Epidemiological and reporting characteristics of predatory journal articles: protocol

Nadera Ahmadzai, Mostafa Alabousi, Marc T Avey, Kelly Cobey, Raymond Daniel, James Galipeau, Chantelle Garritty, Mona Ghannad, Candyce Hamel, Mona Hersi, Brian Hutton, Inga Isupov, Manoj Lalu, Felipe Langer, Trevor McGrath, Matt McInnis, David Moher, Misty Pratt, Kusala Pussegoda, Pauline Quach, Larissa Shamseer, Bev Shea, Anubhav Srivastava, Adrienne Stevens, Kednapa Thavorn, Sasha van Katwyk, Roxanne Ward, Dianna Wolfe, Fatemeh Yazdi, Ashley Yu, and Hedyeh Ziai

Correspondence to:

David Moher

Clinical Epidemiology Program, Ottawa Hospital Research Institute. The Ottawa Hospital, General Campus. 501 Smyth Rd, Room L1288. Ottawa, ON, K1H 8L6. Canada

e-mail: dmoher@ohri.ca

Twitter: @dmoher

Version – 3rd February 2016

Introduction

Researchers trying to publish their research face a duality of tensions. One, to advance their careers they must be very productive and publish in journals with the highest impact factors. Two, passing the scientific rigor of peer review and editorial approval in these journals makes publishing difficult. Questionable businesses, posing as legitimate publishers, and thus termed 'predatory', have moved into this space quickly. They offer to publish anything (for a fee), thus circumventing the very fabric and integrity of scientific publishing. This practice has spread rapidly because these publishers have no physical presence, instead conducting their façade through illegitimate online journals.

Stopping predatory journals requires an international collaborative effort involving multiple groups acting together, unambiguously. Editorial groups, such as the World Association of Medical Editors, and others, such as the Coalition for Responsible Publication Resources, need a united proclamation against predatory publishers. Others should be invited to sign up to this cause. Publishers and editors, partnering with academic institutions and funders, need to develop educational outreach, including online webinars, to let prospective authors know about the hazards of predatory publishers and their journals and how to avoid publishing in them; funders should be explicit about not allowing their funds to be used to cover predatory journal article processing costs (APCs).

To complement these activities requires additional research about predatory publishers, journals, and authors publishing in them. One potential starting point is a social network analysis of jurisdictions of predatory journal corresponding authors and publishers. This could help target educational outreach and other activities in jurisdictions where the problem is more common. In addition, a description of what types of research, and what quality of research, is being published in these journals is essential to better determine why publication in a legitimate journal did not occur. With this in mind, our aim is to describe the epidemiological and reporting characteristics in articles published in a broad spectrum of predatory biomedical journals.

Methods

Sampling strategy

In September 2014, it was estimated that there were more than 11,000 predatory journals published by single and multiple journal publishers included on Beall's lists of potential predatory journals (1). These journals purportedly publish hundreds of thousands of articles covering a wide spectrum of topics, including biomedicine which is our focus (2). For the purposes of this project we will use Beall's lists (3) to identify target journals from which articles will be identified. One of Beall's lists is of single journal publishers while the other list is of multiple journal publishers. Our sampling strategy for each list is described below.

Identifying single journal publishers

In a previous study, we identified a sample of 93 biomedical journals from Beall's list of single journal publishers (3). In July 2014, of the 397 journals on Beall's single journal publisher list, 156 (39%) were identified as publishing biomedical research (using Medline journal selection criteria "Research journals…predominantly devoted to reporting original investigations in the biomedical and health sciences including research in the basic sciences; clinical trials of therapeutic agents; effectiveness of diagnostic or therapeutic techniques; or studies relating to the behavioral, epidemiological, or educational aspects of medicine"). Of these 156 journals, we randomly selected 100 of them for inclusion (using a random number generator), of which 93 were included in the final analysis (seven journal websites were no longer available by the time data extraction took place). Fifty-one percent of our included sample (n=45) were characterized as publishing only biomedical research; the remaining 48 journals published biomedical research alongside research from other disciplines. All screening was carried out by two independent assessors, with third-party consensus, when needed. The 45 included journals, representing 29% of the total number of biomedical journals included in Beall's single journal publisher list, will be included in our sample. Journals in the sample that we determine do not list any articles, or list articles of which none can be retrieved, will be replaced with another randomly selected journal to maintain the sample of 45 journals. We will track the number of journals we encounter without content.

