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The Retraction of a Trial Included in a Meta-Analysis of Interventions to Enhance Oral Medication Adherence

We are writing to draw the attention of the editors to the retraction of a trial by Zolfaghari et al. [1] that was included in the Zomahoun et al. [2] systematic review and meta-analysis published in *Value in Health*. The aim of the review was to establish the effectiveness of interventions to improve adherence in patients taking oral medication for diabetes. The authors included randomized and nonrandomized studies with usual care or active comparator interventions. Searches were performed in September 2013, and the article was published online on May 22, 2015. The review included 14 studies in the qualitative synthesis and 10 in the meta-analysis. A retraction statement was issued on March 29, 2016, relating to one of the studies included in the meta-analysis [1] and published in the *Journal of Clinical Nursing*. In their study, Zolfaghari et al. [1] used a two-group quasi-experimental pretest and posttest design to compare the effectiveness of short messaging service and nurse telephone follow-up on glycated hemoglobin levels and treatment adherence. The authors conclude that both interventions were effective at decreasing glycated hemoglobin levels and enhancing adherence. The article was retracted by agreement of the editor-in-chief and the publisher because, “unknown to the author(s), a similar article had been published in the *Iranian Journal of Diabetes and Obesity* in 2009” [3]. It was also stated in the retraction statement that a second duplicate of the article had been published in the *Journal of Diabetes and Metabolic Disorders* [4]. According to the retraction note in the *Journal of Diabetes and Metabolic Disorders*, the article was retracted on March 7, 2013, because it had been previously published in the *Iranian Journal of Diabetes and Obesity* (the duplicate publication).

Did the Authors Make an Error?

The Zolfaghari et al. [1] trial in the *Journal of Clinical Nursing* was retracted after the Zomahoun et al. [2] review was published. At first glance, it does not seem as though the authors have made an error. Nevertheless, it is curious that Zomahoun et al. [2] did not identify either of the two other duplicates of this article in their search. We reviewed the authors’ search strategy—published as Supplemental Materials document online; it was detailed and well articulated. The authors searched established key databases (e.g., MEDLINE via PubMed). The original report of the trial published in the *Iranian Journal of Diabetes and Obesity* does not appear to be indexed in any of the databases the authors searched. It is, therefore, not surprising that this article was missed. The *Journal of Diabetes and Metabolic Disorders* is indexed in MEDLINE and, especially given that the article titles are similar, we would expect that this article [4] would appear in the search. When the authors conducted their search in September 2013, this article had already

been retracted (on March 7, 2013). If Zomahoun et al. [2] did spot this discrepancy, then they would have an important moral and ethical duty to report the second duplicate publication in the *Journal of Clinical Nursing*. It would be helpful if the authors could confirm that this trial did not appear in their search.

Editorial and Reviewer Error?

There may be some justifiable criticism of the editors of the *Journal of Clinical Nursing*, the *Iranian Journal of Diabetes and Obesity*, and the *Journal of Diabetes and Metabolic Disorders* for failing to require authors to register the trial (noting that the study is described as quasi-experimental and not as a true randomized controlled trial). If the editors of the *Iranian Journal of Diabetes and Obesity*—who published the first version of the article—had, as they arguably should have, insisted on the trial being registered, this would have enabled editors and reviewers to spot and prevent duplicate publication. Review authors, arguably, also need to be more proactive in considering the potential for misconduct (duplicate publication/fabrication of data) in included studies. It is not part of the current Preferred Reporting Items for Systematic Reviews and Meta-Analyses [5] reporting guidelines to report on the registration status of included studies; nevertheless, we would argue that doing this would encourage review authors to be more proactive in considering potential research misconduct.

Most journals put submitted articles through plagiarism software to check for similarity. Presumably, if the editors had done this, the similarity index would have been high for the two retracted articles [1,4]. It seems that the software did not detect the overlap or a check was not done or the editors failed to review the similarity report.

Although it may go beyond the traditional expectations of the duty of the peer reviewer, we did wonder if reviewers could (or should) be expected to check whether studies included in a systematic review and meta-analysis are duplicates. It may be a lot to expect of reviewers who, after all, give their time for free, but it seems like a logical question to ask.

