



Forum agenda
Meeting to be held on Monday 26 February 2018
BY WEBINAR

At 4pm–5.30pm (GMT)

- 1. Update on COPE activities by the Chair**
- 2. Forum discussion: Expressions of concern**
- 3. New cases**
 - 18-01 License for using a published scale (AM)**
- 4. Updates**
 - 17-10 Withdrawing from authorship**
 - 17-15 Stolen article**
 - 17-16 Authorship issues from disbanded consortium**
 - 17-17 Service evaluation as research in a controversial area of medicine**
 - 17-19 Unethical withdrawal after acceptance to maximize the ‘impact factor’?**
 - 17-20 Consequence for dual submission**
 - 17-21 Ethics of non-active management of a control group**

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2. FORUM DISCUSSION: Expressions of concern

<https://publicationethics.org/forum-discussion-topic-comments-please-10>

Expressions of concern are “used to raise awareness to a possible problem in an article” (Council of Science Editors, 2012). They are a relatively new, rare, and non-standardized type of editorial notice compared to corrections or retractions and “considerable differences in policy and practice remain between journals” (Vaught et al., 2017).

The COPE Retraction Guidelines describe when journals could use expressions of concern. For example, editors should consider an expression of concern if:

- they receive inconclusive evidence of research or publication misconduct by the authors
- there is evidence that the findings are unreliable but the authors’ institution will not investigate the case
- they believe that an investigation into alleged misconduct related to the publication either has not been, or would not be, fair and impartial or conclusive
- an investigation is underway but a judgement will not be available for a considerable time

COPE advises that expressions of concern should be linked to the article and state the reasons for the concern. If more evidence becomes available the expression of concern could be replaced by a retraction notice or an exonerating statement, depending on the outcome.

However, journals are grappling with when expressions of concern are appropriate and what happens if the concerns are later found not to be valid. Publishing an expression of concern prematurely when evidence is inconclusive might not be fair to the authors and some investigations are confidential. In addition, while expressions of concerns are usually about errors or potential misconduct, some notices are about the reception or interpretation of an article (for example, the note on Porter and Jick, 1980) or authorship disputes when the accuracy of the accounts of the different parties cannot be resolved.

COPE invites discussion on this topic, including the following questions:

1. What are the barriers to using them?
2. Are the situations described in the Retraction Guidelines the only ones in which an expression of concern can be used? In particular, may the reception of the article or disagreement about authorship justify an expression of concern?
3. If an expression of concern is removed because the concerns were not valid, should the original text remain available and how should the removal be indicated? Using the term “retraction” might cause confusion.
4. If the article is later retracted, should the expression of concern remain or be removed?
5. What affects the decision to publish an expression of concern when there is inconclusive evidence?
6. Should interim expressions of concern be distinguished from those intended to be final?
7. Should journals wait for an institutional investigation to become delayed or inconclusive, or could expressions of concern be published earlier?

8. When might a journal retract the article instead of publishing an expression of concern if there is evidence that findings are unreliable but no investigation will be conducted?
9. What is the best name for this type of notice? Publisher's note and editorial note are among the alternatives.

References

Correcting the Literature, CSE's White Paper on Promoting Integrity in Scientific Journal Publications, 2012 Update <https://www.councilscienceeditors.org/resource-library/editorial-policies/white-paper-on-publication-ethics/3-5-correcting-the-literature/#351>

Vaught M, Jordan DC, Bastian H. (2017). Concern noted: a descriptive study of editorial expressions of concern in PubMed and PubMed Central. *Research Integrity and Peer Review* 2:10 DOI:10.1186/s41073-017-0030-2

Porter J, Jick H. (1980). Addiction Rare in Patients Treated with Narcotics. *New England Journal of Medicine* 302 (2): 123–123 DOI:10.1056/NEJM198001103020221

3. NEW CASES

18-01 License for using a published scale (AM)

A researcher has published a paper in our journal using a scale published in 2008. She wrote to the scale developer in 2014/2015 at least three times (emails are on file) before the start of the project, but the scale developer did not respond despite repeated email reminders. No indication of the need for a license was received. In 2017, when the researcher published the paper using the above scale, she was contacted by a person claiming that he was representing the scale's developer and asked for a retrospective license and license fee, and threatened that if she did not apply for a retrospective license and pay the license fee, she may need to take legal responsibility and retract the published paper. He also said that if she does not pay the fee, then the team's lawyer would contact her. The name of the lawyer is given, with a gmail account. No firm name or any other information is provided. The researcher has searched the internet and found examples of this person asking other people to apply for a retrospective license and receiving money.

