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Abbreviation List

Acronym	Definition
HCS	Healthcare Scientist
NHSSA	National Health Services Scotland Assure
LR	Literature Review
SR	Scoping Review
RP	Rapid Review
SME	Subject Matter Expert





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1. Introduction

Purpose

- 1.1. The purpose of this Standard Operating Procedure (SOP) document is to provide a clear and systematic framework and the governance for conducting scoping, rapid and systematic literature reviews. It applies to reviews incorporating diverse evidence sources such as qualitative and quantitative data, grey literature, expert opinions, and mandatory standards. It is applicable in the context of reviews addressing both human and non-human-related questions.
- 1.2. This SOP aims to ensure consistency, transparency, and rigor in the review process, enabling the identification, appraisal, synthesis, and reporting of evidence in a structured and replicable manner.

Key Terms and Definitions

1.3. This section provides definitions for key terms used throughout this SOP. These terms are essential for understanding the processes, evidence types, and methodologies discussed in the document. The definitions ensure clarity and consistency in how the concepts are interpreted and applied.

Term	Definition
Evidence from	Information provided by manufacturers. When integrating such
manufacturers	evidence, it is crucial to explicitly address and consider any conflicts
	of interest. Consulting independent experts can help provide an unbiased interpretation of the data presented by manufacturers.
Evport opinion	·
Expert opinion	Insights from subject matter experts, including published editorials,
	commentary articles in peer-reviewed journals, panel discussions at
	professional conferences, or direct consultations. In reviews, expert
	opinions supplement empirical evidence by providing reasoned
	judgments that can support or challenge existing findings.
Finding	A finding is the synthesis of evidence extracted from multiple reports
	that fully or partially answers a review question. There may be
	multiple findings under a single review question.
Grey literature	Research material that is either unpublished or published outside of
	traditional peer-reviewed journals. This includes government reports,
	technical papers, theses, conference papers, and manufacturer
	documents.
	documents.

Term	Definition
Peer-reviewed empirical studies	
Qualitative studies	Research that explores people's experiences, perceptions, and meanings using methods like interviews, focus groups, or observations.
Quantitative studies	
Record	Used during the screening stage to refer to the title or abstract (or both) of a report indexed in a database or website (such as a title or abstract for an article indexed in Medline). Records that refer to the same report (such as the same journal article) are "duplicates"; however, records that refer to reports that are merely similar (such as a similar abstract submitted to two different conferences) should be considered unique.

Overview of Responsibilities

1.4. This section outlines the responsibilities of each role involved in the review process, including the Lead Author (Healthcare Scientist (HCS)), Supporting Authors (HCS), Lead/ Principal HCS, Subject Matter Experts (SMEs), Commissioner, Consultation Groups and Information Officer.

Lead Author (HCS):

- The Lead Author is responsible for all aspects of the review and should be considered the first line of contact for any queries and discussions regarding its content.
- Liaises with the Commissioner to gather the required information to initiate the work.
- Leads/ chairs all the meetings related to the review.
- Liaises with the Lead/ Principal HCS to ensure the proposed timeline for the review is feasible and meets internal deadlines.
- Keeps an overview of the scope and timeline.
- Liaises with SMEs allocated to the review, ensuring clear and timely communication, and meets with them on a regular basis to ensure thorough discussion of the topic and address any issues that arise.

- Responsible for setting up a group chat on Microsoft Teams, ensuring all HCS involved, including the Lead/Principal HCS, are included.
- Shares relevant information with other HCS when it is pertinent to the tasks they are working on.
- Regularly checks in with the team, at least once a week, to discuss decisions and progress.
- Seeks assistance from other HCS if there is insufficient time to complete the task.
- Liaises with other relevant parties when required throughout the review process.
- Formats the Evaluation Tool that goes out to consultations groups along with consultation items.
- Ensures all draft documents have been signed off by the SMEs/Commissioner.
- Is responsible for final checks of any drafts following SMEs/ Commissioner sign-off.
- Liaises with the Information Officer to ensure accessibility of drafts for consultation of protocol and final report and publication on the NHSScotland Assure (NHSSA) Website.
- Additionally, coordinate with the designated HCS for uploading of the final report on Q-Pulse and update the HCS Technical Landing Page.
- Assess the suitable of the literature review for publication in a peer-reviewed journal. If suitable, the lead author is responsible for formatting the review in accordance with journal guidelines, managing the submission process, and addressing required amendments throughout the review process.
- Responsible for keeping the file '[Year-Year] HCS Tech Review Timeline' updated for the literature review.
- Ensures that all the review documentation is appropriately saved and filed in the correct locations including sign offs and correspondence.

Supporting Author (HCS):

- If carrying out a two-person review, the Supporting Author will have joint responsibility for developing the protocol, search strategy, screening, retrieving and requesting reports from the library, and conduct the grey literature search.
- Perform 'check' of the critical appraisals and data extraction, subject to resource availability and type of literature review.
- Provide feedback on the confidence assessments drafts.
- Actively engage in discussions with SMEs and attend regular meetings, taking the lead when the Lead Author is unavailable.
- Responsible for conducting a detailed proofread of the final written literature review and appendices, ensuring all citations and references are correct and traceable back to the original source.

- When publishing in a peer-reviewed journal, responsible for proofreading all the revisions leading up to the publication.
- Keep the file '[Year-Year] HCS Tech Review Timeline' updated for their part.

Othe Supporting HCSs:

These individuals are not directly involved in the review but can provide essential support, such as:

- Retrieving records.
- Conducting a detailed proofread of the final written literature review and appendices, ensuring all citations and references are correct and traceable back to the original source.
- Conducting a gap analysis of suitable journals if the literature review is suitable for publication in a peer-reviewed journal, considering potential costs and impact factor.

Lead/ Principal HCS¹:

- The Lead/ Principal HCS is responsible for assigning members of the HCS team to literature reviews and agreeing on proposed timelines.
- Provide a sense check and feedback on the protocol, search strategy, confidence assessments, final report and supporting material prior to sign-off.
- Responsible for singing-off on the final search strategy.
- Responsible for commissioning the literature review using the NHSSA commissioning process when a review is not part of the annual work plan.
- Attend regular review team meetings when available.

Subject Matter Experts (SMEs):

- Responsible for supporting the HCS team throughout the literature review, providing relevant supporting materials and additional insight when required.
- Identify appropriate working groups and individuals for the consultation group, introduce the Lead Author to these groups, and communicate the required input for effective collaboration.
- Share calendar availability with the HCS team to facilitate the scheduling of recurring meetings. Attend scheduled meetings on a regular basis or, if unable to attend, rearrange a suitable date.

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¹ These tasks are typically assigned to the Lead HCS. However, in the absence of a Lead HCS, the Principal HCS will assume some of these responsibilities.

- Be available for ad-hoc contact.
- Review and provide feedback on the protocol and final report and contribute to the confidence assessments.
- Review consultation feedback and draft responses.

Consultation Group:

- Review and provide comments, in a timely manner, on the protocol and final report.
- Declare any conflict of interest.

Commissioner:

- Assign at least one SME to work closely with the HCS team, ensuring that expert input is provided throughout the process.
- Review and sign off on the protocol and final report for consultation, as well as their final versions.
- In some instances, the SME also acts as the Commissioner of the work. In this situation, they will take on the responsibilities of both the Commissioner and the SME.

Information Officer:

- Ensure correct formatting of the protocol and literature review report and adherence to branding guidelines.
- Verify the functionality and accessibility of documents.
- Upload the protocol and literature review report to the NHSSA website.

Types of Literature Reviews

- 1.5. This SOP applies to three types of literature reviews:
 - Systematic Literature Reviews
 - Rapid Reviews
 - Scoping Reviews

For detailed definitions of these review types, please refer to **Appendix A**.

Below is an overview of the characteristics that differentiate these review types, including the number of authors involved, the search and selection processes, data extraction, critical appraisal, and consultation. A table summary comparing the key characteristics of the review types can be found in **Appendix B**.

Systematic literature review

Number of Authors

1.6. These reviews involve two authors: a Lead Author and a Supporting Author. Additional reviewers may be involved for specific tasks as needed.

Search

1.7. Searches are conducted in all relevant databases, including grey literature when applicable. They are reviewed by a Librarian and require citation searching.

Study Selection

1.8. Both authors will independently conduct the first screening of titles and abstracts, followed by a second screening of full texts for eligible studies. Any disagreements will be resolved through a consensus meeting. If consensus cannot be reached, a third reviewer will make the final decision.

Data Extraction and Critical Appraisal

1.9. The Lead Author is responsible for extracting the data using a piloted form, as agreed upon in the protocol, and for critically appraising the methodological quality of eligible reports.

The Supporting Author will perform a full check of the data extraction and a 30% check of the critical appraisals.

Confidence Assessments

1.10. Confidence assessments will be a collaborative effort involving the Lead Author, Supporting Author, Lead/Principal HCS, and at least one Subject Matter Expert (SME).

Consultation and Publication

1.11. Both the protocol and final report, along with confidence assessments, will undergo consultation unless the commissioner specifies otherwise.

They are published on the NHSSA website.

Rapid Literature Reviews

1.12. Rapid reviews are a type of evidence synthesis which follows a condensed version of the systematic literature review process, shortening stages and removing the methodological quality assessments for the purpose of reducing the timeframe. Usual time for completion is around 2- 4 weeks, but this can vary widely per rapid review.

Number of Authors

1.13. These reviews involve one author.

Review questions and inclusion criteria will be developed in conjunction with the Lead/Principal HCS and SMEs.

Search

1.14. Searches are conducted in general databases, with a limited number of specialised sources (one or two) if time permits. Citation searching and grey literature may be restricted. If time allows consultation with the librarian can be considered.

Study Selection

1.15. One author will conduct the screening. For uncertainties, another HCS can be consulted.

Data extraction and Critical Appraisal

1.16. Conducted by one author.

Data extraction may be limited to essential items; existing systematic reviews can be used.

Critical appraisals are generally omitted for rapid reviews.

Synthesis and Confidence Assessments

1.17. The confidence assessments will be conducted by the Lead Author, with SME consultation if time allows. Since methodological quality is not assessed, proxy indicators such as study design and journal reputation will be used to assess confidence.

Consultation and Publication

1.18. Rapid reviews typically do not undergo consultation. However, if time allows or if deemed appropriate, the rapid review may be sent to the relevant short-life working group(s) for a brief consultation period.

They are not published on the NHSSA website. They are sent directly to relevant SMEs.

Scoping Review

Number of Authors

1.19. Two authors: a Lead Author and a Supporting Author.

Search

1.20. Conducted in all relevant databases, including grey literature if applicable. They are reviewed by a Librarian and require citation searching.

Study Selection

1.21. Both authors independently conduct the first and second screening. Disagreements are resolved through a consensus meeting or a third reviewer if necessary.

If resources are limited, alternative approaches regarding the number of reviewers and their level of involvement will be agreed upon with the Lead/Principal HCS. For example, the authors may collaborate, or the process may be conducted solely by the Lead Author.

Data Extraction and Critical Appraisal

1.22. The Lead Author is responsible for extracting the data using a piloted form, as agreed upon in the protocol. If resources allow, the Supporting Author will conduct a 30% check of the extracted data.