Does Retraction Affect the Results of the Meta-Analysis?

Retraction of an article is intended to remove it from the evidence base. It is the subject of debate as to how to handle reviews that include a trial retracted after the publication of the review [6]. Any response—by the author or the publishing journal—may be based on whether the review’s conclusions are affected in a substantive way. In the Zomahoun et al. [2] review, 10 studies—of a moderate methodological quality—were included in the meta-analysis. The

pooled effect size estimate was 0.21, which was not statistically significant (95% confidence interval -0.05 to 0.47). In their conclusion, the authors state that the effect of interventions to enhance oral antidiabetic drug adherence was “small.” We repeated the meta-analysis after removing the retracted trial [1]. There was a modest increase in the pooled effect size (0.27 ; 95% confidence interval -0.01 to 0.54), which was borderline statistically significant ($P = 0.05$). It could be argued that the removal of the retracted trial does affect the conclusion, and equally it could be argued that it does not affect the review conclusion. This is perhaps an author’s and editor’s judgment to make.

Conclusions

The authors of the Cochrane handbook [7] for systematic reviews remind us that publication does not mark the end of the review process. Authors have a duty to monitor changes in the status of included articles (such as retraction). The publication of a single study in three different journals [1,3,4] raises complex questions about the integrity of the systematic review by Zomahoun et al. [2], which the authors need to clarify. We think it is important to transparent reporting of science that you make readers aware that this review includes a trial that was retracted after the review was published.

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<https://doi.org/10.1016/j.jval.2018.07.005>

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Author's Reply

We thank the editor for giving us the opportunity to reply to this letter to the editor. In this letter, the authors raise concerns about our article titled “Effectiveness and content analysis of interventions to enhance oral antidiabetic drug adherence in adults with type 2 diabetes: Systematic review and meta-analysis” and about the publication and review process of systematic reviews and meta-analyses. More specifically, the letter raises three main issues. The first two issues refer to the responsibilities of authors and editors/reviewers, whereas the third issue refers to the effect the retraction of one article may have had on the results and conclusions of our systematic review and meta-analysis. We are happy to comment on each of these issues.

Did the Authors Make an Error?

We thank the authors for acknowledging that at the time our review was conducted we could not identify the retraction of the trial by Zolfaghari et al. [1] published in 2012 in the *Journal of Clinical Nursing* and titled “The impact of nurse short message services and telephone follow-ups on diabetic adherence: Which one is more effective?” Indeed, the literature search strategy of our review was conducted on September 3, 2013 [2], whereas the retraction was later published on March 29, 2016 [3].

Nevertheless, we are asked to clarify why the trial by Zolfaghari et al. [4] published in 2012 in the *Journal of Diabetes and Metabolic Disorders* and titled “Mobile phone text messaging and telephone follow-up in type 2 diabetic patients for 3 months: A comparative study” and its retraction published on March 7, 2013 [5], were not captured in our data search.

Our review aimed to estimate the pooled effect size of oral antidiabetic drug adherence-enhancing interventions and to explore which of the behavior change techniques applied in the intervention groups modified this pooled effect size in adults with type 2 diabetes [2]. Studies included in the review had to meet the following eligibility criteria:

- Types of population: adults 18 years or older with type 2 diabetes who used oral antidiabetic drugs;
- Types of interventions: interventions with at least one component aimed at improving oral antidiabetic drug adherence, regardless of the methods or techniques used;
- Types of comparators: individuals with type 2 diabetes who were exposed to usual care and/or to an intervention of any sort;
- Types of outcomes: original studies in which oral antidiabetic drug adherence was measured both before and after completion of the intervention; and
- Types of study designs: randomized controlled trials, quasi-experimental studies, and controlled pre-/post-test studies.

On the basis of these inclusion criteria, we used the combination of concepts related to types of population (type 2 diabetes), interventions (intervention), and outcomes (medication adherence) to perform our literature search strategy in bibliographic databases from their inception up to September 3, 2013 (see