Eventually an email from the scale developer was received, asking the researcher to comply with what his 'chief investigator' is requesting. Thinking that this might be a scam, the case was presented to the dean of the faculty where the scale developer was based. The response from the dean was that "I am saddened to learn about what has occurred. Our institution does not hold this license and does not support the actions the scale developer is taking". The scale was published in 2008 and its development was funded with public funding. The scale was modified from the original scale, which was published in 1986 and its development was also publicly funded. These two scales are in the public domain.

A number of people have paid a fee, often variable and often in the many thousands of dollars. Some institutions have decided to retract the article instead. The team is using bullying and aggressive tactics to persuade the researchers to pay the fee (they have not told the researcher in question what the fee is yet, but through the internet blogs this seems to be a very variable amount). They have also sent emails to the president of the researcher's university, deputy president and vice president for research, as well as to our journal where the paper is published. They are sending 3-4 threatening emails per day (although this seems to have stopped after a couple of weeks).

Question(s) for the COPE Forum

- What do I do as an editor? Do I ask the author to produce a license, or otherwise we will need to retract the article? The author has applied for permission to use the publicly available scale three times with no response from the scale's developer.
- As this scale is publicly available, is this adequate for someone to use it with the appropriate acknowledgement/reference? There was no mention this was a licensed material in the publications.

4. UPDATES

17-10 Withdrawing from authorship

A journal published a paper that is now under investigation by the host institution for misconduct. All authors signed that they agreed authorship and took responsibility for the content of the paper. After the investigations started, an author asked to be removed from authorship.

Question(s) for the COPE Forum

- What should the journal do in this situation?
- Should the journal permit the author to withdraw, or does agreement to authorship have irrevocable responsibilities?

Advice:

The Forum agreed that the best course of action is to postpone any decision until after the investigation. In the meantime, the journal could consider publishing an expression of concern stating that an investigation on the paper is being conducted but avoiding stating that there is an authorship dispute. The journal should await the outcome of the investigation before making any changes to the paper.

The Forum suggested this could be thought of in terms of an authorship dispute and so the journal should handle it as it would for changes in authorship. Hence the journal may need to go back to the institution, as for an authorship dispute.

Are all the authors from the same institution? The author may have a legitimate reason for wanting to be removed if he is from a different institution. A suggestion for the editor was to ask the author why he wishes to be removed from the article.

The presenter of the case confirmed that the author signed the agreement in good faith and that the signature was genuine. Hence the author signed and consented to publication. According to the International Committee of Medical Journal Editors (ICMJE) guidelines (4th criteria), (<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>) all authors have responsibility for the data and agree to help in any investigation: “Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.”

Most of the Forum agreed with a robust “no” to the request and with contacting the institution.

If the editor decides not to allow removal of the author following the investigation, he could give the dissenting author the option of publishing a comment on the published paper.

Follow-up

The journal found the advice from the Forum very useful and intends to follow the advice. The journal considers their concerns resolved.

17-15 Stolen article

At acceptance but before publication, we found article A submitted to journal A was highly similar to article B, published 5 months earlier in conference proceedings in journal B by another publisher. The abstracts were nearly identical, but the author lists and affiliations did not overlap. We asked the authors to explain this and they said article A is their own work, but it was inadvertently leaked by an unnamed medical company they work with.

We told the authors of article A that in future they must declare the role of any company in their research and consider if this may be a conflict of interests. They said their article was previously submitted 4 years ago to another publisher of journal C, who rejected it. We confirmed this with the publisher, who added that their reviewers and editor are not the authors of article B.

The authors of article A said they spoke with the first author of article B, who promised to withdraw it. Article B was retracted, with the abstract being removed and a retraction notice posted. However, the stated reason for retraction was errors. The authors of article A said they were surprised by this.

What we know appears to be consistent with the authors of article A being the genuine authors, but the authors of article A told us the company does not want to be involved in this matter and they asked to withdraw article A, which we did. We have not contacted the authors or publisher of article B. We advised the authors of article A to contact the institutions of the authors of article B and the editor and publisher of journal B; we suggested they do not necessarily need to share details of the company because proof they are the original authors and the authors of article B are not, may be enough for an investigation. The authors of article A said they would consider this.