Critical appraisals are not performed for scoping reviews.

Confidence Assessments

1.23. Confidence assessments are not performed for scoping reviews.

Consultation and Publication

1.24. Both the protocol and final report will undergo consultation unless the commissioner specifies otherwise.

They are published on the NHSSA website.

2. Administrative and Quality Control

Literature Review Timeline

- 2.1. When initiating a new literature review, the first stage requires the Lead Author to create a sheet for that specific review within the excel file named '[Year-Year] HCS Tech Review Timeline', accessible at 2024-2025 HCS Tech Review Timeline.xlsm. The file should be used to record the hours and days taken for each task of the literature review.
- 2.2. To create a new sheet, the 'Template' sheet must be right-clicked, and 'Move or Copy' selected. In the dialogue box, 'Template' should be selected, the 'Create a copy' option checked, and the new sheet renamed with the review's short title, such as 'Mass Timber SR'. The title should end with the acronym 'SLR' for systematic literature reviews, 'SR' for scoping reviews, or 'RR' for rapid reviews, as applicable.
- 2.3. The template sheet contains all tasks required in the literature review, including the estimated time necessary for each task to be completed and the individuals involved in each task. These estimates are subject to future adjustments as the HCS Team gains more experience from new reviews.
- 2.4. The Lead Author and Second Author are responsible for filling their respective sections of the sheet (indicated in the 'persons involved' column). The Lead Author is also responsible for the completion of the tasks attributed to the SMEs, Lead/ Principal HCS, and

- Consultation Group. The Lead Author has the overall responsibility for the management of the timeline and ensuring all the sections are completed and updated.
- 2.5. It is recommended to update the timeline daily after each contribution to the literature review by the HCS, as well as actions performed by the SMEs or Lead/Principal HCS, to prevent forgetting important details. This record will support weekly team meetings for reporting progress and adjusting timelines as needed.
- 2.6. A review at the end of the year will be conducted for all literature reviews to reevaluate and adjust the estimated timelines (sheet template) as necessary.
- 2.7. The boxes of 'reality time' (reality days and reality hours) spent on a task may deviate from the estimated whether shorter or longer. This will be automatically highlighted in green or orange, allowing the HCS team to review estimated times for future projects. A comment should be added in the same line as the task, under the column 'Notes', to detail the reason, such as annual leave, illness, prioritising other work, a high number of meetings, additional hours dedicated to the review.
- 2.8. The estimated times assume a maximum of 5 hours per day to the literature review, within a 7.5-hour workday. If a reviewer works additional hours in a day due to a compressed workweek, the expected daily hours dedicated to the review should increase accordingly.
- 2.9. In the sheet, three columns are editable. A description and required input for these can be found below.

Table 2.1 – Column description and input required in the Literature Review Timeline file

Column	Description	Required Input
Reality Days	This column automatically calculates the days spent on a task based on the entered Start Date and End Date.	None
Reality Hours	This column is for the number of consecutive hours worked on a task. For example, working 2.5hrs one week and 2.5hrs the following week would be 5hrs worked on the task.	xx Hours
Start Date	Use this column to insert the date you started the task.	DD/ MM/ YYYY
End Date	Use this column to insert the date you finished the task. Note: The Start and End date are used to document an accurate picture of when you start and finish a task and allow to see how much time we can assign for reviews and how much time we work on other projects. For example, the task of 'Grey Literature Search' is an estimated 5 days (25hrs) but if we start this on 01/02/24 and finish	DD/ MM/ YYYY

Column	Description	Required Input
	on 01/05/24 we can see either we have done other tasks in-between times or we have been working on other projects. It allows us to see if we have different workloads during different months in the year.	
Notes	Use this column if you want to provide notes on the task	Free text

Document Control

- 2.10. This SOP adheres to the NSS document version control and naming conventions.
- 2.11. When naming files, the year or date, if relevant for final documents, should be indicated first, followed by the title of the review and the document type (e.g., [YEAR] Fire Suppression SR Report V01.0 (Final) or Fire Suppression SR Review Tool V00.1 (Draft)).
- 2.12. The version number of a document in draft format will always begin at V00.1 (Draft), indicating its draft status. Version V00.2 (Draft) will reflect the second version of the draft, V00.3 (Draft) the third version, and so forth.
- 2.13. Revisions made by the Lead Author and Supporting Author should always be kept under the same draft version. For version control purposes, these are treated as contributions from a single author. However, when amendments are needed based on suggestions from the Lead/ Principal HCS, SMEs, Commissioner, Consultation Groups, these changes prompt the creation of a new draft version.
- 2.14. The Lead Author is responsible for keeping the 'Revision History' table of the 'Document Control Sheet' updated, including amendments made to each draft based on feedback from the Lead/Principal HCS, SMEs, Commissioner, and Consultation groups, clearly indicating the required changes.
- 2.15. Note: All draft reviews must be performed using tracked changes. When the document undergoes review by the Lead/ Principal HCS or SMEs, the version with tracked changes is kept as the original draft version this is the version sent to them. If amendments are necessary, a new document is created under the subsequent draft version number to address these changes.
- 2.16. Every document, when first published (formally approved), will be assigned version V01.0 (Final). After an unscheduled review or minor amendment, the version will be updated to V01.1 (Final). In the case of a scheduled review such as updating the literature review or a major revision, the document will first be labelled V01.1 (Draft) and, once completed and approved, will become V02.0 (Final). Amendments to previous versions, whether draft or final, should be recorded in the 'Revision History' table of the 'Document Control Sheet'.

- 2.17. Under no circumstances should a version number be missed or re-used.
- 2.18. Tables 2.2 and 2.3 clarify the version numbering system and provide an example of how to report the Revision History of the Document Control Sheet, respectively.

Table 2.2 – Version numbering system

Version	Document state	Example Document Name	
V00.1 (Draft)	First draft	Mass Timber Protocol V00.1 (Final).docx	
V00.2 (Draft)	Second Draft - subsequent drafts will employ sequential numbers after the decimal point (V00.3, V00.4, etc)	Mass Timber Protocol V00.2 (Final).docx	
V01.0 (Final)	Published version	Mass Timber Protocol V01.0 (Final).docx	
V01.1 (Draft)	Revision - Draft. Subsequent drafts will employ sequential numbers after the decimal point (V01.2, V01.3, etc.)	Mass Timber Protocol V01.1 (Draft).docx	
V01.1 (Final)	Approved the revision with no substantive change to content or procedure – It changes from Draft to Final despites the version number remains to V01.1.	Mass Timber Protocol V01.1 (Final).docx	
V02.0 (Final)	Approved the revision with mayor changes – It became a new version. Subsequent major revisions will use sequential numbering before the decimal point (V03.0, V04.0)	Mass Timber Protocol V02.0 (Final).docx	

Table 2.3 – Example of reporting the Revision History of the Document Control Sheet.

VERSION	DATE	SUMMARY OF CHANGES	NAME
V00.1 (Draft)	20 05 2024	Initial draft completed.	Michael Sheers (Lead Author) & Mario Sogabe (Supporting Author)

VERSION	DATE	SUMMARY OF CHANGES	NAME
V00.2 (Draft)	23 05 2024	Update search terms as suggested by the Principal HCS.	Michael Sheers (Lead Author)
V00.3 (Draft)	27 05 2024	Made minor changes related to formatting and typographical corrections based on SME feedback. Document finalised for approval for consultation stage.	Michael Sheers (Lead Author)
V01.0 (Final)		Revised review question based on consultation feedback. Finalised the document for publication.	Michael Sheers (Lead Author)

Record Keeping

Folder Structure

- 2.19. The Lead Author is responsible for creating the following folder structure for the literature review:
 - Administration
 - Correspondence
 - Documents
 - EndNote
 - Project Stage
 - Protocol
 - SME Documents
 - Search
 - Database export
 - Screen, Extraction, Appraisal
 - References
 - Exclude
 - Include
 - o Write up

Correspondence

2.20. For the literature reviews, it is necessary to retain certain correspondence with SMEs and the consultations. The specific correspondence that must be kept will be outlined in the relevant section of this SOP.

2.21. When saving the correspondence, the titles should always include the date, followed by the name of the correspondent, along with the subject description. When using personal names in file titles, list the surname in capitals, followed by the first name in title case (e.g., BLOGGS Joe). For example:

2023-09-04 BLOGGS Joe to HCS Technical Team - Report Sing-off.

Standardised Templates and Forms

2.22. To facilitate the review process, standardised template emails have been produced and are available at <u>Literature Review Templates</u>. These templates can be modified as needed and may be used solely for reference. The files are 'locked' from editing, meaning they must be copied to a new location before any changes can be made

3. Review Process

(Add diagram with the main stages of the process here)



4. Review Initiation

Issue Gathering Information Form

- 4.1. The Lead Author allocated to the review is responsible for sending the <u>'Information</u>

 <u>Gathering Form'</u> to the Commissioner or SME allocated to the review. The information provided in this form will be used to conduct a preliminary search and develop the protocol.
- 4.2. There is a two-week timeframe for the Commissioner to complete the 'Information Gathering Form'. If it is not received by then, a follow-up email should be issued.
- 4.3. Once received, the Lead Author should acknowledge its receipt and arrange an initiation meeting for further discussion using the 'Initiation Meeting Invite' email template.
- 4.4. Note: When a new review falls outside the Annual Work Plan, it is the responsibility of the Lead/ Principal HCS to register the review in the NHSS Assure Commissioning System.

Initiation Meeting

Before the Meeting

- 4.5. This meeting should be arranged for the earliest date the SMEs have availability. It should be attended by the Commissioner/ SME involved in the review, the Supporting Author, and if available, the Lead/ Principal HCS.
- 4.6. Before the meeting, the Lead Author and, ideally, the Supporting Author should begin familiarising themselves with the topic based on the completed 'Information Gathering Form'. This can be achieved through an initial search, which should be broad and informal, using platforms such as the knowledge Network, Web of Science, Google/ Google Scholar, and/or any sources provided by the Commissioner/ SME. Gaining this background knowledge will enable any clarifying questions to be addressed during the meeting.

During the Meeting

- 4.7. The Lead Author is responsible for facilitating the initiation meeting.
- 4.8. In this meeting, the following should be addressed:
 - The authors should gain a clear understanding of the ask and the scope of the review.
 - Emphasise the importance of SME input and timely contributions to ensure the review is delivered within the agreed timescales and meets high-quality standards.
 - Agree on update meetings, aiming for every two weeks, with the flexibility for this to change throughout the review.
 - Outline the SME responsibility to introduce the HCS team to the consultation group.

- Inquire whether any member of the consultation group has affiliations outside of NHS/UK Government bodies, such as universities or private consulting firms. If so, a conflict-of-interest form should be sent, signed, and returned, declaring any potential conflicts.
- 4.9. Note: While the primary purpose of the initial search is for the authors to familiarise themselves with the topic, it may occasionally reveal limited evidence. If this occurs, it should be brought to the attention of the Commissioner/SME during this meeting, and discussions should take place on whether the review scope or suggested questions need adjustment. If it is decided that the review scope will remain unchanged, a follow-up

of the available evidence and ensure that the decision to whether proceed or not with the review is based on a comprehensive assessment.