Identifying multiple journal publishers

As of 17th December 2015, 923 publishers were listed on Beall's list of multiple journal publishers. Using a random number generator, one-team member will identify a 20% sample (185 publishers) from the larger list of the 923 of multiple journal predatory publishers. One team member will then obtain the name and URL for all journals published by each of the 185 publishers. The resulting list of journals will then be screened to identify those journals which publish biomedical content only. Two assessors will screen each journal. We will apply the Medline journal selection criteria as described above. Disagreements will be resolved by third party arbitration. From the list of journals identified as 'biomedical only', we will randomly select 200 journals (using a random number generator) for use in this study. A sample of 200 journals was selected due to resource constraints and team member availability. Journals in the sample that we determine do not list any articles, or list articles of which none can be retrieved, will be replaced with another randomly selected journal to maintain the sample of 200 journals. We will track the number of journals we encounter without content.

Identifying articles for inclusion

For the 45 journals identified from single journal publishers and the 200 journals identified from multiple journal publishers, team members will download the 25 most recently published articles in each journal (n ≤6125 articles). Based on previous experience, some journals, however, may not list their content

chronologically. For such journals, we will identify articles using the following approach:

a. Where articles are organized according to study design, we will obtain articles in the following preferential order: clinical trials, systematic reviews, observational studies, preclinical studies, diagnostic accuracy studies, case reports, non-systematic reviews, and then opinions/commentaries/editorials. This means that if there are ≥25 clinical trials, in addition to other study types, we will obtain only 25 clinical trials, starting with the most recently published, if a chronology is apparent within the study design grouping.
b. If studies are ordered by topic area, we will select up to 25 articles from what we view to be the most biomedical topic. For example, if the journal published on biology and pharmacy, and articles are sectioned under these two headings, we will first extract up to 25 articles from the section containing pharmacy articles (i.e. direct biomedical topic) prior to extracting any remaining articles from the biology section. If studies are listed by topic area, but multiple biomedical topics are apparent (e.g. psychiatry and neurology), we will extract from the first appearing category, moving to the next only if the first category contains fewer than 25 articles.
c. Where articles are not ordered by date of publication, study design, or topic area, we will obtain up to 25 articles in the order they appear on the journal website.

Ultimately, we anticipate that this process will generate a pool of biomedical articles published by both single journal and multiple journal predatory publishers for further consideration.

Article selection criteria

Two independent assessors will screen each article to include only those describing research in humans, or whole animals (e.g. in vivo). Methods research and non-research articles such as protocols, editorials, commentaries, opinion pieces, and letters to the editor will be excluded. Non-biomedical research, such as social science research, and research on agriculture, livestock, and wildlife will be excluded.

Sample size

We have not formally calculated a sample size needed for this project. We do not have a formal hypothesis; we consider this a descriptive study. Even though we have a large project group contributing to the study, there are substantial resource constraints, thus we have restricted the number of articles we can assess to a maximum of 6125 (i.e., 25 articles in each of the 245 journals in our sample).

