PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Assessing the Impact of Predatory Journals on Policy and Guidance Documents: A Cross-Sectional Study Protocol
AUTHORS	Brandts-Longtin, Olivier; Lalu, Manoj; Adie, Euan; Albert, Marc; Almoli, Elham; Almoli, Faris; Bryson, Gregory; Dony, Christophe; Dunleavy, Daniel; Grudniewicz, Agnes; Lehmann, Christian; Lhoest, Rémy; Moher, David; Montroy, Joshua; Pitts, Mallory; Ricketts, Alicia; Thirion, Paul; Cobey, Kelly

VERSION 1 – REVIEW

REVIEWER	Kumar, Abhishek Amity University
REVIEW RETURNED	06-Dec-2021

GENERAL COMMENTS	The paper is original in nature and depicts good research problem

REVIEWER	Badrinath, Padmanabhan Suffolk PCT and University of Cambridge, Public Health
REVIEW RETURNED	20-Dec-2021

GENERAL COMMENTS	Review of 'Assessing the Impact of Predatory Journals on Policy and Guidance Documents: A Cross-Sectional Study Protocol' Assessing the Impact of Predatory Journals on Policy and Guidance Documents: A Cross-Sectional Study Protocol. bmjopen-2021-059445
	For the Authors: We would like to thank and commend the authors for undertaking this work, which aims to assess if predatory journal articles are infiltrating policy making. Predatory journals represent poor academic integrity, and if used in policy making may lead to policies which do not benefit those whom they are drafted for. We agree that this work is important to undertake, and we will await the study's findings with interest. We would like to suggest the following amendments for consideration by the authors: Introduction
	 Page 4, Line 50 – Misspelling of 'Empirical' Page 5 Line 51 – The reference cited to demonstrate the outcome of unreliable clinical guidelines relates more to generalised root causes, epidemiology, and common methodological flaws of poor guidelines. Perhaps the authors could cite a reference which estimates real world impact of flawed guidelines or cite a specific example of a situation when a flawed

 guideline has led to the patient safety, resource and economic burdens referenced. Page 7 Line 53 – It may be helpful to the reader if the authors could estimate the percentage of the population of predatory journals published by OMICS – what proportion of the overall field is being sampled?
Objectives • We would suggest rewording objective 3 – it is not very clear to the reader at present.
 Methods While the protocol defines the timeframe of papers to be sampled, it does not specify the time frame over which data extraction and analysis will occur Eligibility Criteria Page 8, Line 40 - Could the authors' formal definition of a 'policy document' be included in an appendix in this protocol? It is critical for the eligibility criteria. Are there any other sources of bias which can be considered and accounted for? It would be helpful to explicitly state in the protocol how the authors have accounted for these (e.g. by using standardised and objective data forms as in Appendix 1). Eligibility Criteria, Page 8 Line 45 - If policy documents are not in English, how will the authors ensure manually retrieved information is accurate? It would be helpful to explicitly state this. Data Extraction, Page 10 Line 8 – If there is a disagreement between the first reviewer and the auditor, is there a process to resolve this disagreement? Page 11 Line 3 – Misspelling of 'number'
Discussion • Page 13 Line 16 – Misspelling of 'evaluation'
Overall Suggestion for Study Design
• It is not apparent to us how this study design can truly assess the impact of predatory journals in policy making, as is suggested by the authors' title and discussion. The objectives and trial design aim to assess the frequency of citation of predatory journals in policy, how they are used, and the correlation between citation in policy and citation in academic literature. However, citation alone in a policy document does not equate to a negative impact on policy itself. For example, an OMICS article could form a limited contribution to background information only, or conversely it could be a critical piece of evidence in formulating key decisions. We recognise that Appendix 1 suggests that information extracted from cited articles will include 'How is the predatory article cited in the policy/guidance document' but methods for collection of this and translation of this information into impact is unclear. Perhaps a small sample of articles could be assessed for the impact of the cited OMICS article on the policy overall, with the process for this explicitly explained in the methods. Otherwise, it should be explicitly stated that any conclusion drawn on negative impact of predatory journals on policy making is an assumption, and not shown empirically by this study's evidence on patterns of citation alone.

