



Forum agenda

Meeting to be held on Monday 6 September 2010 at 3pm

The Council Chamber, The Royal College of Paediatrics and Child Health (RCPCH), 5-11 Theobalds Road, London WC1X 8SH

Agenda

1. Update on COPE activities by the Chair

2. New cases

- 10-25 Breach of peer review confidentiality in second round (AM)**
- 10-26 Suspicion of breach of proper peer reviewer behaviour (AM)**
- 10-27 Authorship dispute (PS)**
- 10-28 No ethics committee approval of a study (LR)**
- 10-29 Falsified references (GP)**
- 10-30 Claim from an author that his name should not have been included as author on a paper (SS/PS)**

3. Updates

- 10-11 The ethics of drug/medication use evaluation audit cycles and publication of the results**
- 10-12 Retract, correct, or both?**
- 10-13 Suspect author**
- 10-14 Supervisor publishes PhD students work**
- 10-17 Is it unethical to reject unregistered (or late-registered) trials?**
- 10-20 Is it unethical to reject unregistered (or late-registered) trials?**
- 10-21 Dual publication**
- 10-23 Lack of acknowledgement of contributor**

CONTENTS

NEW CASES	3
10-25 Breach of peer review confidentiality (AM)	3
10-26 Suspicion of breach of proper peer reviewer behaviour (AM).....	5
10-27 Authorship dispute (PS)	6
10-28 No ethics committee approval of a study (LR)	7
10-29 Falsified references (GP)	8
10-30 Claim from an author that his name should not have been included as author on a paper (SS/PS).....	9
UPDATES	10
10-11 The ethics of drug/medication use evaluation audit cycles and publication of the results...10	
10-12 Retract, correct, or both?	11
10-13 Suspect author	13
10-14 Supervisor publishes PhD students work	15
10-17 Is it unethical to reject unregistered (or late-registered) trials?	16
10-20 Plagiarism of published paper	17
10-21 Dual publication	18
10-23 Lack of acknowledgement of contributor	19

NEW CASES

10-25 Breach of peer review confidentiality (AM)

This case concerns a submitted review article that proposes a new theory in a field of research where there are two polarised positions.

The original manuscript (R0) underwent peer review and was returned with reports indicating a major revision, which took several months. On submission of the revision, one of the reviewers from the previous round was asked to re-review. That reviewer (reviewer A) declined but provided a suggestion for an alternative reviewer (reviewer B). The editor invited reviewer B, who agreed to review the revised manuscript (R1).

Reviewer B delayed reviewing the paper, but finally submitted the review after a reminder from the editor. That review was one of two that were returned for manuscript R1. The other review was complimentary and suggested a very minor revision.

The editor included the reviews with a decision letter to the author explaining that it appeared that certain important aspects of the paper were not yet in order, or representative of a genuine division of opinion in the community, and asking for clarification. The contact author recognised one of the reviewer reports (reviewer B) as identical to that from reviewer A from the R0 round of peer review. Clearly, at this point, the author and editor could only assume that the confidentiality of peer review had been broken between reviewer A and reviewer B, but also that further misconduct/incompetence had occurred between the two.

The editor put this point to reviewer B for clarification, and the reviewer replied (after a delay of 3 days) that he/she did not know what the editor was talking about. With that email reply, reviewer B included a different report with the words of explanation "THIS is my report on the manuscript".

In good faith, and preserving anonymity, the editor forwarded that "second" report from reviewer B to the contact author whereupon the author replied that even that report referred to concepts that were no longer present, or no longer presented in such terms, in the revised manuscript. That observation further added to the author's and editor's concern that the revised manuscript had not been judged properly, or even at all, by reviewer B, and that the process of peer review had been compromised in several ways.

An inevitable conclusion is that the peer review of this manuscript was compromised in respect of the confidentiality and proper conduct that is expected of peer reviewers. Although it is often possible for a second round reviewer to see—verbatim—the report of a previous reviewer included with the author's response letter, this was not the case with the above manuscript. The editor double checked the manuscript submission system: the verbatim version of reviewer A's report was not included with the author's response that reviewer B was able to see, although the author did address reviewer A's points in that response. Therefore, the editor can only assume that the first report that reviewer B submitted actually came from, or by way of, reviewer A.