Extraction of epidemiological characteristics

The following information will be extracted from each included article (from both lists described above): corresponding author's name, email address, country, and academic affiliation (first listed affiliation if multiple affiliations are listed), senior

author's name, email address, country, and academic affiliation (for the purposes of this study, identified as first author if not the corresponding author), location (country) of journal publisher, month and year of publication, number of authors, and the broad ICD-10 classification of disease being reported (http://apps.who.int/classifications/icd10/browse/2016/en), whether the research was reported as funded (yes/no/not reported), and, if so, the name of the funders, and whether there is mention of ethics approval (yes/no/not reported). We will also collect information on the study design of each included article. In order to determine the design within each article, we will use the following approach. If one of the study designs of interest (i.e., clinical trials, observational studies, diagnostic accuracy studies, systematic reviews, and pre-clinical in vivo studies) is reported in the article, we will record this. We will also ask assessors to make a judgment on study design guided by the EQUATOR Network tool for selecting a study design and reporting guideline (4) combined with a study classification algorithm developed by the Agency for Healthcare Research and Quality's Evidence-based Practice Centre program (AHRQ-EPC) (5). For articles in which study design is not made explicit in the article, we will use the judged study design as a surrogate indicator. The following types of research will be excluded from assessment of completeness of reporting: any research which does not fall into one of the specific design categories of interest, any articles reporting on more than one study (with the exception of systematic reviews), and any article indicating more than one study design. An exception will also be made for all pre-clinical studies since in-vivo studies tend to be reported alongside other study types (e.g. ex vivo, in vitro); for articles

containing in vivo studies, we will assess the first in vivo study reported in the article. We will extract the reported total sample size only for articles/study designs included in the completeness of reporting assessment (described in the next section).

The smaller core scientific group (MTA, KC, JG, ML, DM, LS) will pilot the data extraction form on multiple articles and refine it until there is agreement on at least 80% of items across assessors. Following this pilot exercise, members of the larger team will receive specific training on the form, and two team members will then independently complete data extraction for each article. Disagreements will be resolved by third party arbitration.

Assessment of completeness of reporting

Due to resource constraints, we will only assess the completeness of reporting for specific study designs: clinical trials, observational studies (case control, cohort, and cross sectional), diagnostic test accuracy studies, systematic reviews and meta-analyses, and pre-clinical in-vivo studies.

Once the relevant studies have been identified, for completeness of reporting assessment we will use adapted reporting guideline checklist items (due to resource constraints) from the following reporting guidelines, to assess the reporting completeness of each study: the CONSORT checklist for reporting journal and conference abstracts of randomized trials (6) (with the item on randomization

removed for non-randomized trials) (Appendix 1); the draft STROBE statement for reporting journal and conference abstracts of cohort, case control and cross sectional studies (7) (Appendix 2); the draft STARD for abstracts checklist for reporting diagnostic test accuracy study abstracts (8) (Appendix 3); the PRISMA for systematic review abstracts checklist (9) (Appendix 4). Pre-clinical in vivo studies will be assessed using a checklist developed for the purpose of this study with items derived and modified from the ARRIVE reporting guideline checklist (10) and the NIH Reproducibility guidelines (11) (Appendix 5). For each study, checklist items will be assessed as 'not reported', 'partially reported', or 'completely reported'.

The core team will pilot the reporting assessment forms using multiple articles for each study type form, and refine the forms until there is agreement on at least 80% of items across assessors. Following this pilot exercise, members of the larger team will receive specific training on the forms, and two team members will then independently complete data extraction for each article. Disagreements will be resolved by third party arbitration.

Data Management

Data will be managed using a combination of tools; Dropbox and Google Drive will be used to file and manage all included articles; DistillerSR (DSR) online software for which our team has a group license. Specifically, the following tasks will be carried out using DSR: screening for biomedical journals, data extraction of epidemiological characteristics for each article, assessment of completeness of

reporting of the included studies. The list of multiple journal publishers obtained from Beall's list as well as the compiled list of journals for each publisher will be collected and managed in Microsoft Excel. We will use the Open Science Framework for making the project content publicly available (https://osf.io/).