Follow up the Meeting

- 4.10. After the meeting, the Lead Author should proceed with the following:
 - Send a follow up email to the SMEs using the 'Initiation Meeting Follow-up template, including the meeting notes, next steps, and reiterating the importance of introducing the HCS team to the consultation group. If required, a link to the Conflict-of-Interest form should be provided. The signed forms should be saved in the folder [ReviewName]>Administration> Correspondence.
 - Set up a recurring meeting for updates at the agreed times.
 - Email the Research Service Review Management Team with the following information related to the review: Review name, Review type (systematic, scoping or rapid review), Lead Author and Supporting Author(s) names, SME(s) involved, consultation group, and project start date.

5. Protocol Development

Preliminary Search

- 5.1. A preliminary search should be conducted to support drafting the protocol. Unlike the initial search, this search is more systematic and focused, building on the initial findings but with greater rigor.
- 5.2. The Lead Author is responsible for conducting the search using broad terms, including those listed in the 'Information Gathering Form' and identified during the initial search. General databases such as Scopus (Core Collection), Web of Science, and other topic-specific databases should be used. A list of recommended databases can be found in Section 10 of the SOP Literature Review Protocol.

- 5.3. The number and types of relevant reports identified should be recorded. Titles and abstracts should be skimmed to identify key themes, methodologies, and gaps in the literature. This information will be also essential for refining the review questions and inclusion/ exclusion criteria.
- 5.4. Common keywords and subject headings that are identified during this search should be noted and included in the search terms table of the Protocol (Section 12).
- 5.5. The Lead Author is responsible for checking the repository platforms for literature reviews such as PROSPERO and Open Science Framework to confirm whether the review has been or it is currently being conducted. This step is important for avoiding duplication of efforts and ensuring the originality of the review. Similar reviews should be noted to refer back to.
- 5.6. At the end of the search, the Lead Author should be able to:
 - confirm whether there is enough relevant evidence to support a systematic review or scoping review;
 - decide whether to proceed with the review based on a more detailed understanding of the existing evidence; and,
 - provided an informed estimate of the required resources and timescale for completing the review.

Completion of Protocol

- 5.7. The Lead Author is responsible for drafting the protocol using the Protocol Template and adhering to the SOP for protocol development. The Supporting Author is expected to provide some input or, at a minimum, review the document.
- 5.8. For updates to existing literature reviews, the author(s) should review the existing question set and 'Implications for Further Research' section to determine if amendments are required. The author(s) should re-assess the existing search strategy to ensure it aligns with the review questions. If any significant amendments are required, then it should be taken to the Lead/ Principal HCS for a decision on whether a new review is more appropriate.
- 5.9. The search should be limited to the date since the last update.
- 5.10. Once the protocol is produced and both authors are content with it, it should be sent to the Lead/ Principal HCS for a sense check with the 'Track Changes' feature enabled. If they are unavailable, an Advanced HCS can perform this task. The Lead Author should incorporate and respond to any comments provided. If amendments are required, a new draft version of the protocol should be produced.

- 5.11. The draft protocol will then be emailed to the SMEs for their feedback, also with the 'Track Changes' feature enabled. The 'Protocol for SME feedback' template should be used to write the email.
- 5.12. The SME has six working days to provide their feedback. The Lead Author is responsible for integrating this feedback into a new draft version of the protocol.
- 5.13. A meeting needs to be organised to discuss the feedback with the SMEs or it can be addressed during one of the recurring meetings with extended duration. When possible, the updated version of the protocol, with the amendments incorporated, should be emailed to the SME a few days prior the meeting. The body of the email should outline the amendments and highlight any potential discussion points to cover in the meeting.
- 5.14. After the meeting, once all the amendments have been addressed, the Lead Author should send the 'Protocol approval for consultation' email to the SME. The email should outline the changes made to the protocol based on the meeting discussion and seek the SME's approval before proceeding to the consultation stage. If the Commissioner is different from the appointed SME, the Commissioner should be cc'd in the email. The SME has five working days to complete this task.
- 5.15. Note: At this stage, an estimate for the completion of the review can be provided. However, a more accurate timeline can be established following the second screening, once the volume of reports requiring critical appraisal and data extraction is known. The file '[Year-Year] HCS Tech Review Timeline' can be used to support the development of these timescale estimates.

Protocol Consultation

- 5.16. The Lead Author is responsible for drafting an Evaluation Tool for the consultation.
- 5.17. Only for consultation purposes, a new document should be created, including the following sections from the protocol: review background and aim, review questions, search terms, and inclusion/exclusion criteria. The document should be named '[Review Name] Protocol Consultation' and saved in the folder: [ReviewName]>Project Stage>Protocol.
- 5.18. This document, along with the Evaluation Tool, should be sent to the Information Officer to
 - Consultation Group using the 'Protocol Consultation' email template. There is two-week consultation period.
- 5.19. Reminders should be sent one week and two days before the deadline. It is important to adjust the consultation timeline accordingly if it coincides with holiday periods, and in agreement with the SME and Lead/ Principal HCS.
- 5.20. Following consultation, the Lead Author should compile any comments received using the 'RN Consultation' template and name the document 'RN Comments and Responses Protocol Consultation'. Discuss the comments with the SMEs and draft responses together.

- 5.21. If amendments to the protocol are agreed upon, the draft version must be updated, and the amendments should be recorded in the 'Summary of Changes' section of the 'Document Control Sheet.'
- 5.22. The 'Final Protocol Approval' email template should be used to obtain final sign-off of the protocol by the allocated SME, given them five days deadline for their response. If the Commissioner is different from the appointed SME, the Commissioner should be cc'd in the email.
- 5.23. Once approval is received, the draft version of the protocol becomes the final version (e.g. V01.0 (Final)).
- 5.24. The 'RN Comments and Responses Protocol Consultation' document, along with the final version of the protocol, should be sent the consultation group members. These document and all related consultation correspondence are saved in the review folder titled [Review Name]>Administration>Correspondence.

Deviations from Protocol

- 5.25. Deviations from the protocol during the screening and data extraction phases can be expected. However, for systematic literature reviews, significant changes are not allowed. If significant changes are necessary, a new version of the protocol must be produced.
- 5.26. Permissible changes in systematic literature reviews include adjustments to data extraction and synthesis processes, or changes to the reviewers involved in the literature review, but not substantial alterations to any elements of the review question. If there is any uncertainty, this should be consulted with the Lead/Principal HCS.
- 5.27. Amendments to the protocol need to be communicated and agreed upon with SME. An email should be sent clearly outlining the amendments made to the protocol, providing justification for each change, and requesting their confirmation of agreement with these alterations. This email should be stored with approval in the folder [Review Name]>Administration>Correspondence.
- 5.28. All amendments should be made on the initial version of the protocol, using tracked changes without accepting them. Once the amendments are completed, this version (e.g., are then accepted.
- 5.29. When making amendments to the approved protocol version, if the changes are minor, it should be renamed to V01.1 (Final). For significant changes, a new version (V02.0 Final) should be produced. Regardless of the extent of modifications, the approval details must be updated in the 'Document Control Sheet'.
- 5.30. Additionally, the Revision History must be updated, including a detailed summary of all amendments from the previous approved version of the protocol. In the final report, any amendments to the protocol should be clearly indicated in the first part of the methods

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section. If the protocol has been registered in a platform (refer to section X), this should be also amended.

Protocol Registration

- 5.31. After approval of the search strategy, the protocol must be registered in an open-access repository for literature reviews. Registration must be completed before initiating the search.
- 5.32. For systematic and rapid literature reviews not involving human subjects, as well as scoping reviews, the protocol should be registered in the Open Science Framework (OSF). The 'Generalised Systematic Review' OSF template must be completed, and guidance can be found at https://help.osf.io/article/229-select-a-registration-template.
- 5.33. For systematic and rapid reviews involving human subjects, the protocol must be registered in Prospero. All documentation related to Prospero registration is available at PROSPERO (york.ac.uk)

6. Search

Search Strategy

- 6.1. The Lead Author should develop a search strategy using the search terms indicated in the protocol and for each database specified.
- 6.2. The databases are accessible through the Knowledge Network. If a database is not available, the Librarian at Public Health Scotland (PHS)² can assist in developing and running the search strategy.
- 6.3. Before start working on the search strategy, the Lead Author should contact the Librarian at PHS to confirm their availability to assist in reviewing and/ or formulating the search strategies.
- 6.4. In some instances, the Lead Author can create a search strategy for one database and the Librarian can adapt it to the other databases specified in the protocol. However, this should be done in consultation with the Librarian to ensure they have the resources. If resources are available, the Lead Author can create a search strategy for one database and send it to the Librarian, who will review and adapt it to the other databases. Should this not be feasible, the Lead Author is responsible for formulating the search strategies for all databases and sending them to the Librarian for review.

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² phs.knowledge@phs.scot

- 6.5. When sending the search strategy to the Librarian, only the review questions, inclusion/exclusion criteria, and the list of search terms should be provided, rather than all the details from the protocol.
- 6.6. When developing the search strategy, consistency in the application of search terms across all databases should be ensured. A guide on creating search strategies for various databases is provided in the document X.
- 6.7. Either the Lead Author or Supporting Author can develop the search strategies for the grey literature.
- 6.8. All search strategies should be documented in one Word document using the '2024 Search Strategy Template.docx'. This document should be titled '[Year] [Review Name] Search Strategy' and saved in the folder '[Review Name]> Project Stage>Search
- 6.9. The developed search strategy(ies) should be shared with the Supporting Author for feedback and subsequent review by the Lead/ Principal HCS before being forwarded to the Librarian. The Lead Author is expected to integrate any necessary feedback.
- 6.10. The initial draft shared with the Lead/ Principal HCS should be the first version draft. If amendments are necessary, this should be updated to version draft 2. Following this, the search strategies should be sent to the Librarian.
- 6.11. If any questions related to Librarian feedback, then they should be contacted for clarification.
- 6.12. The Search Strategies Document from the Librarian should be kept for our records in the folder' [Review Name] > Project Stage > Search. Thid document should be named '[Date] [Review Name] Search Strategy Librarian Peer-Reviewed'.
- 6.13. The Lead Author should incorporate the Librarian's feedback in the document '[Year] [Review Name] Search Strategy' and report a summary of the amendments to the search strategies developed by the librarian in the 'Revision History' table.
- 6.14. The Lead/Principal HCS must sign off the final version of the Search Strategy.

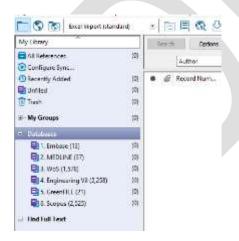
Running the Search

- 6.15. Either the Lead Author or Supporting Author can search the databases. When there is not access to a database, the Librarian may be able to run the search.
- 6.16. When the search is run in a database, all the results should be exported using the format 'EndNote' and the completed reference.
- 6.17. When exporting the search from the database, the file should be saved in the folder '[ProjectName]>Project Stage>Search>Database export'. The file name should follow the format: Date Executed (YYYY-MM-DD) [ProjectName], [Database] (such as, '2024-01-31

- Mass Timber, Scopus'). Some databases only allowed a certain number of records to be saved, in this instance the files must be numbered sequentially when saving.
- 6.18. A copy of the searches, with the number of hits associated with each search line and the links to the search, should also be exported to Word for record-keeping using the file created earlier '[Year] [Review Name] Search Strategy'. This should include the date executed, entire search, link to access the search on each database, the recording of results and limits placed on the search.