Furthermore, the second report from reviewer B refers to concepts that were in the R0 version of the manuscript, but not in the R1 version, hence indicating that reviewer B had reported on the wrong manuscript, which he/she could only have obtained via reviewer A.

On receiving feedback on the second reviewer B report from the author (ie, that it must refer to the R0 manuscript instead of the R1), the editor emailed reviewer B, laying out the events and concerns, as described above. The email ended with the following observation: “Both the contact author and the editor have important concerns about the peer review of this manuscript: ie, that it has been compromised in serious ways that might even have influenced the careers of the younger authors. Clearly, the proper review of manuscripts in a journal that maintains confidential peer review is of paramount importance, given the lack of knowledge that the author has as to who has reviewed his/her paper. I trust that you appreciate my concerns”.

The editor received no reply but has marked both reviewer A and reviewer B as excluded reviewers in the manuscript submission system, and has made the case and identity of the reviewers known to his publishing department. From the course of events, it is highly likely (although not provable), that reviewers A and B conspired to get the manuscript rejected. What further action is necessary/advisable?

10-26 Suspicion of breach of proper peer reviewer behaviour (AM)

An author submitted a paper for peer review with journal X on a topic that refers to a very recently published paper (ie, highly timely). The peer review was rather protracted because of long response times, reviewer substitution and the need to re-review the manuscript after a major revision.

Just before the second decision was rendered, the author contacted the editor-in-chief with a serious concern that the accepted standards of peer review had been compromised: specifically, the author had just seen, in an online version of journal Y, an article that was very similar in many places to the article that he/she has submitted to journal X. The author suspected that one of the peer reviewers had either taken personal advantage of the opportunity or passed the paper on to another scientist who was either the author of the first published paper or a close contact.

The editor-in-chief compared the two papers, noted striking similarities in two large sections (also mirrored by the order of reference citation in those sections) but assured the author—without revealing the identity of the peer reviewers of his/her paper—that there was no obvious connection between the reviewers and the author of the first published paper (a PubMed search for coauthorship and a Google search for association of names revealed no connection whatsoever).

The author thought of other ways in which the similarity could have arisen and finally remembered having submitted a grant proposal with very similar wording, which might have been reviewed by the other author. That, and the assurances from the editor-in-chief, put the case to rest.

However, what should/could the editor-in-chief have done to resolve the matter had the suspicion of breach of peer review confidentiality or personal benefit been more likely (ie, likely enough to suggest more background research)? How could such a case be resolved to the satisfaction of the author (ie, such that the true precedence of his/her work would be recognised by readers in contrast with that of the opportunist author)?

10-27 Authorship dispute (PS)

Professor X claims that he should have been a coauthor on one of two peer reviewed publications and the senior author on the other. The situation is unusual in that Professor X is now retired and his name was omitted from coauthorship of both papers. Professor X argues that he should have been the senior author of the first manuscript since the funds to initiate the project were directly derived from a grant awarded to him.

Professor Y does not dispute this assertion but argues that the direction of the project and the data generated for the paper do not reflect the work proposed in the original grant and that Professor X made no contribution to the final product. Professor X claims that the second publication arose from his initial contact with Professor Z, the eventual senior author on the second publication, and from his proposal for a collaboration. Again, Professor Y argues that Professor X had made no contribution to the final manuscript. There appears to be personal animus between Professor X and Y which complicated resolution.

In telephone conversations with Professor Z, I learned that Professor X had been included as a coauthor until the final version, at which time he was excluded from authorship. Professor Z did know this action had been taken, apparently by Professor Y, but did not question it.

The final resolution involved compromise on both sides, and neither party was happy with my final decision. The resolution involved a corrigendum stating:

“This corrigendum is to note that Dr X should have been acknowledged as an author on the paper entitled, ‘XXXX’ for having contributed to the initiation of the program. Dr X should also be acknowledged as an author on the paper entitled, ‘YYYY’ for his participation and contributions in the early stages of this project.”

Although this issue has been resolved, it took an inordinate amount of my time as editor, requiring multiple emails, telephone calls and involvement of the provost of the institution in which the two investigators worked. The question is whether, for future reference, there is an alternative approach that is equally equitable and effectively more time efficient.