Question(s) for the COPE Forum

- Could we have handled this case differently?
- Should we contact the publisher of article B?
- Should we ask the institution of the authors of article A and/or article B to investigate?

Advice:

The Forum was updated that there has been a further development: one of the authors of article A submitted a new article to the journal, a shorter version of which was published in the conference proceedings.

Generally, COPE recommends that authorship issues should be resolved at the institutional level. Institutions are best placed to investigate these issues, especially if there was a medical device company or drug company involved who funded the work. The institution should have a record of this involvement and they may be able to provide additional information. Also, the further misconduct of one of the authors of article A may indicate a pattern of unethical behaviour which needs to be addressed by the journal, but also by the institution.

The Forum was told that the journal plans to contact the author regarding the latest submission and ask for an explanation. The journal also plans to contact the authors of the conference proceedings to see if they have any insight as to how a different author group submitted the same work to the journal. After evaluating the responses, the journal may then

contact the institutions of the authors of article A and possibly also the institutions of the authors of article B. The Forum agreed this was a sensible course of action.

Follow-up

The authors of the latest submission and those of the conference proceeding said they had collaborated, that the conference proceeding was preliminary work, and the authors of the conference proceeding should have been acknowledged in the submission. Because of the similar issue with the previous article by the same authors, the journal still had concerns and declined to further consider the submission. The journal is asking the institutions to investigate.

17-16 Authorship issues from disbanded consortium

A manuscript was submitted to one of our journals in a special issue. The initial submission included 15 authors with 9 affiliations. The authors were part of a consortium which has now been disbanded. The manuscript was provisionally accepted for publication.

At this point, three of the authors requested to be removed from the author list, citing irreconcilable differences with the corresponding author. When queried, the authors agreed that they qualified for authorship (as per the ICMJE criteria). One of them informed the publisher that three junior members of his research group also qualified for authorship but had never been included in the author list. When contacted, these junior three researchers requested to be included as authors.

The manuscript's publication was put on hold during these checks. The corresponding author was unhappy at the delay in publication. They denigrated and questioned the integrity of the institution where these researchers were based and claimed that one of three authors was involved in perverting peer review in another, named, journal (not related to the publisher). The corresponding author made it clear that they would refuse to accept any recommendations from the three junior researchers' institution if they were to become involved. The corresponding author also insisted that the three removed authors be included in the acknowledgements. The three removed authors explicitly stated that they did not want their names included anywhere on the paper.

The publisher notified the corresponding author that the ICMJE guidelines recommend receiving explicit written consent from anyone included on acknowledgements. The publisher also continued to clarify the situation with the three junior researchers, informing them that such cases should be taken to their institution. As the publication was still on hold, the corresponding author threatened legal action and full media coverage for alleged censorship and unethical behaviour. A journalist for an international newspaper was copied into these threats.

The publisher took the following actions:

- Removed the three authors from author list, as per their request.
- Asked all 12 remaining authors to sign an authorship form re-attesting to the authorship (the publisher's online submission system notifies all authors of manuscript submission).
- Included the three removed authors' names in the body of the article where a summary of the consortium's meeting and attendees was noted.

- Informed the three junior researchers that the publisher would consider a corrigendum changing authorship if they could prove qualification for authorship, according to ICMJE guidelines.
- Proceeded with publication.

Question(s) for the COPE Forum

- Should the publisher have held publication of the article until the findings of the junior researchers provided a report?
- If this issue did become a media concern, how much of the above summary should the publisher publicly divulge, if anything?

Advice:

The general advice from COPE is that journals should always hold off publication of a paper until an authorship issue is resolved. That is what COPE recommends and this advice is outlined in the COPE flowcharts. It is not up to the journal to decide who qualifies for authorship. The Forum agreed that the only option for the journal was to stall publication while the authorship issue was resolved and hence the criticism of the journal for this is unfair.

The Forum noted the importance of the institution and that the editor might still consider contacting them, even if the authors say they will not abide by the findings. The institution can also play their part in terms of educating the three junior researchers. It would be best if the institution, rather than the journal, made the decision to publish a corrigendum in relation to the junior researchers if it is proved that they qualify for authorship, according to ICMJE guidelines. The Forum advised waiting for the institution to provide this proof.

