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Including non-public data and studies in systematic reviews and systematic maps

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ABSTRACT

Systematic reviews and maps should be based on the best available evidence, and reviewers should make all reasonable efforts to source and include potentially relevant studies. However, reviewers may not be able to consider all existing evidence, since some data and studies may not be publicly available. Including *non-public* studies in reviews provides a valuable opportunity to increase systematic review/map comprehensiveness, potentially mitigating negative impacts of publication bias. Studies may be non-public for many reasons: some may still be in the process of being published (publication can take a long time); some may not be published due to author/publisher restrictions; publication bias may make it difficult to publish non-significant or negative results. Here, we consider what forms these non-public studies may take and the implications of including them in systematic reviews and maps. Reviewers should carefully consider the advantages and disadvantages of including non-public studies, weighing risks of bias against benefits of increased comprehensiveness. As with all systematic reviews and maps, reviewers must be transparent about methods used to obtain data and avoid risks of bias in their synthesis. We make tentative suggestions for reviewers in situations where non-public data may be present in an evidence base.

1. Background

Systematic reviews and systematic maps[1] should be based on the *best available evidence* (CEE, 2013); i.e. as much of the complete evidence base as is identifiable and accessible using reasonable means and resources. This comprehensiveness is a central tenet of all systematic reviews (Haddaway et al., 2015), and reviewers should make all reasonable efforts to source and include potentially relevant studies. In practice, however, reviewers may not be able to consider all existing evidence: some studies may not be identified through normal searching (Bayliss and Beyer, 2015); some may not be found at full text (e.g. Haddaway et al., 2014); and some may be behind paywalls (Fuller et al., 2014) (see Table 1). Systematic reviews and maps differ from many other forms of literature review that are susceptible to bias because they aim to search for and include all available evidence from the grey literature. Grey literature can be defined as "*information produced on all levels of government, academics, business and industry in electronic and print formats not controlled by commercial publishing*": i.e. studies that have not been published by traditional, commercial academic publishers. Including grey literature not only increases comprehensiveness, but also aims to mitigate possible publication bias (Haddaway and Bayliss, 2015). Publication bias can significantly reduce accuracy and reliability of systematic reviews and maps: ignoring grey literature can overestimate effect sizes, since academic journals may be more likely to publish positive, significant or affirmative research than negative, non-significant or contradictory research (Dwan et al., 2013; Easterbrook et al., 1991; McAuley et al., 2000).

Two further tenets of systematic reviews are that they must be transparent, reproducible (CEE, 2013; Higgins and Green, 2011). This requires that reviewers document all activities they have undertaken, along with detailed descriptions of the studies included and that the findings of the review could be obtained again if the methods were repeated by a third party. Repeatability is a core principal of the scientific process that enables confidence in study findings, but there are increasing concerns that much published research is unrepeatable (e.g. Collaboration, 2015).

Reviewers may be aware of studies that cannot be obtained (e.g. for financial reasons), but reviewers may also know of completed research

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[1] Systematic reviews are formal methods that "attempt to identify, appraise and synthesize all the empirical evidence that meets pre-specified eligibility criteria to answer a given research question" (http://www.cochranelibrary.com/about/about-cochrane-systematic-reviews.html) whilst for systematic maps "the process and rigour of the mapping exercise is the same as for systematic review except that no evidence synthesis is attempted to seek an answer to the question" (http://environmentalevidence.org/wpcontent/uploads/2014/05/EE_InstructionsforAuthors_SYSTMAPS.pdf). These methods are defined more specifically in detailed guidelines set out by the Collaboration for Environmental Management for syntheses of conservation and environmental management evidence: see http://www.environmentalevidence.org/information-for-authors.

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Table 1
Description of studies in the public domain but difficult to source/include in a review along with advantages/disadvantages of their inclusion in a systematic review and recommendations for systematic reviewers.