10-28 No ethics committee approval of a study (LR)

Our journal received a manuscript describing a comparison of two different techniques for patients in the intensive care unit. There was no information on ethics committee approval and so we asked the authors if approval was obtained. They replied that they had not applied for ethics committee approval “as it was a clinical comparison of two existing methods, none of them experimental. All patients had an indication for the technique, and the technique was introduced in our intensive care units before the beginning of the study period”.

The study is described in the manuscript as a “prospective, comparative clinical study” conducted in 2009 and that “every other patient” who received the technique during the study period was assigned to “the technique of choice at our institution” or to a technique introduced in 2005. It is not clear whether informed consent was obtained.

We believe that this study was not conducted in accordance with the Helsinki Declaration where it is specified that “The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins”.

Regarding informed consent, it is stated that “Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research population. In such circumstances the physician should seek informed consent from the legally authorised representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research should be obtained as soon as possible from the subject or a legally authorised representative.”

We have the following question for COPE: should we wait for the authors to apply for approval from the ethics committee at this stage or should we reject the manuscript and forward our concerns to the person responsible for research governance at the institution?

10-29 Falsified references (GP)

An article was submitted to my journal and was sent for peer review. An editorial board member realised that a number of the references were incorrect: publication dates had been changed to make them more current.

The author was contacted by email and telephone who said he/she had a number of students working for him (who were not listed as authors or in the acknowledgment) and they must have changed the dates because it was well known that faculty preferred current research. He was sorry and was happy to correct the references so the peer review process could move forward.

I told him the manuscript was rejected based on the grievous errors in the reference list. This author also had an accepted manuscript in the production queue. I reviewed that manuscript again after realising the issues above and found the same problems.

Because I had already accepted that manuscript, I gave the author the opportunity to correct the references and add the student's names who worked on the paper to the acknowledgment section. The managing editor and I had to review and further correct the references following his attempt, and this manuscript will be published.

Have other editors experienced similar problems and how does COPE recommend handling them?

10-30 Claim from an author that his name should not have been included as author on a paper (SS/PS)

Dr R submitted a paper to our journal and has since expressed unhappiness about the way in which our journal has dealt with the issue.

The manuscript was submitted to our journal according to the usual accepted procedures. Our journal requires that only a single author (the corresponding author) sign the copyright assignment form (on behalf of all the authors). We require that the author also affirms that all authors have seen and agreed to the submitted manuscript. Dr R was the corresponding author for this paper and she provided the requested assurances.

The paper was reviewed, revised and accepted without any unusual comment. It was published online and was scheduled for print publication. We received a protest letter from Dr M in July (several months after online publication) claiming that he was not consulted about the paper and did not want to be a coauthor. We then removed the article from our website and from the upcoming print issue, pending resolution of the protest.

We wrote to the corresponding author (Dr R) asking for an explanation, which she provided. The gist of the explanation was that Dr M objected to publication as a means of retribution, for her spurning his romantic advances. According to the appendix provided by Dr R, there was no communication between her and Dr M at the time of manuscript submission (because of the split caused by this personal issue). Dr R therefore relied entirely on Dr V (who was her Head of Department) for her determining that Dr M was happy with the submission (assurance that was apparently provided by Dr V).

We have requested a confirmatory letter from Dr V (Dr R's advisor—the senior member of the authorship team). Dr V has responded with a letter indicating the scientific excellence of Dr R's work but not clearly addressing the issue of whether Dr M did indeed see and approve the submitted manuscript. Dr M has written to reiterate his objection, and to clarify that he opposes publication per se. Dr R wrote again indicating her unhappiness with the way this issue was being handled by our journal.

What does COPE advise?

UPDATES

10-11 The ethics of drug/medication use evaluation audit cycles and publication of the results

Anonymised text of the case:

We are seeking guidance on the ethical issues surrounding drug/medicine use evaluation (DUE or MUE) audit cycles, particularly with respect to the publication of findings but also perhaps with regard to the conduct of these audits in general.

