristol Children's Cardiac stories, have fuelled increasingly intrusive administrative and regulatory regimes to supersede "endogenous ethics".

Medical Ethics and the publication process

The Ethical Regulatory Environment

Medical and publication ethics are complex areas of adjudication, where practice has been very variable from institution to institution and from country to country. Standards and perceptions vary with culture and societal norms, and it has often been difficult to find a common approach, both in principle and practice.

Most of the major journals work to the best principles and practices in the major Western jurisdictions. Aspiring surgical authors should, thus, ensure that the ethical foundations of their work meet these international requirements and standards, which may be different from those in their own local professional environment. In recognition of the deficiencies and lack of commonality of approach to publication ethics, and the consequent difficulties met by editors and authors, a number of independent and voluntary

organisations have worked to develop and publish codes of practice, as for example the **World Association of Medical Editors**, based in the US, and the **Committee on Publication Ethics (COPE)**, based in the UK. Their work has in turn been adopted by the major publishers, as for example by Blackwells.

The international Committee on Publication Ethics (COPE) is an excellent example of this voluntary approach at work. For the past two years, I have been privileged to sit on the COPE council. This meets regularly and includes Editors, writers, publishers, ethicists and lawyers. COPE was set up in 1997 to address issues of Ethics and Fraud as they affect the medical literature, and its remit is expanding into other professional disciplines. COPE provides a forum for publishers and Editors of scientific journals to discuss issues relating to the integrity of the work submitted to, or published in, their journals, both print and on-line. It encourages its members to seek investigation into suggested misconduct by the employing universities, hospitals or other funders of prima facie cases. The COPE Forum is open to all members. It meets quarterly to discuss cases and posts its advice and case summaries on its website. It has appointed an Ombudsman to deal with disputes between COPE members or between them and the organisation. It also publishes a **Code of Conduct for Editors** and provides free flowcharts on how to handle the more common publication misconduct problems; and a newsletter. COPE helps fund the UK Panel for Research Integrity and has links with the Council of Science Editors in the USA and the World Association of Medical Editors.

The UK National Research Ethics Service (NRES)

The UK's NRES is a public sector body within the Department of Health's National Patient Safety Agency, which offers a wide range of advice on the setting up, principles and conduct of local and regional ethics committees; and what subject matters fall within and outside the remit of such committees. It offers practical advice on the ethical and oversight issues of various practical topics, including the use of ionising radiation and medical devices.

The role of the Ethical Committee and Ethical Approvals

Regulations on ethical approval vary worldwide, and manuscripts from various jurisdictions may not satisfy a journal's normal requirement for independent ethical approval, leading to rejection. As a sound principle, all institutions and hospitals with responsibilities to patients and their protection should have a robust and independent ethics committee and process in place, comprising individuals who are properly briefed in their role, who bring a range of representative skills and energies to the table, and who are willing and able to consider and address objectively all relevant matters and work.

As COPE points out, the scope of ethical approvals is nevertheless difficult to define:

"The UK's National Research Ethics Service (NRES), specifically excludes projects from requiring ethical approval if they fall into the categories of audit or service evaluation, even

though: (i) both may have considerable ethical implications (e.g. the danger of coercion and threats to autonomy and confidentiality); (ii) their methods may overlap with studies defined as 'research'; and (iii) it may be difficult to decide how to define certain studies, even using the criteria suggested by NRES".

Publication Ethics and Best Practice in Publication

The following guidance has been produced by COPE to help journal editors who are considering the ethical foundations of submitted manuscripts:

1. Is the study scientifically valid and clearly presented; for example is the sample size adequate, are the results adequately and clearly presented and explained, and have the investigators excluded or considered the possible confounding factors and/or biases? Does the study contribute sufficiently to knowledge to make acceptance and publication a possibility?
2. Have the potential harms been minimised? Has due care been taken to avoid coercion or exploitation, to protect confidentiality, to minimise the risk of physical and psychological harm and to respect autonomy where possible?
3. If there is doubt about local law or regulations, editors should clarify this with the authors and ask them to provide a letter from the research ethics committee about the research.

All reputable Journals make clear their attitudes and approach to all issues of publication ethics, through their published guidelines and through generic references and links to independent sources of information. Given the breadth and quality of such information which is now readily available, there can be no excuses for non-compliance.

Transparency as an ethical principle in publication

Openness of information on funding, authorship, prior publication, clinical trials and copyright all contribute to high quality practice and a trustworthy ethical framework.

Transparency of Funding

Editors, reviewers and readers have a right to know who funded the work. Funding by commercial companies, charities or government departments, and their roles (and motives) in producing the work should be clearly identified, as should sources of non-financial support. The Acknowledgement allows contributors whose work falls short of authorship to be identified and recognised.