Import Database Searches to EndNote

- 6.19. Once the searches are conducted, the Lead Author is responsible for exporting the search results to EndNote. To do this, a new EndNote Library should first be created for the specific review, using the EndNote template located in the 'Template' folder. Name the file '[ProjectName] EndNote Library' (e.g., Mass Timber EndNote Library) and save it to the folder [ProjectName]>Endnote.
- 6.20. Note: When working on multiple reviews, it should always be ensured that the correct EndNote library is open so that files are imported into the appropriate library.
- 6.21. Before importing any files, a name for each database searched (e.g., Embase, Scopus) should be created under 'Databases'. A number can be added after the database name to indicate the number of references obtained from that specific database. For example, Medline (37), where 37 represents the number of references from that database before deduplication. This information will be used to complete the PRISMA flow diagram. Although this number will also be recorded in the '[ProjectName] Search Strategy' document, it serves as an additional check to ensure the numbers are accurate.



6.22. Each search should be imported one at a time, starting with high-quality sources such as Ovid Databases. This is because EndNote, by default, sends the most recently added records identified as duplicates to the 'Trash', retaining those added first. The preferred order of databases, which can be adjusted as necessary, begins with Ovid databases such

- as MEDLINE, followed by other reputable sources like CINAHL, Web of Science, and Scopus.
- 6.23. When a search is imported, it will always appear in the 'Imported References' folder. All records should be selected (press Ctrl + A) and moved to their associated folder e.g., if the search imported is from Scopus, move the records into the Scopus folder. Add the number of references to the name of the group, such as Scopus (56).

Deduplicate in EndNote

6.24. After all searches have been imported into EndNote, deduplication should be performed, beginning with automatic deduplication followed by a manual check. Any duplicate records that are missed during this process can be identified during the screening stage.

Automatic Deduplication

- 6.25. To perform automatic deduplication in EndNote, the following steps should be followed:
 - First, go to 'Edit > Preferences'. In the dialogue box, select 'Duplicates' from the left-hand menu. For the first deduplication, ensure the boxes for 'author', 'year', 'title', 'journal', 'volume', 'issue', and 'pages' are ticked.
 - To proceed with deduplication, make sure 'All References' are displayed on the EndNote screen. Go to 'Library > Find Duplicates'. Instead of reviewing each duplicate individually, close the 'Find Duplicates' dialogue box. This action will automatically highlight all duplicates in grey. Then press 'Delete' or right-click and choose 'Move references to Trash'.
 - To ensure all duplicates are removed, perform the deduplication process multiple times using various combinations of reference fields. To do this, navigate again to 'Edit > Preferences'. In the dialogue box, select 'Duplicates' from left hand menu. Try using different combinations at the time to ensure thorough deduplication. For example: 'author, year and title'; 'author and title'; 'title and year'. When using these combinations, review each duplicate individually instead of selecting all. This will prevent accidentally deleting non-duplicate references. When all duplicates are highlighted, if a reference is identified that is not a duplicate, hold down the control key and click to unhighlight it while keeping the others highlighted. Delete all duplicate references or move them manually to the trash.
- 6.26. *Note:* Even when records are deleted, the reference numbers (ID) remain unchanged, as they are unique to each reference, whether deleted or not. However, the number of results in each database group may no longer match the original numbers.

Manual Deduplication

6.27. EndNote's automatic deduplication relies on references having similar fields, including consistent formatting and capitalisation. Variations in data entry, such as differences in author names or journal titles, can cause duplicates to be missed during automatic

deduplication. To ensure all duplicates are removed, a manual check should be performed by reviewing the entire reference list. Ensure that "All References" is selected and the list is organised alphabetically by title or author. When a duplicate is identified, the reference with the higher record number should be deleted.

- 6.28. At this stage, the total number of deduplicated references those in the Trash folder should be recorded and entered in the PRISMA diagram under 'Duplicate records removed'. Additionally, the remaining references after deduplication should be noted under 'Records screened'.
- 6.29. When reviewing the list of references, some records may be missing the title, abstract, or publication year. In such cases, the original source can be accessed via the URL link, and the missing details should be manually copied and pasted by selecting the 'edit' option in the record. For editorials, commentaries, or similar types that often lack abstracts, a comment such as 'editorial letter' or 'commentary' should be added in the abstract field.

Export from EndNote to Excel

6.30. Following deduplication, references from EndNote should be exported to an Excel spreadsheet.

Steps for First-Time EndNote Users

- 6.31. When using EndNote for the first time, the Output Style 'Excel Import (standard)' needs to be added, located in the 'Template' folder. Double-click the file, and it will automatically open in EndNote. Once open, go to 'File' and select 'Save As'. Remove the word 'copy' from the file name and click 'Save'. Then, go to 'File' again and select 'Close Style'. The style will now be added to your EndNote styles.
- 6.32. Additionally, the 'Excel Import (standard)' needs to be included in the 'Output Styles' list. To do this, navigate to 'Tools > Output Styles > Open Style Manager'. Find 'Excel Import (standard)', tick the box, and close the window. This style should now be listed in the 'Output Styles'. This process can be repeated for any other output style wished to be added. For example, when preparing a publication for a specific journal, the referencing style used by the journal can be located in the 'Style Manager' (located under 'Output Styles') or added manually. Having these 'Output Styles' are important for integrating references into the final report or journal article.

Useful to Know

How to Modify 'Excel Import (standard)'

The 'Excel Import (standard)' style is designed to export Record Number, Journal, Author(s), Publication Year, Title and Abstract (in that order) from EndNote.

If additional categories are required – such as in a scoping review where more detailed data is

the time of the request. This discussion is essential because the Excel Review Tool, covered in the next section, is currently set up to import only six columns (categories). If more or fewer than six impact the formulas.

If the request can be accommodated, the following steps should be followed: Navigate to 'Tools >

field from the list. A tab needs to be included between fields. Select 'Insert Field' > 'Tab' to include a tab. To save the new output style, go to 'File > Save As' and name it 'Excel Import ([additions made])'. This template should be added to '**Template**' folder, so it is accessible for future reviews that require similar extractions.

Steps for Exporting EndNote Results to an Excel Spreadsheet

- 6.33. To export EndNote results to Excel, it is important to ensure that 'Excel Import (standard)' is selected in the 'Output style'.
- 6.34. To begin the export, first save the EndNote file as a copy, naming it '[ReviewName] EndNote Library Copy', and store it in the same folder. Once this is done, close the original EndNote file and open the copy.
- 6.35. In the copy, navigate to 'Library > Find and Replace'. In the dialog box, change 'select a field' to 'any field' and change 'insert special' to 'carriage return'. In the 'replace with' box, type '//'. Click 'change' and then 'OK'.
- 6.36. Next, under 'Edit', select 'Select All', then navigate to 'Tools' > 'Output Styles' and choose 'Excel Import (standard)'. Afterward, go to 'File' > 'Export' and click 'Save'. The file will be saved with the .txt extension in the folder [ReviewName]>Endnote and should be named '[ReviewName] EndNote Library Copy.txt'.
- 6.37. This file should now be opened in Excel. To do this, open up Excel and select 'Open'.

 Browse to the EndNote project folder and select the file. To be able to see it, ensure that 'All Files' is selected.
- 6.38. The Import Wizard will then open; click 'Next' twice and then 'Finish'. This will populate the columns. The file should be saved as '[ReviewName] EndNote to Excel' and saved to the folder [ReviewName]>Endnote. Ensure the file is saved with the extension .xlsx.

7. Study Selection

Review Tool

- 7.1. For each new literature review, an Excel Review Tool needs to be created. A template is available at <u>Literature Review Templates</u> named '2024 <u>xlsm</u>. The template should be opened and saved as a copy to the folder [ReviewName]>Review Stage>Screen, Extraction, Appraisal, with the name '[YEAR] [ReviewName] Review Tool'. Macros should be enabled in the file when first opened, if prompted.
- 7.2. The Excel Review Tool contains several sheets, each of which will be explained in the following sections. The '1. Database Screening' sheet includes various column filters to support the automated screening process. If any issues arise when using these filters, assistance from the team should be sought. If the team is unavailable, the process may be completed manually.

Copying Data Imported to Excel to the Review Tool

- 7.3. The .xlsx. file saved with the data imported from EndNote to Excel ('[ReviewName] EndNote to Excel') should be copied into the new project Review Tool. To do this the following steps should be followed:
 - Open the file '[ReviewName] EndNote to Excel'.
 - Click on cell A1 to place the cursor there, then press 'Ctrl + A' to highlight all the cells with data.
 - Once highlighted, press 'Ctrl + C' to copy the data.
 - Open the '[ReviewName] Review Tool' and navigate to the '1. Database Screening' sheet.
 - Click on cell A3, then press 'Ctrl + Alt + V'. In the 'Paste Special' dialogue box, select 'Values' and click 'OK' or press Enter. This will paste the data while retaining the formatting.
 - If the formatting is not retained, select the text and use the 'Top Align', 'Left Align', and 'Wrap Text' options in the 'Alignment' section of the 'Home' ribbon to make the text visible. If any issues occur, use the backspace arrow or press 'Ctrl + Z' to undo and try again.

Screening

7.4. There are two screening stages: the first screening and the second screening. The initial screening of the records is based on their titles and abstracts. Those that pass this stage move on to the second screening, which involves a decision based on the full text.

- 7.5. *Note*: The '1. Database Screening' sheet of the Excel Review Tool is designed for literature reviews involving two authors. If the screening is only conducted by one reviewer, then the columns related to the second reviewer should be hidden. It is not advisable to delete the second reviewer and consensus columns because if resources become available the review could transition easily to a two-author review once it has commenced.
- 7.6. When the review is conducted by two authors, they should be blind to each other's decisions. This can be achieved by selecting either:
 - the purple button labelled '1st Reviewer', which will hide the 2nd author inputs and consensus columns; or,
 - the green button labelled '2nd Reviewer', which will hide the 1st author inputs and consensus columns.
- 7.7. Hiding columns can be also done manually by clicking on the letter(s) at the top of the column wanted to hide and pressing 'Ctrl + 0' (zero). This will hide all the selected columns at once. Hidden columns can be recognised by the appearance of a narrower gap or a double line where the column letters skip.
- 7.8. To unhide the 1st or 2nd Reviewer columns automatically, press the button labelled 'Clear Filters'. If an error occurs, make sure to click on a cell within the table starting from Cell A1. Clicking outside the table may cause the automation buttons to not recognise the table and thus be unable to perform the action. Unhiding columns can be also done manually.

Useful to Know

How to hide cells when working on the same Excel Review Tool simultaneously

At times, two authors might work on the same file simultaneously and need to apply some filters. To avoid affecting each other's views with filters and hidden cells, follow these steps:

- On the top ribbon, select 'View.'
- In the "sheet view" box that appears, choose 'Default,' then select the relevant view from the drop-down list: '1st Reviewer,' '2nd Reviewer,' or '3rd Reviewer.'
- To exit this view, switch back to 'Default.'