DUE is a quality improvement activity that involves data collection and evaluation (usually by audit), followed by 'action' or intervention and a repeat or 'follow-up' audit to monitor changes in practice. DUE methodology was used for a recent national quality improvement activity overseen across approximately 60 hospitals by an independent organisation funded by the government to promote quality use of medicines. Participating hospital 'project teams' were asked to identify a predefined number of patients from their surgical lists for the baseline audit, obtain consent from the patient for inclusion ('if required by local authorities'), conduct a brief postoperative patient interview regarding pain management and, after discharge, retrospectively collect pain management data from the medical record .

Data were submitted to the national project team for collation and assessment, with individual and combined results fed back to hospitals. An educational intervention was then conducted at each site, attempting to address medical, nursing and pharmacy issues, and utilising a number of tools, including one-on-one 'academic detailing', presentations and posters. A follow-up audit (same as the baseline) was then conducted at each institution.

A manuscript was submitted to our journal describing the conduct and outcome of the project in two hospitals, and comparing these with each other and with the national results. The hospitals were not specifically identified but were labelled A and B, although one could be assumed to have been the primary institution of the authors and the other probably one of two smaller institutions in the same area health network. The methods stated that formal patient consent was not required for the inpatient interview component because the questions asked fell within routine postoperative care. Institutional Ethics Committee approval appears not to have been sought for any aspect of the project in either of the hospitals concerned although the overall project appears to have been conducted with the approval of various state health bodies and presumably individual hospital administrations, although this is not clear.

The manuscript was rejected on a number of grounds, mainly relating to questions of methodology and partly related to the question of publishing a small subset of a much larger set of data (also to be published eventually according to the website of the national project). The submission did, however, raise other ethical questions that remain a matter of some debate among the editors concerned, and we seek the help of COPE in addressing these since it appears this sort of situation is likely to come up again with increasing regularity. Our first

question relates to the study subjects study. In the submitted paper, the assumption appeared to be that the patients were the subjects and their 'recruitment' was discussed. However, we feel that the subjects of the investigation were the staff of the participating hospitals since it was their drug prescription administration and documentation behaviour that was being examined before and after a behavioural intervention.

Our second question regards the nature of the project. Is it a quality assurance/improvement activity that does not require ethics approval for its conduct and/or publication of results? Or is it actually a research study examining the behavioural effect of an educational intervention on hospital staff, and as such does require ethics committee consideration, approval and possibly individual participant (staff) consent?

Advice:

This case prompted a discussion on the differences between a study and an audit. Most agreed that if there is an intervention, then it is a study, but it was pointed out that there are regional differences, and different countries have different policies on what type of studies need ethics approval. The Helsinki declaration discusses "human subjects" and so does not make a distinction between patients and staff. The advice from the Forum was for the journal to develop their own policy on this issue and to perhaps commission an ethical debate around the subject for publication in their journal. The Forum also reiterated the fact that even if a study has ethics approval, the editor does not have to publish it if s/he is unhappy about any of the aspects of the study.

Update:

COPE suggested we develop internal policies regarding situations like these, and this was discussed at our subsequent editorial board meeting. The Committee's advice was found to be very helpful by the board, and in particular the agreement with our assessment that the staff, not the patients, were the subjects of this particular "experiment", and some discussion occurred surrounding this and other cases discussed at the COPE Forum meeting involving conflict of interest issues (new ICMJE guidelines) and Clinical Trial Registration.

Notices regarding conflict of interest and trial registration are being considered for inclusion in our instructions for authors and also for a new set of editorial guidelines.

The more difficult ethical question is yet to be fully resolved. However, we will continue to deal with such cases on a case by case basis and hopefully reach consensus among the editors.

10-12 Retract, correct, or both?

Anonymised text of the case

Like many journals, we do not collect actual signatures of each co-author, asking the corresponding author to declare on a form that, among other things, he/she has the authority to submit on behalf of the others

A paper was published in our journal in April 2010. Shortly afterwards, we were contacted by one of the authors saying that he and his colleagues had been unaware of the existence of this paper and that the corresponding author, who had been visiting their department from another country, had taken data from their database and written and submitted the manuscript without the permission of the department or hospital. His first knowledge of the article was when the publishers had sent him a set of proofs (since the corresponding author had not responded to their emails); unfortunately, he did not tell us then, before publication, but contacted the corresponding author directly in an attempt to stop publication and had assumed it had been dealt with

I asked him to check the data and he did so, saying that while they were not inaccurate or unreliable, they presented an incomplete picture and the paper ought to be considerably revised to incorporate other data and a fuller discussion, in order to put it into context

Meanwhile, I have written to the corresponding author without response. My intention is to contact the corresponding author's institution(s) if there's still no response by the end of May. I have also written to the research ethics committee at the hospital concerned to check that approval was given as claimed in the paper (so far also without response).