Data analysis

Once all data are in agreement (i.e. discrepancies between assessors have been resolved) the complete dataset for all included articles will be exported from Distiller SR into Excel where data will be cleaned (i.e. invalid characters will be removed and text data will be converted to numeric where appropriate). We will also resolve data entered into text boxes and categorize data collected on funding sources into the following categories: government, academic, industry, unfunded explicitly stated, funding source not stated. This will be done by one core team member running a Google search of each named funder and making a judgment about which category it fits into.

Descriptive summary statistics will be used to analyze the epidemiological characteristics. Specifically, we will calculate the median and interquartile range for continuous data items and proportions for dichotomous items. Categorical items will be reported as counts within each category. As part of a data exploration exercise to examine possible statistical (2-sided p value < 0.05) differences between single journal publishers and multiple journal publishers in reporting epidemiological characteristics inferential analysis will be completed using t-tests

or chi-square tests, depending on the scale of the characteristic (e.g., ordinal data or continuous data). A similar analysis will be completed to assess for differences between level of reported funding (yes/no) and reports of research approved by ethics committees (yes/no).

Completeness of reporting will be assessed using the proportion of reporting within each category per item on the relevant reporting guideline. No other analysis is planned for examining the completeness of reporting of the included articles.

Team experience

A team of 31 members will participate in this project. Members of the team are experienced systematic reviewers and clinical epidemiologists who have substantial expertise extracting information from a broad spectrum of primary clinical and pre-clinical studies and assessing the quality of these publications. Several members of the team also have expertise and experience in publishing, and specifically in examining predatory journals and publishers. In addition, several members of the team have clinical training.

Team training and piloting

Prior to conducting this study all team members will be required to participate in three 1-2 hour training sessions, given by the project's core scientific group (MTA, KC, JG, ML, DM, LS). The training will include a brief overview of the project, an

overview of predatory journals, a detailed discussion and review of clinical and pre-clinical study design architecture, followed by an exercise in categorizing five different types of clinical and pre-clinical study designs identified in predatory journals. The training session will end with an overview of how the project will be managed in DSR.

All team members approved this protocol.

Reference List

1. Beall J. Beall's List: potential, possible, or probable predatory scholarly open-access publishers [Internet]. 2015 [cited 2016 Jan 7]. Available from: http://scholarlyoa.com/publishers/
2. Shen C, Bjork B-C. "Predatory" open access: A longitudinal study of article volumes and market characteristics. BMC Med. 2015;13(1):230.
3. Shamseer L, Moher D, Maduekwe O, Turner L, Barbour V, Burch R, et al. A cross-sectional comparison of characteristics of potential predatory journals with open access and subscription journals (oral). REWARD-EQUATOR Conference. Edinburgh, UK.
4. Penelope Research. EQUATOR Wizard [Internet]. 2016 [cited 2016 Jan 20]. Available from: http://www.peneloperesearch.com/equatorwizard
5. Hartling L, Bond K, Santaguida PL, Viswanathan M, Dryden DM. Testing a tool for the classification of study designs in systematic reviews of interventions and exposures showed moderate reliability and low accuracy. J Clin Epidemiol. 2011;64(8):861–71.
6. Clavien P, Lillemoe K. A New Policy to Implement CONSORT Guidelines for Surgical Randomized Controlled Trials. Ann Surg. 2014; 260 (6): 947-948.
7. STROBE Group. Draft STROBE checklist for abstracts. 2011.
8. Bossuyt P. Draft STARD for abstracts (personal communication). 2016.
9. Beller EM, Glasziou PP, Altman DG, Hopewell S, Bastian H, Chalmers I, et al. PRISMA for Abstracts: Reporting Systematic Reviews in Journal and Conference Abstracts. PLoS Med; 2013 Jan;10(4):e1001419.
10. Kilkenny C, Browne WJ, Cuthill IC, Emerson M, Altman DG. Improving bioscience research reporting: the ARRIVE guidelines for reporting animal research. PLoS Biol. 2010; e1000412.
11. Principles and Guidelines for Reporting Preclinical Research - About NIH - National Institutes of Health (NIH) [Internet]. [cited 2015 Dec 5]. Available from: http://www.nih.gov/about/reporting-preclinical-research.htm