Type of studies	Reason for being excluded	Advantages/disadvantages of inclusion	Recommendations
'Pay walled' studies	Studies are commercially published and held behind a pay wall for one-off or subscription access.	Advantages: The review will be more repeatable if more than just the readily/freely available studies are included. Including more evidence increases comprehensiveness and reliability of the review. Disadvantage: Depending on subscriptions inclusion of all evidence may become very costly.	Should be included where possible. Reviewers can attempt to obtain inaccessible studies by: i) using co-author subscriptions, ii) checking accessibility status[a], iii) contacting study authors, vi) appealing to the research community to pass on the papers documenting the study, v) paying a one-off fee.
In-print studies	Studies are not available electronically and may only be physically available in single libraries.	Advantages: Including more evidence increases comprehensiveness and reliability of the review. Disadvantages: Inter-library loans and library visits may increase the review's running costs.	Should be included where possible. Reviewers can facilitate obtaining in-print studies by: i) checking co-author library holdings, ii) contacting study authors who may own physical/digital copies, iii) appealing to the research community, iv) paying for an inter-library loan or visiting a holding library.
Non-indexed/poorly indexed studies	Studies are published but occur in journals not indexed or indexed only in minor citation databases.	Advantages: Including more evidence increases reliability of the review. Disadvantages: Repeatability of the review may be reduced unless methods used to locate studies are documented transparently, which may particularly challenging for non-indexed studies that have been difficult to source.	Should be included along with detailed descriptions of how studies were located (holding organisation, contact person, method of identification)

[a] Some pay walled articles are released under green open access following a specified embargo period post publication (often 12 to 24 months). Check http://www.sherpa.ac.uk/romeo/ for OA status of individual journals.

that is not publicly available (i.e. they are not available free-of-charge or for a fee either in a digital or physical public repository). Studies may be *non-public* for many reasons: some may still be in the process of being published, which can take particularly long (Nguyen et al., 2015); some may not be published due to author/publisher restrictions (Schöpfel and Prost, 2014); publication bias may make it difficult to publish non-significant or negative results (Rothstein et al., 2006).

Non-public studies should be included in reviews if reviewers can access the material, for example by personal communication with authors, thereby improving the comprehensiveness of their reviews. However, this may raise concerns where such activities could not be repeated in the future and where there are restrictions on the use and re-use of the non-public studies, since this compromises repeatability and transparency (Haddaway and Verhoeven, 2015). Authors can increase repeatability in these cases by documenting their efforts to source all studies in detail, for example in supplementary files (see Moher et al., 2015). However, in such situations reviewers may feel that there is a trade-off between comprehensiveness and transparency or repeatability. There is currently no universal guidance on best practice for such situations relating to non-public studies.

Here, we consider what forms these non-public studies may take and the implications of including them in systematic reviews and maps. Our experience as systematic reviewers and knowledge brokers we have come across cases where authors were aware of studies but could not fully describe them in their review due to restrictions on public accessibility of the data. These reviewers were unable to find advice on what to do in these situations, representing a real knowledge gap. We thus aim to provide tentative guidance and stimulate discussion within the methodology community.

2. Public studies

Public studies are any research results that are publicly available in an accessible repository, including: physical libraries, digital data repositories, bibliographic databases, or websites identified by public search engines. Sometimes these may be study findings alone (i.e. datasets: collections of quantitative or qualitative study findings), unaccompanied by descriptive meta-data[2] detailing the methods used. Datasets such as these (e.g. http://nrfa.ceh.ac.uk/) are only admissible in systematic reviews or maps if accompanied by detailed meta-data (reviewed in McCain, 1995; Piwowar et al., 2007) or if this information is retrievable from study authors and can be included in the systematic review to ensure repeatability and transparency. This could be done, for example, by including the data and meta-data in supplementary files. Studies may be admissible in systematic reviews and maps even though they may lack certain specific details. For example, in systematic maps, data extraction and critical appraisal are not necessarily undertaken, making it more feasible to include studies that are somewhat deficient in methodological detail. Similarly, systematic reviewers may choose to include information-deficient studies to a certain point in the synthesis (e.g. Pullin and Stewart, 2006). Studies published in the academic literature typically provide descriptive information (Haddaway and Verhoeven, 2015), and grey literature, such as organisational reports and government papers (Haddaway and Bayliss, 2015), may often provide such descriptive information. For example, in a recent systematic review on biomanipulation effectiveness for eutrophication mitigation, 51 of the 124 studies were grey literature, including non-public consultancy reports, and reported sufficient detail to permit critical appraisal and inclusion in meta-analysis (Bernes et al., 2015). Sometimes, reviewers may be aware of datasets that are unaccompanied by descriptive meta-data, such as monitoring results. These are only admissible where sufficient methodological details exist that can allow integration of the results and adequate critical appraisal of the methods used. Where descriptive meta-data is not publicly available such information can be included in supplementary information alongside a systematic review or map (providing this does not contravene data ownership or copyright legislation).