My suspicion is that the claimant is correct, that the corresponding author has behaved improperly. In due course my intention is to publish a notice to this effect, that will include any response (or lack of) from the author and his/her institution; clearly, I will need to gather more information if possible and give the institutions time to respond.

My question is whether it would be better to do this in the form of a correction, setting out the circumstances and including any supplementary information supplied by the claimant, or to retract the paper and allow the claimant to re-submit a revised version, accompanied by a notice of some kind. And whether it would be worth publishing a statement of concern in the meantime while investigations are ongoing. The paper itself is a review of patients of a particular type, undergoing a particular treatment, so it does not claim that treatment X is better than treatment Y although it might contribute to treatment decisions in terms of counselling/offering that treatment to these patients—thus does have clinical implications.

Advice:

The advice from the Forum was that there has been serious misconduct and so the paper should be retracted, even though only the corresponding author was involved in the misconduct. Although the data are not in question, most believed that the paper should be retracted. If the investigation is going to take a long time, then the editor should publish a notice of concern. Going forward, the advice from the Forum was to always contact all of the authors, and not just the corresponding author, when the journal is dealing with any manuscript.

Update:

I intend to issue a notice of retraction after the final deadline for the authors' institutions to respond (or be listed as having not responded). I have had confirmation from the ethics committee that they did not know about the study, even though it was claimed that ethics approval had been granted. The remaining authors say they have a revised manuscript in preparation and we will consider this as a new submission if/when it is submitted. In the meantime, the journal has adopted the suggested policy of emailing all of the authors, and not just the corresponding author, when the journal is dealing with any manuscript.

10-13 Suspect author

Anonymised text of the case:

Author A has published approximately 150 original articles since ~1994, with ~100 on one particular topic. Since some of these events were up to 16 years ago, and there are no formal records from then relating to these studies, the only information we have is the memory of the editors of the affected journals in post at the time. According to their accounts, suspicions were aroused over the validity of the data, in particular the similarity between baseline data of some of the different studies. When author A was pressed to provide raw data, he stopped responding and stopped submitting papers to the specialty journals, switching to general journals where he continues to publish. The editor of one specialty journal raised concerns with the author's institution (in another country) approximately 12 years ago; it responded saying it saw no reason to investigate further. A letter, published in one of the specialty journals in 2000 by an independent researcher, asked the question "Why are author A et al's data so nice?", pointing out that the probability of such results occurring by chance were infinitesimally small, but as far as we know there have been no formal investigations of author A's work

Following an April 2010 editorial in one of the specialty journals about research fraud in general, that mentioned this particular author by name, a correspondent raised the lack of investigation into author A, stating that his update of a systematic review was being hampered by the (suspect) influence of author A's work in this area. The current editor-in-chief of that journal contacted the current editors of seven other affected specialty journals, who until this point were largely unaware of the problem, or its extent, having not been in post at the time the papers were submitted to their journals. We have since been discussing the problem and possible courses of action. The points raised are:

(1) Regarding the older papers:

(i) the journals themselves do not have the ability to mount an investigation;

(ii) it is unlikely that an investigator, bona fide or not, will still have original data from the older studies;

(iii) it is unlikely that author A's institution will be interested in investigating studies so old, and we think he might have moved universities since then;

(iv) currently we do not have any firm data of wrongdoing, just suspicions. Options for gathering more data include asking the original correspondent and the systematic reviewer to provide a more formal commentary, although we have not done that yet. Meanwhile, one of the editors has gathered data on all author A's studies: there are 135 in which author A is the first author, reporting almost 12,000 randomised patients in 17 years. Most are with one of the same three co-authors. The largest group of papers (by topic) are all very similar in design, with very little variability in baseline placebo event rates, and generally similar results although the outcome measures differ and there are one or two 'surprising' (at best) findings. One particular drug features in 71 studies. Dropouts are hardly ever reported.