The key issue is to provide transparency. The editor might like to consider publishing an editorial on this issue, laying out all the facts.

A similar case was brought to the Forum previously, involving an author attempting to prevent co-authors from getting their work published (see Author disagreement blocks submission <https://publicationethics.org/case/author-disagreement-blocks-submission>)

Follow-up

The journal received no further correspondence on this case from any party. The journal is willing to re-open/re-examine the issue if this happens, but otherwise they consider the case closed.

17-17 Service evaluation as research in a controversial area of medicine

We received an email from a reader relating to the ethics statement in a research article published in 2011. The article presented data collected at a clinic relating to a controversial area in medicine. The ethics statement in the article indicates that, in accordance with regional guidelines, the research ethics committee deemed that the study was a service evaluation and formal ethical review was not required.

Using the reference number cited in the article, the reader obtained the relevant documents from the research ethics committee via a freedom of information request. The reader argued that the documents from the ethics committee related to data that predated what was presented in the article. A review of the documents indicated that this appeared to be the case.

In addition, the reader argued that service evaluations should not be presented as research articles as these are two separate things.

The editor of the journal wrote to the author of the article and asked for comment on the issues raised. The author replied that there had been regular contact with the ethics committee as the service period of the clinic was extended, and the ethics committee continued to indicate that the data were being collected as part of a service evaluation and further ethical review was not required. In addition, the data were collected anonymously, which would further exempt the study from requiring formal ethical approval. The ethics committee also provided the authors with a letter indicating that “this letter ... may be provided to a journal or other body as evidence that ethical approval is not required under [the regional] research governance arrangements”.

The author indicated that similar requests had been made in the past and that, due to the controversial area of the work, many attempts were being made to retract articles that used the data from the clinic. Attempting to prevent further queries, the author asked the institutional head of research to post a public statement indicating that the work was conducted appropriately and met the highest ethical standards. As requested, the head of research issued a statement on the institutional website in support of the work.

The editor then responded to the reader indicating that the journal was satisfied with the author’s response and the support of the head of research. The reader was not satisfied with the editor’s response and forwarded the details of the case to a high profile blogger who writes extensively on this controversial area of medicine. The blogger then posted a blog criticising both the article and the journal’s handling of the case. The blog was shared widely on social media. From the journal’s perspective, the blog was inaccurate, misrepresentative and damaging to the publisher’s reputation.

Question(s) for the COPE Forum

- Should we allow data collected in service evaluations to be published as research articles? In medical journals, this is often seen as an acceptable exception; however, if research ethics committees are declaring a study "not research", should journals do the same?
- Should the journal have posted a correction on the article to provide a more detailed ethics statement, bearing in mind that anything labelled a "correction" in a controversial area would be misinterpreted as an error in the research by the critics?
- How should journals respond to blog posts that they feel portray them unfairly and are damaging to the publisher's reputation?

Advice:

The Forum suggested that perhaps the issue is not whether or not the service evaluation is research, but was the evaluation carried out in human subjects (which would require a sound ethics approach) or were the data contained in registries where the patient data were anonymised. It would appear that the latter is the case and that this is a secondary data analysis, but the editor could ask for clarification from the author on the methodology as it needs to be adequately described. Was this a dataset developed out of a research project that had ethics approval for human subjects? If so, the secondary analysis might not need new ethics approval if additional analyses were covered in the initial approval. The methodology is confusing the issue of whether ethics approval was required. The Forum suggested these

points need to be clarified before a decision on whether to add a correction on the article or to respond to the blogger.

This issue often arises with audit articles, which is often a term used for service evaluations. There is a contradiction in that journals publish research articles and yet audits or service evaluations are not thought of as research requiring ethics approval. However, it is up to the ethics committees and their procedures to decide what is research for the purposes of ethics approval. Separately, journals need to decide what they can publish so it is the editor's decision on what to publish in their journal, irrespective of the decision of the ethics committee.

The Forum suggested that the journal may need to provide more information or specific guidelines for authors on what they mean when they say they accept waiving of ethics approval for service evaluations. What is meant by service evaluations?