Note: This method prevents filters and hidden cells from impacting other reviewers' views. All cell edits, such as adding information, will still be visible in all views. These views are only set up in the sheet '1. Database Screening' and '2. Other Methods Screening'.

If you wish to bring someone's attention to a particular cell or highlight a potential error, you can right click that cell and select 'comment' and tag the person with the comment.

Identifying Duplicates During the Screening Stage

7.9. Even if deduplication was performed in EndNote, duplicates can sometimes still be identified during the screening stage.

- 7.10. For two reviewers, the approach to identifying duplicates should be as follows: the first instance of the duplicate should be screened as usual, marking it as 'Y', 'N', or 'U'. Subsequent duplicates (lower rows in Excel) should be marked as 'D'. This ensures both reviewers consistently identify the same record as a duplicate, resulting in 'DD'.
- 7.11. Occasionally, only one reviewer might identify the duplicate, resulting in combinations such as 'YD' or 'DY'. This discrepancy must be verified, and reviewer's entry must be changed to 'D'. Therefore, in the consensus column it will appear as 'DD'.
- 7.12. If duplicates are encountered, they must be deleted from both the EndNote Library and the Excel Review Tool. Ensure the PRISMA diagram, both 'Duplicate records removed' and 'Records screened', are updated accordingly.

First screening

- 7.13. The first screening of the records is based on their titles and abstracts. If conducted by two authors, each should record their decisions in the 1st screening column, using the following labels: Y (Pass screening/ Included), N (Fail screening/ Excluded), U (Unsure), and D (Duplicate).
- 7.14. A notes column is available for each reviewer to note any observations that might be helpful during the consensus meeting.
- 7.15. Once both reviewers have completed the first screening, the '1st Screening Consensus' column in the Excel spreadsheet will display all the results from the screening process:
 - Agreements are indicated in the consensus column as:
 - o 'YY' and 'NN': Both reviewers agree to include or exclude the record.
 - Disagreements are indicated in the consensus column as:
 - 'YN' or 'NY': One reviewer decides to include the record while the other decides to exclude it.
 - o 'YU', 'NU', 'UY': One reviewer is uncertain ('U') while the other provides a definitive answer (either 'Y' or 'N').
 - Uncertainty by both reviewers:
 - o This is indicated in the consensus column as 'UU'.
- 7.16. In the case of disagreement, the reviewers must make a final decision on whether to include or exclude the record. Once decided, the consensus should be updated to 'Y' or 'N'.
- 7.17. If the reviewers cannot reach a decision, "U" should be used to flag the record for review by a third party. Notes should be added to help the third party understand the disagreement. The "U" will then be replaced with 'Y*' or 'N*', indicating that the third party resolved the disagreement.

- 7.18. Uncertainty by both reviewers is considered as neither an agreement nor disagreement and it is indicated in the consensus column as 'UU'. In this case, a third reviewer will assess the record and provide a definitive decision. The 'UU' in the consensus column should then be replaced with 'Y**' or 'N**', indicating resolution by a third party following the uncertainty of both reviewers.
- 7.19. During the consensus meeting, each disagreement should be reviewed and changed to either pass (included) or fail (excluded) based on the consensus decision.
- 7.20. The automatised button (red thumbs down button) on top of the '1st Screening Consensus' column, automatically identifies all disagreements, 'UU' entries, and duplicates. To do it manually, scroll down the filter of the column '1st screening consensus' and tick all combinations, except 'YY' and 'NN'.
- 7.21. Once the process is finalised, there should only be the following combinations:
 - 'YY' and 'NN': indicates initial agreement.
 - 'Y' and 'N': Indicates agreement through consensus.
 - 'Y*', N*': Indicates third reviewer took a decision when the reviewers disagreed.
 - 'Y**', N**': Indicates third reviewer took a decision when the reviewers where both uncertain 'UU'.
 - 'DD': Duplicates
- 7.22. At the end of the first screening consensus, when pressing the button (red thumbs down button) nothing should appear. This indicates that all disagreements have been resolved. It is essential to maintain a clear record of all initial screening choices by each reviewer and consensus decisions. The results will be included in the final methods section of the report. Below is an example of the text to be included in the report:
 - 'During the initial screening, agreement was reached on 70% of the records, while 20% showed disagreement. Of these discrepancies, 18% were resolved through a consensus meeting between both reviewers, and 2% required a final decision from a third reviewer. In 10% of the records, both reviewers were uncertain, and the final decision was made by a third reviewer.'
- 7.23. To obtain the necessary results and calculations for the report without manual effort, go to the Review Tool sheet 'A. PRISMA Data', and click the 'Refresh all data' button to update the tables. The first two tables are dedicated to the 1st screening.
- 7.24. Include in the PRISMA flow diagram the number of records that pass the first screening.
- 7.25. Before moving on to the next stage, in the 1st screening consensus column, only the studies that passed the initial screening should be ticked ('YY,' 'Y,', 'Y*' and 'Y**').

Reports Retrieval

- 7.26. Retrieval of reports can be performed by either the Lead Author and/or the Supporting Author. The responsible person should not start the second screening process until all reports have been retrieved, except for those still awaited from the Library.
- 7.27. Reports can be accessed through resources like Google Scholar, the National Library of Scotland, or The Knowledge Network. For convenience, the Excel Review Tool includes a 'Google Scholar Search' column that provides links to the reports in Google Scholar. However, as this is an automated method that only searches by title, due diligence should be taken to ensure it is the correct report.
- 7.28. The browser extension LibKey Nomad can also be used to access all reports available through the Knowledge Network by accessing them directly through publisher websites or via search engines. Instructions on how to install this extension are provided in the link.
- 7.29. In the Excel spreadsheet's retrieval column, mark 'Y' if the report has been retrieved, or 'R' if the report has not been retrieved and needs to be requested.
- 7.30. For those reports that have been retrieved, download the pdf and save them within the folder [ReviewName]>Review Stage>Screen, Extraction, Appraisal>References. Name the record as follows:
 - For a single author, use the EndNote reference number, author's surname, and year (such as, Ref504 Nicol 2008).
 - For two authors, use both surnames and the year (such as, Ref21 Nicol and Kinloch 2020).
 - For more than two authors, use the first author's surname followed by 'et al.' and the year (such as, Ref123 Labajos et al. 2006).
- 7.31. If no pdf is available but a webpage is accessible, a pdf can be created by right clicking on the webpage and selecting print to pdf. The pdf should be saved using the naming indicated above. It is important to check that the website has been converted correctly to pdf.
- 7.32. All the reports that have not been retrieved should be requested from the library providing the full list at once. To produce this list automatically, go to 'A. PRISMA Data' sheet and press the orange button 'Refresh Data'. In the table labelled 'Record Retrieval', double click on the number cell next to the 'R'. This will open another sheet containing all the records that need to be retrieved. Keep only the first six columns (A-F) and delete the other columns, as they are not relevant for the Librarian.
- 7.33. If a report cannot be retrieved by the Librarian, mark it as 'N' in the retrieval column. For reports successfully retrieved by the Librarian, update the status to 'Y'. By the end of this stage, the cells in the retrieval column should only display 'Y' or 'N'.
- 7.34. In the PRISMA flow diagram, the number of studies that have not been retrieved should be indicated.

7.35. Before proceeding to the next stage, ensure that the 'Report Retrieval' column displays only the records that have been retrieved (marked as 'Y').

Second Screening

- 7.36. Decisions for the second screening should be made based on the full text. Each reviewer must document their decision in their respective 2nd screening column, using the same labels as in the 1st screening: Y (Pass screening/ Inclusion), N (Fail screening/ Exclusion), U (Unsure), and D (Duplicate).
- 7.37. When conducting the 2nd screening, when a record is excluded, a reason for exclusion needs to be provided. For the system to allow the reason to be entered in the cell, if this is the first time the exclusion reason is used, it must first be added to the 'Exclusion List' table in the 'A. List' sheet. This will then automatically appear in the drop-down list under each cell in the 'Exclusion' column. The filter 'Go to Exclusion List' will take directly to that sheet. Additionally, there is a 'Spell Check' button to check there are not spelling mistakes.
- 7.38. When conducting the second screening each reviewer should identify the type of study design. This will automatically appear in the drop-down list under each cell of the 'Study Design' column. If the study design does not appear in the dropdown list, this has to be brought to the attention of the HCS team for discussion.
- 7.39. From this point, the same stages as outlined in the first screening should be followed. For those reports that are excluded, there should be an agreement on the exclusion reason, if different between reviewers.
- 7.40. Reports that do not pass the second screening should be moved to the 'Exclude' folder, while those that pass should be moved to the 'Include' folder, located in the folder [ReviewName]>Review Stage>Screen, Extraction, Appraisal>References.
- 7.41. The 'A. PRISMA Data' sheet can be used to populate the PRISMA flow diagram with the number of records that were included and excluded after the 2nd screening and report the reason for exclusion.

Citation Search

- 7.42. Some reports may not be captured through database searches alone, making it important to conduct citation searches, both backward and forward.
- 7.43. **Backward citation** During the second screening, data extraction, or when reviewing available literature reviews related to the topic e.g. systematic, narrative, etc relevant citations that were not captured in the initial database search may be found.

To ensure these citations are not overlooked, first verify if the citation identified is already in the Excel Review Tool. If not, include the reference in the 'Other Methods Screening' tab. Under the 'Sources' column, select 'Citation Searching' from the dropdown list and indicate whether it is a peer-reviewed study, using yes or no under the column 'Studies'.

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Manually add the reference to the EndNote Library under the 'Citation Searching' group to allocate a reference ID.

Forward citation – Conduct a forward citation search for all the included reports. Tools like Google Scholar can facilitate this process. Quickly scan to identify relevant reports that were not retrieved through the initial database search. If these reports have not been already screened, follow the same process as above.

Additionally, include reports identified through grey literature searches in this tab. In this case, under the 'Source' column, indicate 'Grey literature searching'.

- 7.44. All the reports in this tab need to undergo a second screening:
 - For peer reviewed studies, the screening must be conducted by two reviewers, following the same process as database screening.
 - For grey literature, screening will be conducted by one review.
- 7.45. The reports that could not be retrieved should be requested from the Library.
- 7.46. Update the PRISMA flow diagram to reflect the number of reports identified through citation searches and grey literature. These are reported under 'Identification of studies via other methods'. Document the number of reports not retrieved, those assessed for eligibility, and those that did not pass the second screening (including reasons for exclusion). Add the number of reports included through 'other methods' to the database number.

Useful to know

EndNote Unique ID and Review Tool Integration

There are various ways to add references to EndNote, either manually or automatically. To add a reference, go to Google Scholar, Science Direct, or the publisher's website and click on the citation option for EndNote. Ensure the EndNote library for the correct project is open, then double-click the downloaded item or navigate to the 'Download Folder' on the PC. The reference will open in the currently open EndNote library, or if none is open, it will open the last saved one. A unique reference number will be allocated to this reference. Move the reference to the required group.