(2) Regarding the newer papers:

(i) these may be easier to investigate since the data should still exist;

(ii) we could contact the editors of the non-specialty journals (there are many, publishing just 1-2 of A's articles each) to alert them but the problem of having only suspicions remains (compounded by the relatively large number of journals, each with a small number of papers);

(iii) we could ask a respected academic in author A's country to make discreet enquiries of author A's co-investigators, some of whom may not realise what is going on, or they may have concerns themselves. However, this could be a delicate situation for such a person. We would welcome COPE's advice on how best to proceed.

Advice:

The Forum was unanimous in their opinion that this should really be resolved by the researcher's institution. Although there is no hard evidence, it was suggested that all of the journals, as a team, approach the institution and ask the institution to conduct an investigation. It was felt that this would provide a more powerful case than a single editor on his own. Meanwhile, the editor should try and gather more evidence, perhaps by contacting the ethics committees who supposedly approved these studies. The editor may then be able to determine whether in fact the studies took place as reported. The Forum advised against informing the non-specialty journals at this point as there is no real evidence at this point, so it would be difficult for them to know what to do. The Forum also suggested that the editor should advise anybody doing a meta-analysis on this subject to include a sensitivity analysis to test the effects of including the data from these studies.

Update:

The group of editors-in-chief are planning on sending a letter to the author and the institutions. The delay has been in obtaining an independent analysis of the suspect works, which so far indicates that the likelihood of fabrication is very high.

10-14 Supervisor publishes PhD students work

Anonymised text of the case:

The PhD supervisor and a co-supervisor published a paper. The paper contained the work of a PhD student; approximately 90% of the paper was from the thesis. The PhD student found out when the paper was electronically pre-published. He contacted the supervisor. The supervisor's first reaction was "How did you find out"? The supervisor did not want to include the PhD student as an author since he himself had done most of the work. The editor decided to remove the paper from the journal until the case was decided.

The editor contacted the supervisor and he stated that he would have included the student as an author when the paper was accepted. Contact with the co-supervisor (and co-author) showed that he was not aware of the paper. He found the quality too low and did not want to be involved. He informed the editor that a similar case with the supervisor had occurred in another journal, 2 years earlier. (The editor contacted the editor of the other journal who confirmed that a similar case had occurred and the paper had not been published.) The paper was finally removed from the journal; no paper version had been printed.

What do we do in this case? We want to ban the supervisor but allow the student to publish. The editor told the PhD student that he could submit a paper himself. However, the quality may not be sufficiently high for it to be accepted. To date, the PhD student has not submitted a paper to the journal.

Advice:

The Forum emphasised the fact that if something is published online (especially if it has a DOI number), then it should be considered published. Hence, an editor cannot simply remove a paper from their website. A paper should only be removed from an online site if it has been formally retracted. In this case, the paper should be re-instated on the website, with an expression of concern. The editor should contact the author's institution at a high level—perhaps the head of department or dean of the university—and request that they conduct an investigation into this case. An expression of concern can be published on the website while the editor is waiting on the outcome of the investigation. Depending on the outcome, the editor may then decide to retract the paper. COPE does not recommend banning any author because of the legal implications. The editor may want to discuss this with his publisher.

Update:

I followed the advice from COPE and contacted the university in question and asked them to investigate the case. They have responded that they will investigate and come back with their results.

10-17 Is it unethical to reject unregistered (or late-registered) trials?

Anonymised text of the case:

We would like other editors' opinions as to whether adhering to the journal's policy on trial registration may contribute towards the non-publication of trial results (and thus bias in the literature).

All of our journals have the same policy on trial registration—for studies started before July 2005, we permit retrospective registration (providing it was done before submission) but for trials started after July 2005, we require registration to have been done before enrolment of the first participant.

In recent years we have tried to enforce this policy strictly and have rejected many papers reporting trial results where the trial was not registered in line with our policy. A very quick audit reveals about 20 or so studies which have been rejected in the past year or so due to non-compliance. For these studies, we have informed the authors of our policy and advised them they can retrospectively register, for free, at clinicaltrials.gov, where they are also able to deposit results (should they be unable to secure journal publication).