It is important to note that critical appraisal must be performed for all included, relevant studies in a systematic review, irrespective of their source.

3. Non-public studies

Here, we define *non-public studies* as those that are not available to the public, either physically or digitally (Merriam-Webster, 2016). The term non-public studies (also referred to as unpublished studies) is not synonymous with grey literature, which can be defined as "reports that are produced by all levels of government, academics, business and industry in print and electronic formats but that are not controlled by commercial publishers" (Higgins and Green, 2011). Hence, grey

[2] Meta-data are descriptive information that outline key aspects of study design, study setting and experimental and measurement methods. Typically this consists of short textual descriptions or quotations.

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literature is a broader group of studies that is defined by the lack of a commercial publisher. In fact, grey literature is commonly published, typically by placing it in an online repository or website. Non-public studies are a form of grey literature, but the lack of publication makes these studies difficult to identify. It is worth noting that publication does not necessarily mean accessibility: studies may exist only on the dark web (i.e. placed online but known to and identifiable by only the authors (Lander and Rajasekar, 2015)), studies may exist in a very small print run and not online, they may exist behind paywalls, or they may be inappropriately or inadequately indexed. In the following pages we refer to non-public studies synonymously with non-public data that is accompanied by meta-data, and we focus on issues relating to restrictions of use rather than restrictions in identification and retrieval. A substantial literature exists providing practical guidance on locating difficult-to-course studies (e.g. Hopewell et al., 2007).

Systematic reviewers may be aware of non-public studies for a number of reasons, including: personal communication, for example with the producers/owners or their broader networks; and registries of research, such as lists of successful research grants or research permits (De Angelis et al., 2004).

There are many reasons why studies that have been undertaken may not be published (see Table 2). For the purposes of critical appraisal, it is useful to carefully consider whether these reasons relate to a possible bias in the way the data were collected that could affect the reliability of any synthesis. It may be particularly appealing to include non-public studies in a systematic review or map in an effort to combat publication bias. However, as with all studies, both public and non-public, reviewers should carefully consider whether each study is unacceptably biased in some way, for example being of lower internal validity (Bell et al., 2006).

4. Reasons studies may be non-public

Non-public studies or reports may not have been placed in the public domain for benign reasons, relating to them being conducted by or aimed for internal end-users (Table 2). However, some studies may be restricted because of a perception of political or commercial (current or perceived future) sensitivity. Academic studies may not be made public because of a failure to submit them to an academic publisher, due to several reasons, including: a lack of resources; a perception of low academic interest; or difficulties in analysing/interpreting results. Reports may remain unpublished because of a failure to pass editorial or peer-review scrutiny. Additionally, academic authors may not publish their research because of perceived commercial/political sensitivity or future research/commercial value.

5. Examples of the use of non-public studies in a systematic review

In a recent systematic review of the impacts of biomanipulation for mitigation of eutrophication, Bernes et al. (2015) identified three relevant reports written in Danish that were available only in closed repositories, authored by environmental consultants (see Additional File 8 in Bernes et al. (2015) for further details). Two reports were indexed in online bibliographic databases, whilst one was uncatalogued. The authors of the systematic review ensured transparency by providing details of the review team member who sourced the reports, enabling a degree of repeatability for those wishing to source the relevant studies themselves.