APPENDIX 1 – REPORTING ASSESSMENT FORMS FOR RANDOMIZED AND NON-RANDOMIZED TRIALS

CONSORT reporting assessment items – FOR RCTs

Please indicate your selection with an "x" in the appropriate box

Checklist Item	Yes	No	Partially Reported
Title: Is the trial described as 'randomized' in the title?			
Objective: Is the specific objective or hypothesis of the trial stated?			
Trial Design: Is a description of the trial design (e.g. parallel, cluster, non-inferiority), including allocation ratio provided?			
Participants: Are eligibility criteria for participants and the settings where the data were collected described?			
Interventions: Are the interventions for each group, with sufficient details to allow replication, including how and when they were actually administered stated?			
Outcome: Is there a clearly defined **primary** outcome, including details of how and when it/they were assessed?			
Sequence generation: Is the method used to generate the random allocation sequence described?			
Allocation concealment: Is the mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned, described?			
Blinding (masking): If blinding was done, is there a description of who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how? If blinding was not done, is a rationale provided?			
Numbers randomized: Is the number of participants randomized to each group reported?			
Flow Diagram: Is there a flow diagram? (may be in an appendix)			

Outcome: For the primary outcome, is a result for each group as well as the estimated effect size (e.g. the size of the difference between groups) and its precision (such as 95% confidence interval) reported?			
Harms: Are important adverse events or side effects reported or if none are reported, is it mentioned that there were none?			
Conclusions: Is there an interpretation of findings that is consistent with results, balancing benefits and harms, and considering other relevant evidence?			
Trial Registration: Is a registration number and name of the trial register provided?			

CONSORT reporting assessment items – For CCTs (non-randomized)

Please indicate your selection with an "x" in the appropriate box

Checklist Item	Yes	No	Partially Reported
Title: Is the trial described as 'non-randomized' in the title?			
Objective: Is the specific objective or hypothesis of the trial stated?			
Trial Design: Is a description of the trial design (e.g. parallel, cluster, non-inferiority), including allocation ratio provided?			
Participants: Are eligibility criteria for participants and the settings where the data were collected described?			
Interventions: Are the interventions for each group, with sufficient details to allow replication, including how and when they were actually administered stated?			
Outcome: Is there a clearly defined **primary** outcome, including details of how and when it/they were assessed?			
Sequence generation: Is the method used to generate the non-random allocation sequence described? (e.g. alternation [alternating between two interventions], rotation [cycling through more than two interventions])			
Allocation concealment: Is the mechanism used to implement the allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned, described?			
Blinding (masking): If blinding was done, is there a description of who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how? If blinding was not done, is a rationale provided?			
Numbers randomized: Is the number of participants assigned to each group reported?			
Flow Diagram: Is there a flow diagram? (may be in an appendix)			
Outcome: For the primary outcome, is a result for each group as well as the estimated effect size			

(e.g. the size of the difference between groups) and its precision (such as 95% confidence interval) reported?			
Harms: Are important adverse events or side effects reported or if none are reported, is it mentioned that there were none?			
Conclusions: Is there an interpretation of findings that is consistent with results, balancing benefits and harms, and considering other relevant evidence?			
Trial Registration: Is a registration number and name of the trial register provided?			