We are now also considering removing the 'grandfather' clause for old trials (pre-2005) (ie, that we would be unable to consider these for publication unless they had also been prospectively registered). One specific case we handled recently relates to a large cancer screening trial, which we felt was likely to be methodologically sound, and addressed a question where there was little data in the peer reviewed literature. The results would undoubtedly have informed future clinical practice and may have had the potential to save lives—the trial results suggested benefit for a screening approach which is not currently routine practice. The trial had been done after July 2005 but was only registered some months after enrolment started. We rejected purely on the basis that the study had not been properly registered in line with our (and other journals') policies. We did not think that selective reporting was an issue with this particular study.

However, would other editors have a concern about strict application of the registration rule (ie, that editors have a duty not just to apply policy regardless but to consider their responsibilities to the integrity of the evidence base in a more flexible way, which in some cases may be achieved by overriding their own policies)? However, we are concerned that having some laxity in our policy (eg, with the grandfather clause for older trials) may encourage triallists to think that prospective registration is not mandatory (and thus avoid registration in the future).

Advice:

The advice from the Forum was that, in general, it is probably best to judge each paper on a case by case basis. Some argued for leniency in the case of trials published in and around 2005, as many authors may not have been aware of the new requirements for registration. However, whether or not a trial is registered has little bearing on the quality or ethics of the

study, and so it is up to the editor to decide whether or not a study should be published. All authors should now be aware of the regulations so there is no excuse for not registering a trial. However, it was pointed out that many journals do not require trial registration and so the authors can always have their work published elsewhere. Editors need to balance the benefits of having a strict policy requiring prospective registration (which should encourage trial registration) against the harms of non-publication of individual studies that have not been properly registered but may contain valuable information.

Update:

The advice from COPE was very helpful, and we are still handling new cases which relate to this problem. Our journals have not changed their policies. We still have a strict policy requiring prospective registration for trials done since mid-2005, although we are more lenient still and permit retrospective registration for trials done before mid-2005. Very sadly, the journals continue to reject some numbers of trials which were not registered in line with our policies. We continue to refer authors to clinicaltrials.org to deposit their results along with their registry details.

10-20 Plagiarism of published paper

Anonymised text of the case:

My subeditor handling this case told me he had found similarities with the protocol of a paper published elsewhere. The subeditor decided to send the paper for review to one of the authors of this published paper. The reviewer reported that the manuscript had the same figures and conclusions as a second paper he had published. All figures and the conclusions of the manuscript were the same as the second published paper. The reviewer also noted that most of the data were the same or had been only slightly changed and the text in the materials and methods section was also mostly identical. The reviewer asked me as editor to inform the first author's institution asking for an in-depth investigation of this case of scientific fraud. The reviewer also said that he would inform the director of his own institute about this case of unethical behaviour.

This paper was first submitted to my journal in February 2010 and rejected on initial review by a different subeditor because it was missing many references and was incomplete.

I could not find any other papers written by the other authors on the paper so I'm assuming they were probably students, with the last author the professor. It is not clear to me if the paper was submitted with the approval of all authors as this was not stated in the covering letter.

Advice:

The advice from the Forum was to follow the flowchart on 'Suspected plagiarism in a published article'. In the first instance, the editor should contact the corresponding author and

ask for an explanation. If there is no response the editor should try to contact all of the other authors. If the response is unsatisfactory, the editor should consider informing the author's institution and asking them to investigate the case. The editor should inform the authors that this is the course of action that he is pursuing. The Forum noted that it is very important to give the author a deadline for response, and most considered a month a reasonable length of time. The editor might also consider posting a registered letter to the author if there is no response to emails.

Update:

On 18 June the editor sent an email to all of the authors informing them that we were concerned about a possible case of plagiarism and asking the authors to provide an explanation. A deadline of 2 weeks was offered and we informed them that we would contact the universities involved after this date. The corresponding author replied that he was not aware of this manuscript and he believed someone has used his name to submit the manuscript. However, one of the authors replied that he was not aware that the data were plagiarised and he offered to help in this case. He provided a number of pieces of evidence confirming the identity of the corresponding author. The Dean of the University where the corresponding author is working was informed about the situation on 10 July, followed by a second email on 29 July. The Dean finally acknowledged receipt of our letter on 1 August saying he will investigate the case. The editor sent a follow-up email on 25 August and the Dean immediately replied that the case is now under investigation.