Grey Literature Search

- 7.47. If resources are limited, the librarian may conduct the grey literature search, provided they have the capacity.
- 7.48. The time spent on grey literature should be limited to a maximum of three to five working days, conducted by a single author, either the lead or Supporting Author, or both.
- 7.49. The grey literature search strategy should be documented in the Review Review Tool within the sheet titled 'A. Grey Literature Search'. The following has to be recorded: the name of the source (e.g., Google Scholar, 'CDC') or organisation if the search was conducted

directly, the date of the search, the search string (including the Boolean operators and exact terms), the URL (preferably linked to the search but the website page if not), the number of hits, relevant results, and any necessary notes should be recorded. If multiple searches using different terms are conducted for a specific database, each should be documented separately.

- 7.50. A review of the full-text report should be conducted at the time of searching grey literature. For studies that are not peer-reviewed (treated them as grey literature), the title and abstract should be reviewed, and if deemed relevant, the full text should be downloaded and recorded in the sheet '2. Other References Screening'.
- 7.51. References included in the review through grey literature search should be included to EndNote under the group 'Grey literature searching'.

8. Critical Appraisal

- 8.1. The Lead Author is responsible for conducting the critical appraisal of the included reports. The level of involvement of the Supporting Author depends on the type of review and the agreement at the initiation stage.
- 8.2. It is recommended to complete the critical appraisal before going into comprehensive data extraction. This approach ensures that reports with serious methodological concerns are identified early, preventing the unnecessary effort on data collection from reports that may not meet the inclusion criteria for methodological quality.
- 8.3. All reports, including empirical studies, expert opinion and grey literature, should be critically appraised for methodological quality/risk of bias by the Lead Author using the checklists and their respective guidance provided in the Critical Appraisal Checklists Document.
- 8.4. For mixed methods studies, the qualitative and quantitative parts are assessed and reported separately.
- 8.5. **Note:** Currently, there are no available checklists for assessing the methodological quality of experimental non-human studies. As a result, these studies cannot be evaluated for methodological quality. However, they must still undergo assessment using the two initial
 - were not assessed for methodological quality.
- 8.6. **Note**: When guidance documents are identified that may potentially answer the review question, or part of it, they should first be assessed using the AGREE tool. A full assessment is not always necessary; a quick review can provide an indication of quality. If the guidance appears to be of low quality at first glance, it should be immediately classified as grey literature. However, if the quality is unclear, a full assessment should be conducted. If the score is less than 60%, the guidance will be classified as grey literature and assessed using the AACODS checklist.

8.7. Mandatory or legislative documents are exempt from assessment.

MS Forms Setup

- 8.8. The critical appraisal process will be conducted using the MS Forms template accessible in the <u>Literature Review Templates</u> folder, named '2024 PN Critical Appraisal Checklists Template'. Alternatively, the orange button labelled 'Complete Critical Appraisal (CA)' in the '4. CA Tables' sheet of the Review Tool can be used to access the form.
- 8.9. The MS Forms template is a non-editable copy to prevent it from being overwritten. Therefore, once the template opens, the 'Duplicate it' button should be clicked. It is essential to be signed in to MS 365 to access MS Forms. The duplicated form is named 'Review Name Critical Appraisal Checklists (Copy).' The name should be changed to reflect the title of the review and removing '(Copy)'. Once changed, the address bar should be copied and assign the link to the button on 4.CA Appraisal Edit/View CA Response.
- 8.10. All forms are saved to the MS Forms Home page, accessible through MS 365 online. The newly created form should be assigned to 'HCS Tech' to ensure full accessibility for all team members. If the required form is not visible under 'Recent,' navigate to 'My forms.' Hover over the form, click the three dots and select 'Move to a group,' scroll down, choose 'HCS Tech,' and click 'Move.' If the form is being viewed under 'My forms,' it will disappear from the list and will now be located under 'My groups.' To find it, scroll down on the page to 'My groups' (it may be necessary to click 'show more') and select 'HCS Tech.' All forms associated with this group will be visible on this page.
- 8.11. A link to this new MS Form should be assigned in the Review Tool. To do this, click on the 'Collect Responses' button within the MS Form, then select 'Copy link.' In the '4. CA Tables' sheet, right-click on the orange button labelled 'Complete Critical Appraisal (CA),' select 'Edit link,' paste the new link into the 'Address' bar and click 'OK.' This action will override the current link. It is important to double-check that when clicking the 'Complete Critical Appraisal' button, it directs to the correct form for completing the CAs.
- 8.12. Once this is done, the 'Complete Critical Appraisal' button should be clicked to 'conduct the critical appraisal for each report that passed the second screening.
- 8.13. The MS Form contains all the checklists needed for conducting the CAs. The study design selected on the first page determines which checklist appears on the following page. If an error is made when selecting the checklist, it is possible to scroll to the bottom of the checklist and click 'Back' to select the correct checklist. It should be ensured that any questions already completed on the incorrect checklist are deleted by using the 'eraser' icon next to the question.
- 8.14. **Note:** Once a form is completed and submitted, the response cannot be edited. If an error is noticed after submission, the response associated with the specific report can either be deleted (i.e. the entire form) or edit the specific error once the response has been exported to Excel.

Critical Appraisal Procedure

- 8.15. At the start of the form, there are two screening questions. If the answer to either of these screening questions is 'No' or 'Unsure', the appraisal will conclude, and the report will be excluded. However, it is important that the relevant checklist is still selected. Do not answer the checklist questions; instead, scroll to the bottom (or press 'End' on the keyboard) and click 'Submit.' This procedure ensures that even though the report failed the screening questions, the study design is still documented.
- 8.16. Although currently experimental non-human related studies currently do not have a checklist, these studies must still go through the screening questions to minimise bias as much as possible. This process helps determine if the study should be excluded based on the screening criteria. Once the screening questions are answered, the survey will automatically conclude.
- 8.17. For expert opinion and grey literature, the screening questions might not apply. In this case, 'N/A' should be selected.
- 8.18. Responses to checklist questions should be marked as 'Y' for Yes, 'N' for No, 'U' for Unclear or Can't Tell, and 'N/A' for Not Applicable.
- 8.19. A comment box is provided at the end of each checklist for documenting justifications, flagging items that require further discussion, or seeking additional information from the study authors. It is important to include the checklist question number being referred to in this box to ensure clarity when reviewing the comments later.
- 8.20. After completing each checklist, it is essential to click 'Submit' to ensure the response is saved. If 'Submit' is not clicked, the next time the form is opened, it will display the last checklist that was worked on. In such cases, clicking 'Submit' at that stage will save the progress.
- 8.21. If there is uncertainty about how to answer certain questions or difficulty completing the critical appraisal, support should be sought from other HCSs.

View and Delete Responses

- 8.22. To view and delete the responses, the orange button 'Edit/View CA Responses' should be clicked, which will direct to the MS Forms responses.
- 8.23. To delete a response, click the 'Edit/View CA Responses' button, then select 'Responses', and 'View Results'. Use the arrows to navigate through the responses until the one to be deleted is found, click the three dots, and select 'Delete response.'
- 8.24. **Note:** If an error is noticed after the response have been exported to Excell, then the error could be corrected in Excel there is no need to delete the entire response.

Exporting Responses to Excel

- 8.25. Once the critical appraisals have been completed, the responses should be exported to excel. To do this:
 - Click the 'Edit/View CA Responses' button, then select 'Responses' and choose 'Open results in Excel.' This will open the results in an online Excel table, which is automatically created and saved to the general folder in HCS Tech. To move this file to the project folder, click on the name of the file.
 - [Review Name]_Critical Appraisal Checklists ① 💪 🗸
 - Then, click the dropdown arrow, and in the 'Location' box, select the right-facing arrow to browse to the folder [ProjectName]>Project Stage>Screen, Extraction, Appraisal.
 - Finally, click 'Move here' to relocate the file.
- 8.26. This Excel file will automatically update as new responses are received. Note that it may take some time for updates to appear if the file is opened immediately after submitting a response.

Importing Responses to the Review Tool

- 8.27. Once the responses have been exported into excel, the Lead Author should copy and paste the results from the Excel file generated by the form into the '4. CA Tables' sheet. To do this, either press Ctrl + A to select all the data or click on the first cell of the first entry and drag across until the end is reached. Once selected, copy the data and paste it directly into the Review Tool.
- 8.28. **Note**: The sheet 'CA Tables' in the review tool is automatically populated with the exact number of columns from the downloaded Form responses, which are the same number and location in every Form based on the template.
- 8.29. To help with visualising the data on this table any cells which are blank have been conditioned to remain a dark grey colour.

Quality Scoring and Report Categorisation Process

Quality Score

- 8.30. At this stage, a quality score for methodological quality risk will be assigned to each report that passed the screening questions. This process is conducted automatically (last two columns of the '4. CA Tables' sheet).
- 8.31. The quality score is calculated as follows:
 - Any questions in the checklist marked as 'N/A' (Not Applicable) are excluded from the total number of applicable questions that account toward the calculation.
 - Responses marked as 'Can't Tell' or 'Unclear' are treated as a 'No' answer.

- 8.32. For example, if a checklist has 10 questions and the report assesses 7 as 'Yes', 1 as 'Unclear', 1 as 'No', and 1 as N/A, then the final score is 78% (7 'Yes' answers out of 9 applicable questions).
- 8.33. **Note:** For experimental non-human studies, where a checklist is currently not available, the cells in the 'Quality Score' column will be marked as 'N/A'. Additionally, if a report does not pass the screening questions, the final score will be marked as 'N/A.

Methodological Quality Assessment

- 8.34. A methodological quality assessment is also automatically calculated in the 'Assessment Column' to be used for the next stage assessing confidence in the evidence. Based on the final score, reports will be categorised as follows:
 - Very minor methodological limitations/risk of bias: 76-100%
 - Minor methodological limitations/risk of bias: 51-75%
 - Moderate methodological limitations/risk of bias: 26-50%
 - Serious methodological limitations/risk of bias: 0-25%
- 8.35. **Note**: For experimental non-human studies, where no checklist is currently available, the cells in the 'Assessment' column will be marked as 'No assessment'.

When to Exclude a report due to Methodological Quality

- 8.36. As standard, studies with serious methodological limitations will be excluded from the review, and the PRISMA diagram should be updated accordingly, citing "serious methodological quality/risk of bias" as the reason for exclusion.
- 8.37. The same applies to reports that did not pass the screening questions. In this case, the exclusion reason should be "serious methodological quality/risk of bias didn't pass screening questions".
- 8.38. When a report is excluded from the review due to methodological quality:
 - Its assessment and final score must still be reported in the final tables produced for methodological quality/risk of bias assessments.
 - It should be indicated in the 'Results' section of the literature review report.
 - The references should be included in final table of excluded reports citing the reason "serious methodological quality/risk of bias" or "serious methodological quality/risk of bias – didn't pass screening questions".
- 8.39. At this stage, to facilitate referencing for the final report, the EndNote library for the review should be opened, and all the included reports should be added to the 'Included' folder.