APPENDIX 2 – REPORTING ASSESSMENT FORMS FOR OBSERVATIONAL STUDIES

STROBE reporting assessment items – Cohort studies

Please indicate your selection with an "x" in the appropriate box

Checklist Item	Yes	No	Partially Reported
Title: Is the study's design (e.g. cohort) is indicated?			
Objectives: Are specific objectives or hypothesis stated?			
Study Design: Is there a statement of the study design (e.g cohort) in the methods section?			
Setting: Is there a description of the study setting, follow-up dates or dates at which the outcome events occurred/were present?			
Participants: Cohort study: Are the i) eligibility criteria, ii) the sources and methods of selection of participants, and ii) methods of follow-up described?			
Participants: Cohort study: For matched studies, are matching criteria and the number of exposed (e.g. smoking) and unexposed (non-smoking) subjects reported?			
Variables: Is there a clearly defined primary outcome/endpoint/dependent variable?			
Statistical methods: Are statistical methods, including those used to control for confounding, described?			
Results - Participants: Are the number of subjects at the beginning AND end of the study reported?			
Flow Diagram: is a flow diagram reported? (may be in an appendix)			
Main Results: Are the numbers of outcome events or summary measures over time reported for each study group?			
Main Results: Are unadjusted effect estimates (e.g. relative risk) and, if applicable, confounder-adjusted effect estimates and their precision (e.g., 95% confidence intervals) reported?			
Conclusion: Is there a general interpretation of study results referencing study objectives?			

STROBE reporting assessment items - case-control studies

Please indicate your selection with an "x" in the appropriate box

Checklist Item	Yes	No	Partially Reported
Title: Is the study's design (e.g. case-control) is indicated?			
Objectives: Are specific objectives or hypothesis stated?			
Study Design: Is there a statement of the study design (e.g case-control) in the methods section?			
Setting: Is there a description of the study setting, follow-up dates or dates at which the outcome events occurred/were present?			
Participants: Case-control: Are the i) eligibility criteria, and ii) the major sources and methods of case ascertainment and control selection described?			
Participants: Case-control: For matched studies, are matching criteria and the number of controls per case reported?			
Variables: Is there a clearly defined primary outcome/endpoint/dependent variable?			
Statistical methods: Are statistical methods, including those used to control for confounding, described?			
Results - Participants: Are the number of subjects at the beginning AND end of the study reported?			
Flow Diagram: is a flow diagram reported?			
Main Results: Are the numbers in each exposure category (e.g. cancer patients) or summary measures of exposure reported?			
Main Results: Are unadjusted effect estimates (e.g. relative risk) and, if applicable, confounder-adjusted effect estimates and their precision (e.g., 95% confidence intervals) reported?			
Conclusion: Is there a general interpretation of study results referencing study objectives?			

STROBE reporting assessment items - cross-sectional studies

Please indicate your selection with an "x" in the appropriate box

Checklist Item	Yes	No	Partially Reported
Title: Is the study's design (e.g. cross-sectional) is indicated?			
Objectives: Are specific objectives or hypothesis stated?			
Study Design: Is there a statement of the study design (e.g. cross-sectional) in the methods section?			
Setting: Is there a description of the study setting, follow-up dates or dates at which the outcome events occurred/were present?			
Participants: Cross-sectional study: Are the i) eligibility criteria, and ii) major sources and methods of selection of participants described?			
Variables: Is there a clearly defined primary outcome/endpoint/dependent variable?			
Statistical methods: Are statistical methods, including those used to control for confounding, described?			
Results - Participants: Are the number of subjects at the beginning AND end of the study reported?			
Flow Diagram: is a flow diagram reported? (may be in an appendix)			
Main Results: Are the numbers of outcome events or summary measures reported for each study group?			
Main Results: Are unadjusted effect estimates (e.g. relative risk) and, if applicable, confounder-adjusted effect estimates and their precision (e.g., 95% confidence intervals) reported?			
Conclusion: Is there a general interpretation of study results referencing study objectives?			