VERSION 1 – AUTHOR RESPONSE

Reviewer #1: Comments: The paper is original in nature and depicts good research problem

Response: We thank the reviewer for taking the time to review our manuscript. We appreciate their supportive words.

Reviewer #2 Comments:

We would like to thank and commend the authors for undertaking this work, which aims to assess if predatory journal articles are infiltrating policy making. Predatory journals represent poor academic integrity, and if used in policy making may lead to policies which do not benefit those whom they are drafted for. We agree that this work is important to undertake, and we will await the study's findings with interest.

Response: We thank the reviewer for their careful review of our manuscript and their kind words. The suggestions have all been addressed in the manuscript.

1) Comment 1: Page 4, Line 50 – Misspelling of 'Empirical'

Response: This typo has been resolved.

2) Comment 2: Page 5 Line 51 – The reference cited to demonstrate the outcome of unreliable clinical guidelines relates more to generalised root causes, epidemiology, and common methodological flaws of poor guidelines. Perhaps the authors could cite a reference which estimates real world impact of flawed guidelines or cite a specific example of a situation when a flawed guideline has led to the patient safety, resource and economic burdens referenced.

Response: We have added the example of opioid guidelines in the early 2000s and their widespread repercussions.

"Flawed guidelines, like those historically encouraging widespread opioid prescribing, can stem from low quality untenable and misleading research.13-16 These guidelines can cause serious systemic issues, such as for patient safety, resource use, and economic burden.13-15

3) Comment 3: Page 7 Line 53 – It may be helpful to the reader if the authors could estimate the percentage of the population of predatory journals published by OMICS – what proportion of the overall field is being sampled?

Response: We agree that this estimate would be helpful. Unfortunately, due to the nature of predatory publishing, particularly with inconsistent indexing, it is challenging to obtain an accurate estimate of the scale of this problem. The last key study attempting to do so was published in 2015 (C Shen & BC Björk, BMC Medicine) and is unlikely to reflect the current landscape. However, we have added an estimate of OMICS' output using the scholarly literature search engine The Lens. This reveals an estimated 92 662 journal articles published by OMICS from 2012-2019.

We have added this context to the manuscript. The section of discussion now reads:

"OMICS is a very large predatory publisher - a search of The Lens estimates OMICS published 92 662 journal articles from 2012-2019 - but it is not known what proportion of predatory journals OMICS represents; journals from this publisher may not be representative of predatory journals more broadly. Due to the nature of predatory publishing, it is a challenge to estimate the true scale of the problem, with the last key study in 2015 unlikely to reflect the current landscape."

4) Comment 4: We would suggest rewording objective 3 – it is not very clear to the reader at present.

Response: The wording has been revised as follows:

"Assess whether or not correlations or patterns exist between how predatory journal articles are cited and used in these policy documents, and how these same predatory journal articles are cited and used in the traditional scientific literature."

5) Comment 5: While the protocol defines the timeframe of papers to be sampled, it does not specify the time frame over which data extraction and analysis will occur

Response: We have added a new section to the methods "study timeline" which states:

"The Overton database search was conducted on June 18th 2021. Exporting Overton data, preparing data for extraction, and recruiting and training extractors will be completed in February 2022. Extraction will follow with completion expected by June 2022. Data analysis is expected to be complete by August 2022."

6) Comment 6: Eligibility Criteria Page 8, Line 40 - Could the authors' formal definition of a 'policy document' be included in an appendix in this protocol? It is critical for the eligibility criteria

Response: We have expanded our definition in the "Eligibility Criteria" section as follows:

"We will include statements from any agency or organization that put forward a policy on a statutory, regulatory, or technical issue, or interpretation thereof, or documents otherwise primarily intended for policymakers. This definition will include: working papers, briefs, clinical guidelines, regulatory submissions, and other documents released by these agencies that report on their policies or are otherwise obviously intended for policymakers. We will exclude: original scientific research (articles, journals, and conference proceedings, with the exception of clinical guidelines published as research articles), and documents unrelated to policy and their audience."