10-21 Dual publication

Anonymised text of the case:

The authors submitted a paper to our journal which went through the review process and was accepted for publication. It was then placed online in corrected proof. While online we were informed by a reader that the paper appeared to have been published in a journal local to the authors, although only an abstract was available in English. We requested that the authors submit an English language version of the original paper so that we could assess whether this was a case of dual publication. In the meantime, we removed the online version.

Following this, the authors withdrew the paper. The question now is, should we pursue this further by reporting the authors to the regulators in their country for an apparent attempt at dual publication and, if so, to whom should we report?

Advice:

The Forum reiterated the fact (raised in case 10-14) that if something is published online, then it should be considered published. Hence, an editor cannot simply remove a paper from their website. In this case, the author cannot withdraw his paper as it has been published. A paper should only be removed from an online site if it has been formally retracted. If the editor has clear evidence of duplicate publication (ie, if he can review the translated published paper and determine the degree of overlap between the two papers), then he should

re-instate the paper on the website along with a notice of duplicate publication. The editor should follow the flowchart on ‘Suspected redundant publication in a published article’. He should contact the authors for an explanation. If no response or an unsatisfactory response is obtained, he should consider contacting the authors’ institution.

Update:

The authors formally retracted the paper. Therefore, the paper was not re-instated. The reason given by the authors was that they did not want to go to the expense of providing an English translation of their original paper. At this stage my inclination is to do nothing further.

10-23 Lack of acknowledgement of contributor

Anonymised text of the case:

Our case relates to a paper (by author’s A and B) that was retracted because of lack of acknowledgement of the contribution of another author (C). The retraction statement noted: “While the A/B paper is largely the work of A and B, it includes some sentences and ideas that previously appeared in an unpublished paper and/or Power Point presentation only with A and C listed as authors. We regret that the paper was published without any acknowledgement of the earlier collaborative work.” Author A has contacted the journal expressing concern that this retraction is damaging his reputation.

The basis for the retraction was evidence from C that parts of the A/B paper were the same as parts of a paper started by A and C but never finalized or published. C provided six specific cases involving about 23 lines of duplication. While this represents a small percentage (about 4%) of the total number of lines in the paper, because they duplicated lines from some version of the A/C paper, the editor believes there was a moral obligation on A and the new author (B) to acknowledge the earlier paper and/or the collaborative efforts of C.

However, A claims that (1) s/he wrote all of the A/C paper, (2) asked C to identify his/her own material, (3) offered to delete any such material from the final paper with B, (4) received no instructions regarding what to delete and (5) proceeded to use whatever he liked and drop whatever he did not like. There is no way for anyone now to know exactly what A and/or C wrote in the various versions of the A/C paper or what exactly each contributed to the ideas that were presented in the PowerPoint presentation.

The editor felt that there was a clear obligation on the part of A to acknowledge the earlier collaborative work with C, and that there was an equally clear obligation on the part of the journal to inform its readers that this acknowledgement was neglected in the A/B paper. A’s obligation resulted from (1) all the collaborative efforts between himself and C, (2) the fact that both A and C were listed as authors of the PowerPoint presentation and the various versions of the unpublished paper, and (3) the fact that A’s signature on the Statement of Authorship claiming originality of the entire work was not true.

Author A is contesting the retraction and states that the posting has damaged his personal reputation and career. The case was referred to the publisher's Plagiarism and Piracy Task Force, but this committee could not agree, since some felt the editor had acted correctly, but others felt some sympathy with author A.

Advice:

The Forum was unanimous in their opinion that they would not recommend retraction for misattribution of authorship or a missing acknowledgement (which could be resolved by a correction) or as a form of punishment for the authors (as stated in the COPE guidelines). A correction, rather than a retraction, would appear to be more appropriate in this case. An article should be retracted only if the findings are unreliable or in cases of serious misconduct such as plagiarism. Also, COPE does not advocate banning offending authors from publication for any period of time as it may have legal implications. The advice from the Forum was to retract the retraction using carefully agreed wording and publish a correction that acknowledges the original co-authorship of the original complainant. The Forum advised the editor to check the journal's guidelines on retraction and consult COPE's guidelines on retraction.

Update:

We have implemented COPE's recommendations. We consider the case now closed.