The Forum agreed that posting a correction may be excessive and perhaps a short editor's note would be more appropriate. The Forum advised against responding to the blogger and getting into a spiral of communication that could become problematic. A suggestion was to write an editorial on the concepts more broadly and how the journal's policy is going to evolve in the future regarding secondary research being conducted as service evaluations/audits/quality improvement reporting and what the ethics requirements will be in the future. What are the expectations of the journal for future submissions of service evaluations?

The Forum suggested the editor may wish to consult the SQUIRE 2.0 (Standards for Quality Improvement Reporting Excellence) guidelines on how to publish quality improvement studies, which can be found on the Equator Network website (<https://www.equator-network.org/reporting-guidelines/squire/>).

Follow-up

The journal chose not to respond to the blogger and considers the case closed.

17-19 Unethical withdrawal after acceptance to maximize the 'impact factor'?

We are a publisher with a portfolio of about 25 journals, with journal X being the flagship journal. Journal X has a high impact factor. We also publish a range of other, newer journals, some of which are ranked highly but most have no impact factor.

An author submitted a manuscript to journal Y where it underwent peer review and was accepted after revisions. After acceptance, the author contacted the editor saying that he had made a mistake and wished to have the paper considered by journal X instead, because it has an impact factor, and stated that if the editor would not publish the article in journal X, the consensus of all authors is to withdraw the paper from journal Y in order to submit it to a journal with an impact factor. The editor informed the author that the paper was not suitable for journal X and that his behaviour was unethical: withdrawal after acceptance violates scientific community norms, as it wastes editorial and peer reviewer resources, in particular if there are no scientific reasons to do so.

The editor wrote to the authors stating that if they insist on a withdrawal at this stage there would be three sanctions: 1) they would be blacklisted (ie, none of the publisher's journals would consider future submissions from any of the authors, 2) the journal would write a letter to the superiors of the authors outlining the case and 3) they would still be responsible for the Article Processing Charge which is payable on acceptance; ours is an open access journal, with the fee schedule clearly disclosed and agreed upon by the submitting author (the fee schedule specifies that if the paper is withdrawn after acceptance it is still payable and will not be refunded).

The author continues to say that they made a mistake—they thought that journal Y was a section within journal X (in reality the submission form clearly allows the author to pick a journal from a dropdown list and the submission acknowledgement email also contains the name of the journal, as does all subsequent communications). On submission, the author checked a box where he agreed on a possible transfer of the paper within the publisher family.

The author pleads that “The kinds of journals that my PhD student publishes in potentially affects his graduation prospects” and that publication in journal Y “could have terrible repercussions for a very promising PhD student”, as well as “going to negatively affect my prospects [for promotion and tenure]”. The editor is not impressed by these arguments as they illustrate a misuse of the impact factor, and PhD students should be taught to respect the journal submission and peer review/publication process and not taught that it is acceptable to waste editorial resources in order to play impact factor games.

Question(s) for the COPE Forum

- What does the Forum think about the ethics of withdrawing a paper during or after peer review in order to publish in a higher impact factor journal?
- If the Forum agrees with the assessment that the authors acted in an unethical fashion, are the sanctions proposed by the editor in this case reasonable?
- Is there anything else that should be done?

Advice:

The Forum agreed that this was not good behaviour on the part of the author, but COPE would always advocate a more educational rather than a punitive approach. COPE guidance also advises against blacklisting authors.

Although it seems that the authors' behaviour was intentional, it is the authors' prerogative to withdraw a paper at any point before it is published. While the Forum agreed that such behaviour is deplorable and a waste of editorial resources, the advice was to communicate this message clearly to the authors but not necessarily to directly punish them. This is especially applicable to more junior authors.

A suggestion was to write an editorial on this issue in general, explaining why it is not good practice.

Another suggestion was to review the journal submission system and consider outside user testing to make sure there is no confusion for authors regarding submission to different journals in the publisher portfolio. The Forum also noted that it is unusual to charge an author

if they withdraw a paper that is not published and hence the editor may wish to reconsider this decision.

Follow-up

Despite communication with the authors that their behaviour was "not good" and in fact "deplorable" (citing the COPE Forum), and despite communication from the dean of the university that the authors' behaviour is based on a gross misunderstanding on how the university evaluates the value of a publication (which is not based on the impact factor), the authors still insisted on withdrawing their manuscript.

The journal and publisher refrained from any further sanctions, such as blacklisting authors or charging the Article Processing Fee for a peer-reviewed and accepted (but not published) manuscript. The publisher has also discontinued its use of any formal blacklist.