7) Comment 7: Are there any other sources of bias which can be considered and accounted for? It would be helpful to explicitly state in the protocol how the authors have accounted for these (e.g. by using standardised and objective data forms as in Appendix 1).

Response: We have expanded our discussion of bias mitigation in the "Data Extraction" section as follows:

"In order to reduce bias and between extractor variation, we have created standardized and objective data extraction forms to collect the above-mentioned data. These are available in Appendix 1. We have also created a 'codebook' with objective question and answer descriptions, and will require all extractors to pilot test the extraction forms on the same 10 articles, to ensure consistency, as part of their training."

8) Comment 8: Eligibility Criteria, Page 8 Line 45 - If policy documents are not in English, how will the authors ensure manually retrieved information is accurate? It would be helpful to explicitly state this.

Response: Our multilingual research team will work together to collect data on policy documents in as many languages as possible. If two team members do not understand a given language, the language will be noted and manually collected questions for that policy document will be marked as unable to assess. The following sentence has been added: "If two team members are not fluent in the language used in the policy, manually extracted questions for that document will be marked as unable to assess."

9) Comment 9: Data Extraction, Page 10 Line 8 – If there is a disagreement between the first reviewer and the auditor, is there a process to resolve this disagreement?

Response: The statement "If necessary, any conflicts will be resolved by discussion or by senior investigators (KDC, ML)." has been revised and moved from eligibility criteria to data extraction where it is more appropriate.

- 10) Comment 10: Page 11 Line 3 Misspelling of 'number'
- 11) Comment 11: Page 13 Line 16 Misspelling of 'evaluation'

Response: These typos and others have been resolved.

12) Comment 12: It is not apparent to us how this study design can truly assess the impact of predatory journals in policy making, as is suggested by the authors' title and discussion. The objectives and trial design aim to assess the frequency of citation of predatory journals in policy, how they are used, and the correlation between citation in policy and citation in academic literature. However, citation alone in a policy document does not equate to a negative impact on policy itself. For example, an OMICS article could form a limited contribution to background information only, or conversely it could be a critical piece of evidence in formulating key decisions. We recognise that Appendix 1 suggests that information extracted from cited articles will include 'How is the predatory article cited in the policy/guidance document' but methods for collection of this and translation of this information into impact is unclear. Perhaps a small sample of articles could be assessed for the impact of the cited OMICS article on the policy overall, with the process for this explicitly explained in the methods. Otherwise, it should be explicitly stated that any conclusion drawn on negative impact of predatory journals on policy making is an assumption, and not shown empirically by this study's evidence on patterns of citation alone.

Response: We thank the reviewer for their insightful comment. We agree that citation patterns alone would give limited information on the impact of predatory journals in policy, since the information may be used simply as background or be more influential. The reviewer rightly points to our question in Appendix 1 asking "How is the predatory journal article cited in the policy/ guidance document". The options for this question are "Included in the policy in a narrative fashion e.g. background information", "Used in a quantitative manner to inform statements in the policy", "cited as an exclusion from the policy document", "other", or "unable to assess". Data from this question should allow us a basic understanding of how the predatory journal articles are being used in policy documents. We have expanded discussion of this point in the data extraction section as follows:

"Details on how the predatory article is being cited represents a key component of our study. This will provide a basic understanding around whether articles are being cited simply as background information, or if they are being used in a manner that may directly inform policy recommendations."

VERSION 2 – REVIEW

REVIEWER	Badrinath, Padmanabhan Suffolk PCT and University of Cambridge, Public Health
REVIEW RETURNED	25-Feb-2022
GENERAL COMMENTS	Thank you again to the authors for undertaking this important work. We would like to thank the authors for addressing all our previous suggestions and note that the quality of the protocol has improved significantly. We do not wish to make any further requests for amendments