6. Access restrictions compromise transparency and repeatability

Including non-public studies in systematic reviews is not problematic if study results and meta-data are freely obtainable and can be made public by systematic reviewers, for example by publishing them within supplementary files or appendices (Kenyon and Sprague, 2014). Where authors of systematic reviews and maps are granted unrestricted access to non-public studies, and the study producers allow further use and publication of their data, the studies used in the synthesis can be described in detail (for example, including the non-public studies in full within supplementary information) along with the efforts taken to obtain the studies, thereby ensuring transparency and repeatability.

However, a problem occurs where restrictions are put in place by owners or copyright holders that prevent reviewers from making these studies publicly available. Here, transparency and repeatability are compromised.

Owners of studies may entirely prohibit access to study data, precluding their inclusion in systematic reviews. Alternatively, owners may allow access to the studies, but permission may be needed to use or publish the data or meta-data. For example, studies on genetically modified organisms can be identified by accessing applications from

Table 2
Description of studies not in the public domain along with advantages/disadvantages of their inclusion in a systematic review.

Type of studies	Reason for being non-public	Advantages/disadvantages of inclusion
Unpublished organisational reports	Internal reports and evaluations not published due to: i) political sensitivity, or ii) a perceived lack of external audience.	Advantages: Including more evidence increases comprehensiveness and reliability of the review. Disadvantages: Including selected, non-public studies potentially introduces selection bias and reduces the repeatability of the review since others may not be able to access the same evidence. Research funded by organisations with vested interests may be more susceptible to specific bias, which should be carefully assessed during critical appraisal. Some organisations may be unwilling to release private studies.
Unpublished commercial studies	Studies may include or may be related to sensitive data or information that is of current or future, real or potential commercial value.	Advantages: Including more evidence increases comprehensiveness and reliability of the review. In some topics, commercial research may form a substantial proportion of the evidence base. Disadvantage: Including selected, non-public studies reduces the repeatability of the review since others may not be able to access the same evidence. Commercially-funded research may be more susceptible to specific bias, which should be carefully assessed during critical appraisal. Commercial organisations may be unwilling to release private studies.
Unpublished academic studies	Studies have not been published: i) in order to protect potential future publishing rights, ii) due to a lack of resources or iii) difficulties in publishing non-significant or negative results	Advantages: Including more evidence increases comprehensiveness and reliability of the review. Unpublished studies may be 'file drawer' research that also help to counteract publication bias. Disadvantages: Repeatability of the review may be reduced unless methods used to locate studies are documented transparently. Authors may be unwilling to release unpublished data.

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the European Food Safety Authority that assesses applications for the market release in the EU. However, permission for the further use of study data must be obtained from the data owner (Kohl et al., 2015).

There is a significant conflict for reviewers if they become aware that restricted studies could affect the findings of their synthesis. In some cases the raw data may not be provided to reviewers, but summary data (such as means, standard deviations and sample sizes) and meta-data may be accessible. Here, reviewers should provide as much information as possible in their review and transparently document the methods used to access the studies included. If reviewers cannot access studies or are not allowed to include them in their review, this should be explicitly stated.

7. Considerations

Authors of systematic reviews and maps should be aware of several considerations when attempting to integrate non-public studies into a review. Many of the actions relating to these considerations will already be undertaken for public studies, but the implications of not doing so for non-public studies may be particularly substantial.

Firstly, reviewers should carefully assess the evidence base for 'dual publication' (Bird, 2002), since it may not be immediately obvious that the studies have already been published. This is equally an issue for publicly available grey literature, such as PhD theses, but should be considered carefully wherever grey literature is added to a review to complement traditional academic sources. Failing to account for dual publication can produce inaccurate results in a synthesis due to overweighting results from certain studies.

Secondly, reviewers should ensure they carefully consider the reliability of studies initially withheld from publication because of political or commercial sensitivity (as with all studies in a systematic review), since they may have been withheld for reasons of reliability (Bhandari et al., 2004; Shah et al., 2005).

As with public studies, reviewers should also be aware of possible reporting bias, where primary research authors present only some of their data (Dwan et al., 2008), possibly because of a clear pattern or the direction or significance of the results.