17-20 Consequence for dual submission

An author submitted work to our journal (journal A) which, after two rounds of peer review, was accepted and published. One week after it was published, the editors of journal B contacted our journal stating that this work, with the exact same title, authors and content, had been submitted to journal B and, after receiving an acceptance letter, the author withdrew the paper, informing them that it had been accepted by a different journal.

When the editor of journal B asked the author for an explanation, the author did not provide a satisfactory response. Journal B, in consultation with their editorial board, banned the author from submitting to the journal in the future.

Editor B contacted us, alerting us to the situation. After verifying the submission records, we concluded that the submission to both journals had been done on the same day. We contacted the authors for an explanation. The author replied that indeed he had submitted to two journals but that the submissions were several weeks apart. He said he forgot to withdraw the article from journal B and apologized for the situation. However, the submission records for both journal A and journal B indicate that this statement is not true.

We have discussed with the editor of journal B what action should be taken in relation to the author. Journal B has already banned the author. The editorial board of journal B would like to make this misconduct known to the author's institution and suggests that it should be us who contact the institution. We are reluctant to contact the institution as the author has apologized, admitted his mistake and withdrew the article from journal B. We believe journal B should contact the institution.

Question(s) for the COPE Forum

- What is the appropriate action in such a case. Should the institution be informed or is banning the author from both journals for a period of time enough?
- Who should initiate the action—journal A or journal B?
- Both editors agree that something should be done so that the author does not repeat the behaviour at other journals, but are unsure of what to do.

Advice

The Forum advised that in deciding whether to inform the institution, the editor may want to take into consideration the seniority of the author and the country of origin of the author. If the author is from a country where ethical norms are not well entrenched, the editor may wish to be more lenient. COPE would always advocate educational rather than punitive action. Even if the editor feels that the author deliberately tried to deceive, COPE would still recommend an educational approach in the first instance. If the author demonstrates a repeat pattern of misconduct, then the editor might consider contacting the institution.

However, while contacting the institution for punitive reasons is not necessarily helpful some argued informing the institution may be preventative rather than punitive, especially if the authors are junior researchers. The institution has a role in mentoring the author and to ensure that this type of behaviour does not persist. This may also serve to convey to the author the seriousness of the infraction.

A suggestion was to write an editorial on the issue of dual submission. Do authors really understand what it means, and the consequences of declaring that their paper has not been submitted to another journal?

COPE does not recommend banning authors because of the legal repercussions.

Follow-up

The editor considers the case closed.

17-21 Ethics of non-active management of a control group

An article was submitted involving over 200 pregnant patients with a systemic illness (from 2010 to 2015) who were recruited and assigned to a control group or an active intervention group (of their systemic illness). The control group received routine antenatal care while the intervention group had active surveillance and management of their systemic illness during the pregnancy.

There was a significant increase in morbidity and mortality in the non-actively managed control group. We (reviewers and editors) are concerned about the ethics of this study design. Specifically, it seems pregnant patients who were assigned to the non-active treatment/control group did not have their systemic condition managed in what would today be regarded as 'standard of care'.

Question(s) for the COPE Forum

- Despite apparent local ethics board approval, and a statement from the authors declaring adherence to the Declaration of Helsinki, is it ethical to include a non-active intervention group for a disease which is known to have negative fetal and maternal outcomes?

Advice:

The Forum advised that this appears to be unethical research conduct and egregious violation of human ethics.

Withholding known effective treatment for experimental purposes is not ethical in human subjects' research. If there is a known effective treatment, the study cannot ethically be done,

and any institutional review board would raise a question about such a protocol. If the active management (treatment) is not known to be effective, and the researchers are attempting to establish efficacy of the active management, then a rigorous research protocol should be in place. Such a protocol would ensure informed consent of all human subjects, as well as a process for breaking the randomization if it becomes clear that the subjects in the control arm of the research are in any medical jeopardy. If this is not the case in this research, the authors should be reported to a research integrity office at their institution or at the country level.

Editors can reject a paper for ethical concerns despite local ethics approval, and a journal can ask the institution to reassess this approval. If it is known that a treatment/management is effective, withholding it is unethical.

Follow-up

The manuscript was rejected for a variety of reasons, including the concerns regarding the ethics of the study design.