Second reviewer conducting 30 % check

8.40. This section applies only to literature reviews requiring a 30% check.

- 8.41. The '30% Check' button has been set up to randomly assign reports for the supporting author to check, based on the total number of critical appraisals recorded. When clicking this button, the reports that need to be checked will appear with a 'Y' in the '30% Check' column, indicating that the supporting author must review these reports. If new critical appraisals are added, the button can be clicked again to ensure the 30% check covers all included studies. This will not change the already allocated.
- 8.42. When the supporting author completes the check of a CA, they should add a comment in the relevant cell stating 'Check completed' to indicate that the critical appraisal has been reviewed. If discrepancies are identified and further discussion with the Lead Author is required, this should be noted in the comment. The Lead Author should be tagged in the comment using @ followed by the Lead Author's name.
- 8.43. If the Lead Author disagrees with the comments, they should add their own comments and initiate further discussion. Once resolved, click 'Resolved' but the original comments should not be deleted, as they need to be kept for our records.
- 8.44. If any changes to the current responses are made, the cell should be shaded green.

Generating and Including Methodological Quality Assessment Tables

- 8.45. A table with the methodological quality assessments for each study design must be generated and included as an appendix in the final literature review report.
- 8.46. To do this, navigate to the '4. CA Tables' sheet. In cell L1 (highlighted in yellow), use the drop-down list to select the relevant study design. Once selected, the table will automatically filter to display only the rows and data related to that specific study design.
- 8.47. Templates for each study design have been created to streamline the process. These can be accessed in the document Appendix E: Critical Appraisal Assessment Tables Template. Copy the relevant study design templates into the literature review template for the final report.
- 8.48. To include the data in the table templates, copy the entries from the columns labelled 'Study Citation' to 'Quality Score.' Then, paste them directly into the final tables using the 'Use Destination Styles' paste option. To exclude the comments column, hold down Ctrl and click the mouse to deselect it.

9. Data Extraction

9.1. The Lead Author is responsible for extracting the data of all the included reports. The level of involvement of the Supporting Author depends on the type of review and the agreement at the initiation stage.

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- 9.2. Data needs to be extracted using the sheet named '3. Data extraction' of the Excel Review Tool. The Data Extraction table features predefined columns consistent across all literature reviews. To accommodate specific data requirements unique to a particular review, as outlined in the Protocol, additional columns may be added.
- 9.3. Pivot tables that summarise key data extracted from the "3. Data Extraction" sheet should be used. These tables are important for assisting in the writing of the results section of the final literature review report. The tables can be tailored for each review by selecting specific extraction categories.
- 9.4. For some pieces of evidence, certain columns may not be applicable; in such cases, 'NA' should be entered. If a specific item or data is not documented in the report, 'NR' (Not Reported) should be used.
- 9.5. If additional information or clarification is required from the authors during data collection, the authors should be contacted directly. A record of all correspondence with each study's authors must be maintained in the folder [ReviewName]>Administration>Correspondence.
- 9.6. Each report must be also assessed for relevance during the data extraction stage. A rating of directly, indirectly, partially, or unclearly relevant should be assigned to each report, accompanied by a brief explanation. Section X of the confidence level assessment should be consulted for further guidance on how to assess the 'Relevance' of a report.

Supporting Author Review

- 9.7. This section applies only to literature reviews requiring to be checked by the supporting author.
- 9.8. When the supporting author completes the check of a reference, a comment should be added in the ID cell stating 'Check completed' to indicate that the specific reference has been reviewed.
- 9.9. If discrepancies are identified and further discussion with the Lead Author is required, this should be noted in a comment within the relevant cell. The Lead Author should be tagged in the comment using @ followed by the Lead Author's name. If the Lead Author disagrees with the comments, additional comments should be added to initiate further discussion. Once resolved, click 'Resolved,' but the original comments should not be deleted, as they must be kept for records.
- 9.10. If any changes to the current responses are made, the cell should be shaded green.

Notification and Coordination with the Information Officer

9.11. At this stage, it is important to provide an estimate of the time required for completing the confidence assessments and the final write-up. The Information Officer should be contacted one month before the final review report is expected to be ready for consultation.

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10. Evidence Synthesis and Confidence Assessments

10.1. The Lead Author is responsible for conducting both the evidence synthesis and the confidence assessments for each finding. These should be carried out simultaneously for each finding. For new and less experienced HCSs, the confidence assessments should be done with support from a more experienced HCS.

Evidence Synthesis

- 10.2. The synthesis method must strictly adhere to what is stipulated in the protocol. Any deviations from this protocol must be formally amended in the final approved version of the protocol and documented accordingly.
- 10.3. When writing the synthesis, it is recommended to use introductory phrases such as:
 - "An observational study recommends/finds..."
 - "The findings from an observational study suggest..."
 - "This literature review identified two experimental studies..."
 - "Observational studies conducted in healthcare settings consistently observed..."
 - "The results of five observational studies suggest..."
 - "An experimental study conducted in a residential setting suggests that..."
 - "Contradictory evidence was observed by two studies..."
 - "WHO guidance recommends that..."
 - "Guidance from the HSE states..."

Confidence Assessments

- 10.4. Assessing the confidence in the evidence enables transparent assessment of how much confidence can be placed in the review findings from the syntheses of the literature reviews.
- 10.5. The methods for assessing the confidence in the evidence are often subjective and cannot be implemented mechanically. Thus, a degree of subjectivity is unavoidable in each decision. Two authors evaluating the same body of evidence might reasonably arrive at different conclusions regarding its confidence. Therefore, conducting this process through discussion with the review team and thoroughly documenting every decision is essential.
- 10.6. To conduct the assessments, the 'Confidence Assessment Table' template should be used and titled '[Review Name] Confidence Assessment Table'.

Approaches for Assessing the Confidence in the Evidence

- 10.7. The approach for assessing the confidence in the evidence for each finding will depend on the type of evidence included in the review. Therefore, for literature reviews that include:
 - a mix of different evidence sources such as qualitative, quantitative, grey literature, and expert opinion, the Confidence Assessment of Integrated Findings method developed by the HCS Technical Team should be used.
 - only qualitative evidence, use the criteria and guidelines provided by GRADE for qualitative reviews (GRADE-CERQual).
 - only of quantitative evidence and have the potential for meta-analysis, follow the GRADE guidelines for quantitative literature reviews.
 - only of quantitative evidence and does not have the potential for meta-analysis, follow the method developed by the HCS technical Team.

Confidence Assessments of Integrated Findings

- 10.8. The first step is to produce a summary for each finding. This summary should not include references, and it is based on the synthesis of that finding.
- 10.9. If there are contradictions within the evidence, these must be explicitly addressed in the finding summary and asses the contradiction under the criteria of coherence.
- 10.10. Once a summary has been produced, proceed with the assessment based on the following criteria (described in more detail in the following sections):
 - methodological limitations (reliability),
 - relevance,
 - adequacy,
 - coherence, and
 - publication bias.
- 10.11. Each criterion will be assessed as 'No or very minor concerns', 'Minor concern', 'Moderate concerns' and 'Serious concerns. All criteria have the same weight in the final assessment.
- 10.12. Note: Government policy, regulations, legislation, and mandatory standards that apply to Scotland are considered mandatory, and no confidence assessments should be conducted for this evidence. Similarly, guidance that has scored above 60% in the AGREE Tool should be assessed as high confidence.

Criteria 1: Methodological limitations (reliability)

- 10.13. Two primary factors determine the level of concern for this component:
 - Critical appraisal score: This refers to the score the report received based on its methodological quality or risk of bias assessment (refer to Section X).

 Study design: Study designs that are considered more rigours and have a lower susceptibility of bias have more weigh in this assessment. For example, high quality meta-analyses and randomised controlled trials (RCTs) carry more weight than quasiexperimental studies or expert opinion. Table 10.1 provides further guidance.

Table 10.1 - Levels of Evidence

- 1. High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
- 3. Meta analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
- 5. High quality case-control, cohort studies or controlled pre- and post-intervention studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is
- Well conducted case control, cohort studies and controlled pre- and post-intervention studies relationship is causal
- 7. Case control, cohort studies or controlled pre- and post-intervention studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
- 8. Non-analytic studies, e.g., case reports, case series, qualitative studies
- 9. Expert opinion
- 10.14. However, given the diversity of topics and evidence in our reviews including human and non-human subjects the weighting of different study designs should be adapted based on each review's specific context and needs. This flexibility allows to appropriately value the contributions of various types of studies to the topic.
 - In reviews combining qualitative and quantitative data, qualitative studies will not automatically be deemed less rigorous than RCT. Their relevance and weight will be assessed based on the context and nature of the research question.
 - In areas were conducting RCTs is not feasible, this limitation will be considered, potentially leading to re-evaluating the weight given to alternative study designs.
 - For non-human-related reviews, where RCTs are not applicable, emphasis will be placed on controlled laboratory and in situ experiments and in vitro and simulation studies, which may be considered more suitable and rigorous for those specific fields.
- 10.15. All decisions regarding the level of concern attributed to the reliability component must be explicitly documented and justified in the assessment table, including detailed explanations for deviations from standard study design hierarchies.
- 10.16. When completing the reliability component in the 'Confidence Assessment Table', include the number of reports for a specific study design followed by their methodological quality

scores. For qualitative study designs, indicate only "qualitative" without specifying the type of study design.

For example:

- 3 Qualitative (2 Moderate, 1 Serious)
- 1 Quasi-Experimental (Very Minor)
- 2 Controlled laboratory experiment (1 Minor, 1 Serious)
- 2 Guidance documents (grey literature)
- 3 Expert Opinion
- 10.17. Note: If a finding predominantly relies on grey literature or expert opinions, the level of concern for reliability should be classified as 'Moderate' or 'Serious'. This stance is due to the potential for biases and the non-peer-reviewed nature of these sources, which typically require more critical scrutiny to confirm their validity.

Criteria 2: Relevance

- 10.18. The relevance component examines how well each report's context, characteristics, and conditions align with those specified in the review question. Relevance ensures that the studies included do not just fit broad criteria (inclusion/ exclusion criteria) but are relevant to the specific questions and objectives of the review.
- 10.19. Note: It should not be mistaken relevance with the inclusion-exclusion criteria. For example, some reports might meet all inclusion criteria but only partially address the specific research questions or do so in a slightly different context. For example, in a literature review aiming to inform a decision on the use of mass timber for healthcare buildings, the lack of focused reports on healthcare may require including evidence related to buildings in other settings, such as universities and government facilities.
- 10.20. Each piece of evidence (i.e. empirical studies, expert opinion, grey literature) should have been assessed for relevance and be recorded in the Data Extraction Table of the Review Tool, along with a short explanation.
- 10.21. Relevance is rated as direct, indirect, partial, or unclear relevance.
 - **Direct relevance:** When the evidence of a report directly addresses the review question, providing specific evidence on the effectiveness, outcomes, or impacts of an intervention or phenomenon within the exact context or population specified.
 - Partial relevance: Part of the context of the review question (such as population subgroup, settings, so on) is addressed directly but where evidence is lacking for the complete context specified in the review question.
 - Indirectly relevance: In some instances, when the team is unable to identify reports
 that fully represent the context of the review, it can be decided to identify studies that
 correspond with some elements from the context of the review question but not with
 others.

• **Unclear Relevance:** Occurs when it is challenging to determine how well the report findings align with the review question due to missing or inadequately detailed information. The reports under consideration fail to report these details sufficiently.