Transparency of Authorship

The list of authors should accurately reflect who did the work. Authorship disputes including gift, poly-authorship and unfair omissions are not uncommon, and many individuals may wish to jump on the bandwagon of authorship of a successful published paper. Authorship guidelines are published by the **International Committee of Medical Journal Editors (ICMJE)**. Their adherence should be encouraged by formal declarations of authorship and clear statements of contribution of each author. This may help to discourage 'ghost' authorship (individuals who qualify for authorship but are not listed) and 'guest' (or honorary) authorship (individuals who are listed for influence despite not qualifying for authorship).

The authors should acknowledge all significant contributions made to their publication by individuals who did not meet the journal's criteria for authorship. These might include, for example and depending on their contribution, author's editors, statisticians, medical writers, or translators.

Transparency and prior publication

Journals and readers have a right to know whether research has been published previously. This responsibility lies with the authors. It is also a great help to know that work is not concurrently being considered for publication elsewhere. In cases of uncertainty, the authors must disclose co-publication and potential conflicts, so that the Editor and reviewers can come to an informed decision. For example, there may be merit in republishing in an international journal a piece of work which has previously been published in a local language or obscure journal, to secure a wider audience for important material, so long as the co-publication is clearly identified as such to prevent confusion and subsequent errors. The scientific literature becomes distorted by duplicate and near duplicate publication. This has important consequences, for example, where results are inadvertently included more than once into meta-analyses.

Transparency and clinical trials

Since 2005, medical journals edited by members of the International Committee of Medical Journal Editors have made registration in a publicly accessible trial register a requirement for publishing clinical trials. Free on-line clinical trial registries include clinicaltrials.gov, clinicaltrials-dev.iftma.org/ and isrctn.org/. Early and complete registration of clinical trials is important, because it ensures that "negative" trials findings are also identified and recorded, and that their omission from subsequent reviews and meta-analyses does not inappropriately distort the literature.

The World Health Organisation (WHO) International Clinical Trials Registry Platform sets out twenty criteria in its **Trial Registration Data Set** (TRDS) which fully define a trial.

Transparency and meta-analyses

Papers that present new analyses or syntheses of data that have already been published (for example, sub-group analyses) should identify the primary data source, including reference to the clinical trial registration number, if one is available, and full reference to the related primary publications.

Transparency and Copyright

Copyright is both an ethical and a practical economic issue. It exists to provide an incentive for creative expression, which it recognises as a form of property. It is a legal concept which dates back to the 16th century, and whose applications and interpretations vary considerably from one jurisdiction to another. In general terms, any idea which is turned into material form invests the owner with copyright, or legal rights to protect that material. Coverage of copyright legislation includes: Literary works, Dramatic works, Musical works, Artistic works, Computer programs and databases, The Internet, Audio recordings, Video recordings, Films, Radio and TV programmes - broadcast or cable. As Graham Davies of Thames Valley University points out,

"Copyright hinges on the question of ownership of an original work. An original work can take various forms: text, image, audio recording, video recording, computer software, website, etc. Copyright is immediately effective upon the creation of an original work. The creator of an original work does not have to register his/her copyright in the work before it is protected. Copyright automatically belongs to the author or creator - but it may also be assigned to a third party, for example a publishing business. The copyright owner has the exclusive right to prevent any third party from doing any of the following without permission:

- * copy the work - which includes photocopying, scanning in texts or images and reproducing them in electronic format, and duplicating audio and video recordings;*
- * communicate copies of the work to the public - which includes, for example, making a copy available on a public website or intranet;*
- * perform a drama or play, a piece of music or a song before the public - which includes making recordings of such performances and uploading them to a public website or intranet;*
- * make an adaptation of the work - also known as creating a derivative work.*

UK Copyright in a work lasts for 70 years after the death of the creator and 50 years in the case of audio and video recordings, audio and video broadcasts, and computer-generated works. Unless a work is clearly stated to be copyright-free, or out of copyright by virtue of its age, it is illegal to download, scan or otherwise copy the said work for onward dissemination, even if no financial gain takes place.

Copyright infringement applies where the copyright material is being used. In other words, in the UK you are subject to British laws on copyright irrespective of the country of origin of the item you intend to copy."

Copyright and the doctrine of Fair Use

It would clearly be ridiculous and impractical if no-one could ever use, reproduce or quote a work without formal permission, and particularly for non-profit or educational purposes. The doctrine of fair use allows another author or creator to make short quotations for whatever purpose of commentary, so long as the source of the original quote is clearly identified. There is no clear line between fair use and infringement of copyright law, as for example in photocopying and other forms of exact reproduction. In scientific practice, authors write academic tracts to be read and used, and have a public service ethos in doing so. It would be an absurd situation where each and every infraction were subject to legal challenge, particularly as publicity is the oxygen of science and research. Nevertheless, the principles of copyright remain extant. The best test of whether copyright law is likely to be invoked probably lies in whether breaching it is likely to have significant and sufficient economic consequences for the author to justify reverting to the expensive processes of law.

