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Letter: Effective quality control in the medical literature: investigation and retraction vs inaction

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Dr Andrea Tricco
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Dear Dr Tricco

Effective quality control in the medical literature: investigation and retraction vs inaction

Thank you for your email, and we are happy to resubmit this as a letter rather than as a Commentary. As before, all authors have approved this submission, and it has not been published nor is it submitted elsewhere. We have shortened it slightly, and although I realise it is more than the 500 words specified in the Author Information, I was encouraged to see that longer letters are published.

Given our e-mail correspondence, I have not elaborated on our submission here. I would add that all authors contributed to this version and have approved it, including the order of authorship. We have no relevant disclosures to make, or conflicting interests to declare, but it may be considered relevant that some of us are on the editorial boards of these and other pain journals.

In case you send letters for review, we suggest: Mark Bolland m.bolland@auckland.ac.nz, Andrew Grey a.grey@auckland.ac.nz, Alison Avenell a.avenell@abdn.ac.uk, Lisa Parker lisa.parker@sydney.edu.au, and Peter Tugwell ptugwell@uottawa.ca.

Yours sincerely

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Effective quality control in the medical literature: investigation and retraction vs inaction

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Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

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Authors' contributions:

AW Conceptualization, investigation, writing - original draft
LH Conceptualization, investigation, writing – review and editing
AM Conceptualization, investigation, writing – review and editing
GS Conceptualization, investigation, writing – review and editing
EF Conceptualization, writing – review and editing
CE Conceptualization, writing – review and editing
NO'C Conceptualization, writing – review and editing

Dear Editor

Effective quality control in the medical literature: investigation and retraction vs inaction

How should editors and publishers act on concerns raised about the trustworthiness of published papers? Despite the Committee on Publication Ethics (COPE) [1] guidelines, journal responses can be slow, inadequate, and opaque [2]. The potential harms of failure to retract untrustworthy studies - to clinical practice and public confidence - are considerable. We describe here our experience with six journal editors with whom we raised concerns.

In 2022 we published our doubts about the integrity of several trials [3,4]. We had noticed three divergent trials with the same first author in a large systematic review and meta-analysis of psychological treatments for chronic pain [5]. The first author was unable to explain the extraordinarily positive results; after sensitivity analyses, we excluded them from meta-analyses. In a subsequent study, we used the Cochrane risk of bias tool [6] and the Cochrane Pregnancy and Childbirth Review Group Trustworthiness Screening Tool (CPC-TST) to evaluate trustworthiness [7] of trials of spinal pain by this author group.

For eight of the 10 trials in six journals, from 2012 to 2021 [4], applying the CPC-TST identified concerns about trustworthiness. None was prospectively registered; protocols, ethical approval and data were not provided on request; baseline differences appeared inconsistent with randomization (see also Bolland et al. [8] on anomalous baseline data by the same first author in 17 trials); some data were identical or highly similar across nominally independent studies; results of all were judged implausible. Given our findings, we emailed the relevant editors, attaching our paper, asking that they consider retraction.

Three editors acted consistently with COPE guidelines [1]. Two immediately initiated investigations, informed us of progress, and ultimately retracted the trials (one each). The third journal editor, with two published trials (one of major concern), also investigated, resulting in retraction by the authors of the problematic trial for errors in data collection; this journal added a link to our trustworthiness paper to the trial of less concern and published an editorial on ways to improve research integrity [9].

The other three editors seemed reluctant to act.

The editor of the journal with four trials contacted the first author, receiving notice of his long-term sickness. Since this author had subsequently responded to other editors, we recommended further approaches, but heard nothing more.

Another editor advised us to address our concerns to the first author and his employer. Having previously been unsuccessful in this, we reminded him of the duties of editors outlined by COPE, and updated him on other editors' initiatives. Following this, he wrote to the first author, receiving some data from the trial concerned, with complaints about our "*unjustifiable attack*". These data, forwarded to us, confirmed our concerns of implausibility.

The sixth editor was reassured by his journal's "*fair review process by three experts*", so that "*the results are likely to be useful to other researchers in the field*", and professed to being *"against academic intimidation*". We responded that unreliable results, which we already knew were included in multiple systematic reviews and clinical guidelines [10], were misleading rather than useful, while peer review of single papers would not identify duplicated data across trials.

After further correspondence with the first author, this editor decided against retraction but invited us to write to the journal expressing our concerns, for publication with a response from the first author: "*this may ensure full transparency and promote critical debate*." We declined the offer, explaining that this was not an intellectual difference but an editorial responsibility. We have no evidence of any formal investigation. This journal's ethical policy includes the statement: "*Despite*

vigorous peer-review, it is possible that a paper that is fraudulent in some manner may be published. If this is discovered, it will be retracted" [11].

What have we learned? That open science practices, including publishing data, cannot come too soon; that we need better tools to detect problematic data within and across studies; that while error and fraud are acknowledged as widespread, some editors appear disinclined to believe that their journals are affected; that whistleblowers may still need to pursue concerns that are editors' responsibilities [12]. We know data can be flawed, futile, or fabricated, with documented examples in pain research [13]. Left unaddressed by those tasked with tackling them, such data go on to influence evidence reviews and guidelines, and increase the risk of harm to patients. We no longer worry about being too sceptical – we worry that we are not sceptical enough.

Williams ACdeC, Hearn L, Moore RA, Stewart G, Fisher E, Eccleston C, O'Connell NE

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