APPENDIX 3 – REPORTING ASSESSMENT FORM FOR DIAGNOSTIC ACCURACY STUDIES

STARD reporting assessment items

Please indicate your selection with an "x" in the appropriate box

Checklist Item	Yes	No	Partially Reported
Title or Abstract: Does the title indicate that this is a study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or area under the ROC curve)?			
Background and Objectives: Are study objectives or hypotheses stated?			
Study design: Is it clear whether the study is prospective (i.e. data collection was planned before the index test and reference standard were performed) or retrospective (i.e. data collection was planned after the index test and reference standard were performed)?			
Participants: Are i) eligibility criteria for participants and ii) the settings where the data were collected, described?			
Participants: Is it clear whether participants formed a consecutive, random, or convenience series?			
Test methods: Is a *replicable* description of the index test and reference standard provided? (i.e. enough detail that either can be replicated)			
Results: Are the number of participants with and without the target condition who were included in the analysis, reported?			
Flow diagram: Is there a flow diagram? (may be in an appendix)			
Test Results: Are estimates of diagnostic accuracy (e.g. area under the curve/ROC, likelihood ratios, odds ratios) and their precision (e.g. 95% confidence intervals) reported?			
Discussion: Is there a general interpretation of the results?			
Discussion: Are implications for practice, including the intended use of the index test, described?			

APPENDIX 4 – REPORTING ASSESSMENT FORM FOR SYSTEMATIC REVIEWS

PRISMA reporting assessment items

Please indicate your selection with an "x" in the appropriate box

Checklist Item	Yes	No	Partially
Title: Is this review identified as either: a systematic review, meta-analysis, or both in the title?			
Objectives: Is there an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS)?			
Eligibility criteria: Are eligibility criteria reported, including the following study characteristics: i) PICOS (study design) ii) length of follow-up; and the following report characteristics: i) years considered, ii) language, iii) publication status?			
Information Sources: Are all information sources included in the search (e.g., databases with dates of coverage, contact with study authors to identify additional studies) and the date last searched reported?			
Risk of bias: Are methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information was used in any data synthesis, described?			
Flow diagram: Is there a flow diagram? (may be in an appendix)			
Synthesis of results: For all outcomes considered (benefits or harms), are simple summary data for each intervention group reported for each study?			
Description of the effect: For all outcomes considered (benefits or harms), are effect estimates and confidence intervals, ideally with a forest plot, reported for each study?			
Strengths and Limitations of evidence: Are the limitations at study and outcome level (e.g., risk of bias), and at review level (e.g., incomplete retrieval of identified research, reporting bias) reported? (or stated that there were none)			
Interpretation: Do the authors report a general interpretation of the results in context of other research and important implications for future research?			
Registration: Is a registration number and registry name reported?			

APPENDIX 5 – REPORTING ASSESSMENT FORM FOR PRE-CLINICAL IN VIVO STUDIES

Pre-Clinical Reporting Assessment items

If more than 1 in vivo study is reported, please only assess the first one encountered in the methods section

Please indicate your selection with an "x" in the appropriate box

Checklist Item	**Yes**	**No**	**Partially**
Title: Does the title indicate that this is a non-human animal study?			
Objective: Are the study objectives/hypotheses clearly stated?			
Blinding: Is it clear whether the following groups were blinded: experimenters and/or caregivers, outcome assessors, or those analysing data?			
Eligibility Criteria: Are inclusion/exclusion criteria for data/samples/subjects clearly stated?			
Replication: Is replication, reproduction, or repetition of in vivo experiments (e.g. done multiple times) described?			
Were control and experimental groups used in this experiment?			
If Yes to above: **Allocation:** was the method of allocation to groups, including randomization, stated?			
Statistical Analyses: Are details of the statistical methods used for each analysis provided?			
First Result: Were summary estimates (e.g measures of central tendency)*, for each group, if applicable,* with measures of variance (e.g. error bars defined as SD, SEM, or CI) reported for the first reported *in vivo* result/outcome in the results section?			

Effect Estimate: Are effect estimates (e.g. difference between groups) with measures of precision (e.g. error bars defined as SD, SEM, or CI) reported for the first reported in vivo result/outcome in the results section?			
Adverse Events: Were any adverse events described (or was it stated that there were none)?			