Copying and reproduction on the Internet and on web pages

The principles of attribution for images and text apply as much to web pages as to printed media,

and to formal permission for significant reproduction. The duty of permission is upon the user of material and not upon the original author to police the internet. In practice, the entire blogosphere would probably collapse overnight if every copied and reproduced image were to be subject to rigorous copyright oversight, and policing such law has immense practical difficulties on the Web.

The laws on downloading in relation to copyright infringement become confusing, because it is not possible to access or read a web based document without downloading it to temporary memory. In the use of copying, saving and printing internet sourced material, the following practical rule would appear to apply. If the actions are for personal or limited use, then they are acceptable and indeed may be essential if any use is to be made of the material which after all has been posted on the Web for public use by definition. If they are being done to circumvent the economic benefits of the original authors (eg through sales of printed or electronic material, or the distribution of textbooks and course material) then copyright infringement may well be invoked.

The ethics of confidentiality, libel, and the law in scientific publishing

Editors and reviewers face a number of ethical challenges in the course of their duties, for which common sense, courtesy and experience are the best defences. It is uncommon for well run clinical journals, unlike newspapers, to be involved in significant breaches of confidentiality or of libel. However, an unsubstantiated allegation of plagiarism, misconduct, unethical or merely dubious conduct is clearly defamatory. Southampton based solicitor Elaine Heywood addresses this subject from a UK legal practice perspective as follows:

"Libel is defamation in permanent form—an article, review, correspondence or an email—through publication (communication) of a defamatory statement to a third party. A statement is defamatory if it lowers someone's reputation or makes one think worse of a person or a company. It does not matter that the libel was unintentional or not what was meant or not meant to be seen. What matters is how an ordinary and reasonable person would interpret it. The author, editor and publisher of the defamatory allegation can be sued."

The onus is then on the editor or publisher of the journal to prove the truth of the allegation. Truth can be hard to prove, particularly in the absence of clearly documented evidence. Defending a libel claim will be expensive and potentially damaging to a journal's reputation.

There are two important defences which frequently apply:

- * fair comment (statements of opinion as opposed to fact in the public interest) and
- * qualified privilege (a duty to publish information to a third party who has a reciprocal interest in receiving it or a public interest in publishing fairly).

Both these defences are defeated if the author can show malice, which is a possibility in the world of

academic rivalry and review. In the case of fair comment, malice has the narrower meaning of absence of an honest belief in the truth of a statement or reckless indifference as to the truth. Malice is generally very difficult to prove and the burden of proof is on the complainant. If a journal is being run well and objectively, and its intolerance of unpleasant or malicious commentary is made clear in its guidelines to reviewers, allegations of malice should rarely arise. A policy of multiple reviewers and good editorial judgement helps offset the risk of acceptance of derogatory reviews which are subsequently found to be malicious.

Editors need to exercise particular caution when dealing with allegations of unethical behaviour or suspected misconduct, but no-one should fear the pursuit of the truth in advance of publication. Allegations can be put courteously and directly to an author by way of enquiry without risk of libel. However, the international nature of publication does complicate matters. In terms of data protection, jurisdiction depends on who the data controller is and where the data is held. For libel, an author can bring a libel claim in any country where publication has taken place or defamatory content has been downloaded and where he/she has a reputation to protect.

In summary, it is very unusual for complaints about the editorial process to proceed to law in a well run journal or publishing house. Journals can reduce the risks of claims for breach of confidence or libel, though clear guidelines and policies, including an email policy and an effective data protection policy.

In conclusion, ethical considerations impinge upon the work of aspiring and established surgeons who are intent upon writing for publication in many ways. While much of this is common sense, a full awareness of the issues underlying your work and the obligations of reviewers and editors will help speed your work to publication, enhance the quality of your work and promote harmony in your professional lives.

Selected References and website resources

Guidelines from the UK's National Research Ethics Service (NRES)
www.nres.npsa.nhs.uk/applications/guidance/#clintridir

Best Practice Guidelines on Publication Ethics
www.blackwellpublishing.com/publicationethics/

The Committee on Publication Ethics
www.publicationethics.org/

The WHO International Clinical Trials Registry Platform
www.who.int/ictcp/en/

Elaine Heywood
Confidentiality, libel, peer review and the law
The Journal of the European Medical Writers Association 168
The Write Stuff Vol. 17, No. 4, 2008

Adam Jacobs
Inside a research ethics committee
The Write Stuff Vol. 17, No. 4, 2008

Davies G
General guidelines on copyright
In Davies G. (ed.) *Information and Communications Technology for Language Teachers (ICT4LT)*, Slough, Thames Valley University [Online]. Available from: http://www.ict4lt.org/en/en_copyright.htm [Accessed 10.02. 2010].