Reviewers should confirm that their use of non-public studies conforms to all necessary legislation relating to use of such data. This may be a case of proper attribution and acknowledgement of sources, or it may be a case of restricting certain non-essential meta-data or raw data in the review report. In all cases, reviewers should strive for the maximum degree of transparency possible within the confines of the law.

Authors of systematic reviews and maps must ensure that their work is undertaken in a transparent and reliable manner, and that their syntheses are accurate representations of the evidence base (CEE, 2013; Haddaway et al., 2015). In some cases reviewers may be able to see data but not publish analyses based on it. In these instances, reviewers may know that their review findings would be affected by including the non-public studies. Here, in our opinion, reviewers must detail their awareness of both the studies and the potential effect on their results (irrespective of the direction or significance of the effect) by stating if and how their findings would be affected within the 'Limitations of the systematic review' section of their review report. In practice, this may best be presented as a sensitivity analysis: including an additional meta-analysis, if feasible, to demonstrate the impact of including non-public studies on summary statistics.

8. Practical recommendations

We offer the following advice to systematic reviewer and map authors considering including non-public studies in their syntheses:

- In general, non-public studies should be included in a systematic review where summary statistics (i.e. mean, variability and sample size) and key meta-data needed for meta-analysis and critical appraisal can be made public (with permission).
- Studies should not be included where reviewers must withhold critical information (i.e. information that compromises transparency or repeatability) from the reader, including details of how the studies were obtained. In all cases, reviewers should be transparent about every study that is considered for inclusion in a review but that cannot be included for whatever reason. If results are non-public and cannot be included, reviewers must state this explicitly, for example listing and explaining these decisions.
- Reviewers may wish to include non-public studies in sensitivity analyses, presenting analyses including and excluding the data, clearly stating the limitations of such non-transparent approaches.
- Where reviewers are aware of the implications of including or excluding the studies in a synthesis, they should comment on the implications of inclusion or exclusion of restricted study data in 'Limitations of the systematic review'.
- Where reviewers are aware of non-public studies that cannot be reused in a synthesis and their influence on the synthesis is known to be strong, reviewers should consider carefully whether completing a systematic review is appropriate given the known lack of comprehensiveness. In these instances another form of evidence review may be more appropriate, since there is a risk that end users may place unwarranted weight on the results of such an inaccurate synthesis.
- Where raw data may not be made public but summary statistics (such as means and standard deviations) may, reviewers should request permission to publish summary statistics and meta-data necessary for critical appraisal and synthesis from the owners, since restrictions may concern only raw data.
- For systematic maps, inclusion of quantitative or qualitative data (i.e. study findings) and certain meta-data may be less critical.
- Taking the above points into account, reviewers should make all reasonable efforts to be inclusive with respect to non-public studies in order to make reviews as comprehensive as possible, making use of thorough critical appraisal to ensure high reliability.

9. Conclusions

Including non-public studies in reviews provides a valuable opportunity to increase comprehensiveness, potentially mitigating negative impacts of publication bias. Reviewers should carefully consider the advantages and disadvantages of doing so, weighing risks of bias against benefits of increased comprehensiveness. Assessments of these risks of bias should consider the study source and content. As with all systematic reviews and maps, reviewers must be transparent about methods used to obtain studies and avoid risks of bias in their synthesis. Reviewers should consider at an early stage the likelihood that a significant body of evidence may be non-public and must decide whether a systematic review or systematic map is the most appropriate course of action if this could affect the accuracy of the review findings: instead another form of review may be appropriate (Grant and Booth, 2009). However, in many cases a systematic review or map may still be appropriate, providing the authors give clear caveats concerning what they know about the non-public evidence base.

We hope that reviewers who are aware of non-public studies that would influence their review findings would strive to include studies transparently or document their existence for the reader in their discussion. Finally, we call for authors of research reports and other forms of non-traditional (i.e. grey) literature to attempt to ensure their research is made publicly available (i.e. Open Access) to facilitate assimilation into secondary syntheses such as systematic reviews.

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Authors' contributions

NRH drafted the manuscript and all authors edited the draft.

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