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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for many reasons: some may still be in the process of being published (publication can take a long time); some may not be published due to author/publisher restrictions; publication bias may make it difficult to publish non-significant or negative results.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. © 2016 Published by Elsevier Ltd.

1. Background

Systematic reviews and systematic maps¹ 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

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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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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-systematicreviews.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.

 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-data² 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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