EDITORIAL

The importance of being statistical

Andrew Blance

In the previous Editorial (December, 2004), the Editor-in-Chief discussed the *raison d'être* of the journal. With specific regard to the scientific papers it contains, this purpose unarguably has to be the advancement of science—the 'gospel' that should lie behind every clinical decision made. The question then becomes 'how best to aid this advancement?' A reasonable answer would be to provide papers of the highest scientific quality. Study design, execution, analysis and reporting of the findings all then become central.

When undertaking research, collaborations as part of a multi-disciplinary team would seem to be sensible. Clinicians and statisticians (with other specialities as required, specific to each project), working in partnership, would appear to have the best potential for producing studies of a high scientific quality that are in line with the Declaration of Helsinki. One should remember that it is as unethical to conduct research using unsound statistical procedures, as it is with any other violation. High quality research, by definition, should be consistent with the philosophy of ethical approval, with the proposed study being able to answer the research question with the highest possible degree of scientific robustness.

The question posed by the Editor-in-Chief 'would we get a statistician to do orthodontics on our patients?' should hopefully be answered by a resounding and emphatic no. However, the situation is not so clear-cut for the clinician. Once a paper is published, it is ultimately the responsibility of the clinician to consider the science and act upon it accordingly. That again poses another question—how does the clinician 'consider' the science. Many may suggest that, after reading the title of a paper, the next step is to skip to the conclusion section and read the take-home message. Unfortunately, that is far from job done. Critical appraisal is a skill that practising clinicians should have in their arsenal and invariably requires an understanding of at least the most rudimentary medical statistics. The consequences of not carefully critically appraising the evidence can be disastrous—clinical practice may change without the sound evidence to support it.

In writing this, it would appear that the key word is 'highest'. We all continually work to improve standards and, for things to improve, things must change. Hopefully, everyone is agreed that it is best that these changes are based on the 'highest' standards of evidence. By introducing a more rigorous statistical element to the peer review process, the journal hopes to prompt contributors to continually strive to undertake research of the highest scientific standard. In particular, we hope to stress the necessity for appropriate statistics. One consequence of this will hopefully be to provide the interested clinician with high quality scientific evidence, which they can then subject to their critical appraisal skills. We may not achieve our goal, but if we do not try we will never succeed.

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EDITORIAL

Publishing without ethical approval

Friedy Luther

The Notes for Contributors to the Journal of Orthodontics informs authors that articles involving clinical research should conform to the guidelines issued in the Declaration of Helsinki where applicable, and must have received ethical committee approval.

Several papers have recently been submitted to the Journal of Orthodontics which have not (apparently) gone through the ethical approval process and/or gained informed consent. Unfortunately these papers have had to be returned to authors with a request that evidence of ethical approval be submitted (i.e. a letter of confirmation from an appropriate ethics committee) if the paper is even to be considered for review. Alternatively, if authors consider ethical approval is not required then the Journal would require evidence of this too — once again, a letter of confirmation from an appropriate ethics approval committee.

This editorial is intended to highlight what is potentially an increasing problem and advises authors against such inappropriate submissions. Despite the ethical approval process becoming increasingly stringent and laborious (see Editorial J. Orthod. 2004 31: 167–168) nevertheless, it is essential that we not lose sight of the fact that a major purpose of the ethical review process is to provide an independent view of whether research we intend to undertake is indeed ethical or not. Authors are always likely to be at a disadvantage in determining this for themselves in relation to their own work as they are likely to be biased — hence the need for ethical approval.

This is not simply a matter for the UK. International agreements exist (notably the Declaration of Helsinki) to protect research subjects, no matter where in the world they live or whether they are in private, hospital or government practice. See for example:

http://www.corec.org.uk/applicants/help/guidance.htm#gcp then click World Medical Association Declaration of Helsinki). Furthermore, other major national and international bodies such as the Committee of Publication Ethics (COPE, http://www.publicationethics.org.uk/cope1999/gpp/gpp_study.phtmland and the World Association of Medical Editors (WAME): Recommendations on Publication Ethics Policies for Medical Journals (http://www.wame.org/pubethicrecom.htm#study) all make clear what types of research require ethical approval.

Authors should also bear in mind Paragraph 27 of the Declaration of Helsinki which states: 'Both authors and publishers have ethical obligations……Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.'

So, please be aware: don't waste your time — authors must ensure that they seek and obtain appropriate ethical approval and gain informed consent. For studies involving people, medical records, and/or human tissues (now including teeth) — it is most unlikely that ethical approval was not or will not be needed.

Friedy Luther, Editor in Chief

Some other useful websites:

http://www.corec.org.uk/ Central Office for Research Ethics Committees (COREC).

http://www.corec.org.uk/recs/guidance/guidance.htm#audit For help distinguishing audit from research.

http://www.corec.org.uk/applicants/help/faqs.htm For advice including types of research that require ethical approval.

The Medical Research Council's website has many helpful links including advice regarding the use of human tissues (see ethics series):

http://www.mrc.ac.uk/index/publications/publications-ethics_and_best_practice.htm.

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