10.22. Key aspects to consider for assessing relevance:

- **Population characteristics**: Evaluate whether the characteristics of the population in the evidence align with those specified in the review question.
- **Setting characteristics**: Assess how closely the setting of the report mirrors the context of the review question. For example, the setting and place could be considered in terms of physical location (such as urban vs. rural), type of study (such as laboratory setting vs in-situ within a hospital), type of institution (such as private vs. public), type of building (such as hospital vs. residential), characteristics of the facility (such as mental health vs geriatric vs general healthcare facilities), socioeconomic context (such as low income vs. high income), and so on.
- **Temporal characteristics:** Consider when the data were collected and any significant changes that might affect the relevance of the findings.
- Phenomenon of interest/intervention characteristics: Assess if characteristics of the intervention or phenomenon are clearly reported and relevant to the review question. A lack of reporting concerning the intervention/ phenomena of interest raises concerns regarding the study's relevance to the review question.

Examples:

Scenario Description	Review question elements/context	Assessment of Relevance
A literature review focusing on adult mental health facilities. The initial search yields studies that encompass a broad range of participants in the population samples, including geriatric patients, disabled individuals, children and adolescents, and adults.	The population in the review question is adult with mental health diagnosis. This means that studies primarily based in paediatric mental health and geriatric populations might not directly meet the criteria.	Direct Relevance: Studies conducted entirely within adult mental health facilities. These directly address the research question. Partial Relevance: Studies in mental healthcare facilities that include multiple types of populations in the study sample (such as, a mix of geriatric, children and adult with mental health diagnoses). These might provide valuable insights but are not fully aligned with the specific context of the review question which focused on adults. They might be used to support findings or to discuss broader implications.

	OOT Eliciature reviews	
A literature review on the benefits and challenges of using mass timber in healthcare facility construction	While primarily focused on healthcare settings, the review includes studies from other institutional buildings to draw broader architectural and structural insights.	Direct Relevance: A study examining air quality and patient recovery rates in mass timber-constructed healthcare facilities. Indirect Relevance: Research on the acoustic properties and energy efficiency of mass timber in educational facilities.
A literature review on the impact of mental health facility design on patient outcomes including studies dating back to the 1980s	The inclusion criteria is broad to capture the evolution of facility design from the 1980s to the present.	Partial Relevance: Studies from the 1980s provide foundational data on design elements but do not fully cover the modern advancements in mental health facility design and treatment protocols. These studies are included to understand historical perspectives and their evolution but do not address the modern context.

10.23. Concerns with relevance should be rated as:

- No or very minor concerns: The majority (or all) of the included reports directly address the review question. The reports collectively provide a strong alignment with the specified context, population, and intervention.
- Very minor: Some reports directly address the review question, while others only
 partially align. Collectively, the evidence covers most aspects of the question, but there
 may be some gaps.
- Moderate concerns: A few studies might directly address the review question, but the majority are only indirectly relevant. The context, population, or intervention is not wellrepresented in much of the evidence.
- Serious concerns: The majority of the evidence is unclear or only indirectly relevant to the review question. It is difficult to form a robust finding from the included studies because of a lack of relevant detail or context alignment.

Criteria 3: Adequacy

10.24. The adequacy criteria assesses whether the data is sufficient to robustly support the finding claim – i.e. does the data collectively (from one or several reports) cover the necessary breadth and depth required to fully understand and support the finding? To assess adequacy, both data richness/depth and data volume need to be assessed holistically.

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- 10.25. **Data richness/ depth:** This only applies to findings that include qualitative data and/or expert opinion/grey literature (excluding non-pee reviewed studies)
 - For qualitative data: Assess how deeply qualitative data explores participants' experiences, settings, contexts, etc.
 - For expert opinion/grey literature: Assess the extent of these reports contribute to a deeper understanding of the topic beyond what is available from empirical data.
- 10.26. Data volume: Consider the overall amount of data supporting the finding across all sources:
 - Number of studies
 - Number of observations
 - Sample size (only applies to quantitative data do the studies have an adequate sample size that can provide the statistical power necessary to detect a significant effect if one exists?)
 - Number of samples or experiments run
- 10.27. While there is no fixed rule about what constitutes a sufficient number of studies, sample size, number of samples or observations, it is likely to have less confidence in a review finding that is supported by data from only one or very few studies, participants or observations. This is because when only few studies or studies with small samples, we are less confident that studies undertaken in other settings or groups would have reported similar findings.

Criteria 4: Coherence

- 10.28. The coherence of a review finding is an assessment of how clear and cogent the fit is between the evidence/ data from the reports and the review finding.
- 10.29. Examples of coherence issues:
 - The summary of a finding might only describe the most dominant patterns in the data and does not sufficiently capture the presence of 'outliers' and/ or ambiguous elements in the data. By outlier, we refer to data that do not fit the dominant data patterns across the different reports forming the finding. For example, some contradictory data was omitted in the review finding more common in descriptive findings –, because review authors either wanted to highlight only the dominant patterns or addressed a specific policy or guideline question requiring a narrower response. In these cases, the evidence that is not well captured within the review finding may be considered a threat to coherence.
 - Key aspects of the underlying data may be vaguely defined or described. In these
 cases, the supporting data are not clearly or sufficiently described, and cannot always
 be sure that the data in fact clearly support the review finding. Elements of the
 underlying data may be defined in slightly different ways across different reports. In
 these cases, the data may appear reasonably comparable, but we are not sure if they
 are comparable.

• More interpretive or explanatory review findings are often more complex and include several aspects, e.g. descriptive data, ideas, concepts or relationships. We may have strong evidence from the underlying data for certain aspects of the review finding, but insufficient data to support other aspects of the interpretation or explanation. These gaps in the evidence for an interpretive or explanatory review finding are not contradictory data, but rather the absence of data in certain places. When the data provide this kind of incomplete support for a review finding, you may have concerns about the coherence of a finding.

10.30. Identifying and addressing coherence issues:

- During the review, if the authors find that the finding summary does not quite fit with all
 the data/evidence, they may need to revise the finding. This process checks if the
 summary has overly simplified the data or overstretched an explanation too far beyond
 what is supported by the data/evidence.
- The goal is not to achieve perfect coherence but to ensure there are no significant concerns about coherence that might reduce confidence in the findings.
- In some cases, findings with series coherence concerns may still be helpful if they
 highlight important considerations, even if they do not align perfectly with all the
 data/evidence.
- When assessing coherence, it may also be necessary to return to the primary studies or develop further coding if details necessary for assessing how well the data support a particular review finding were not initially captured in the data extraction table.
- 10.31. When there is clear and cogent support for a review finding across the underlying data, there should not be serious concerns about the coherence of the finding. Concerns about the coherence of the fit between a review finding and the underlying data may arise when patterns in the data are not well explored or explained, either by the review authors or the primary study authors.

Criteria 6: Publication bias assessment

- 10.32. Publication bias refers to the tendency for studies with positive or significant findings to be more likely to be published, while studies with negative or non-significant results are less likely to appear in the published literature. This can lead to a distorted or unbalanced view of the available evidence.
- 10.33. Key factors to assess for publication bias include:
 - Diversity of studies: If the finding is supported by only a few studies, particularly those
 published in high-impact journals, there is a greater risk that studies with non-significant
 or negative results are missing from the evidence base, skewing the conclusions. A
 larger and more diverse set of studies reduces the risk of publication bias.
 - Reporting patterns: Investigate whether there are discrepancies between the study protocols and published reports. For instance, if planned analyses or outcomes mentioned in study protocols are missing from the final publication, this could be a sign of publication bias.

- Grey literature inclusion: Studies found in grey literature (e.g., reports, theses, conference papers) may reduce the risk of publication bias since they are not influenced by the same pressures as peer-reviewed journals.
- Funnel plot analysis (if applicable): For meta-analyses, a funnel plot can be used to visually assess potential publication bias. A symmetrical funnel suggests no bias, while asymmetry may indicate its presence.
- 10.34. Concerns about publication bias should be rated as:
 - No or very minor concerns: The body of evidence includes a large number of studies from diverse sources, with no clear indication of missing or unreported data.
 - Minor concerns: The evidence base is relatively comprehensive, but some discrepancies in reporting or an absence of grey literature raise mild concerns about publication bias.
 - Moderate concerns: The evidence base is smaller or predominantly from high-impact journals, raising the likelihood that studies with null or negative results are underreported.
 - Serious concerns: A very limited number of studies are available, and there is a high likelihood of publication bias, either due to the selective reporting of results or the absence of non-significant findings.

Final assessment

- 10.35. For the final assessment, the level of concern for each criterion will inform the confidence in the review finding. The level of confidence in a review finding can be high, moderate, low or very low.
 - High confidence: Indicates strong, consistent evidence from multiple high-quality reports. There is little or no doubt about the reliability of the finding.
 - Moderate confidence: Reflects some level of uncertainty due to variability in the
 evidence. The findings are likely reliable, but there are some concerns regarding the
 quality, quantity or consistency of the evidence.
 - Low confidence: Represents substantial uncertainty about the findings. The evidence is limited or inconsistent, raising questions about the reliability of the finding.
 - Very low confidence: Shows high uncertainty and indicates that the finding may not be reliable due to significant limitations in the evidence.
- 10.36. All review findings start off by default as 'high confidence' and are then 'rated down' by one or more levels for example, from high to moderate confidence if there are concerns regarding any of the components. In practice, minor concerns will not lower the confidence in the review finding, while serious concerns will lower the confidence. Moderate concerns may lead to consider lowering the confidence in your final assessment. Having concerns about one criterion may not necessarily lead to a downgrading of overall confidence in a review finding, as the final confidence has to be assessed alongside the other three components as a whole. Each component of the confidence in evidence assessment weights equal in the assessment.

10.37. In addition, in the absence of strong empirical evidence, if a finding is predominantly based on evidence from grey literature or expert opinion, the level of confidence should be low due to serious concerns.

Agree on Confidence Assessments

- 10.38. The first draft of the 'Confidence Assessments Table' document, once completed, should be sent along with the synthesis document to the Supporting Author for feedback. This should remain the same version number, even if amendments are required.
- 10.39. Once both authors are content with the confidence assessments and synthesis, the Lead Author should incorporate them in the literature review draft and send it to the Lead/ Principal HCS for review. After receiving feedback, make any required amendments and change the version draft number.
- 10.40. A meeting should be scheduled with the SME using the Email Template to discuss the confidence assessments and recommendations for further research.
- 10.41. For extensive literature reviews, two meetings may be necessary. Send the literature review report draft with confidence assessment tables to the SME for review prior the meeting. If the SME has not previously been involved in this process, it could be beneficial to arrange a brief call once the documents have been sent to explain how the assessments are conducted prior the meeting takes place.
- 10.42. During the meeting, an agreement should be reached with the SMEs for each assessment and the suggested recommendations for future research. The Lead Author should incorporate feedback and finalise the confidence assessment tables.
- 10.43. The Confidence Assessment Table document should be included as an appendix in the final report. A summary table will be produced and provided within the Discussion section of the report, following the template 'Confidence Assessment Table Summary'. Stage 5: Write up and Publication.

11. Write -Up and Publication

Write-up the Literature Review Report

- 11.1. The Lead Author is responsible for drafting the final report using the 'RN Final Report' template. This draft should be proofread by the Supporting Author and undergo a sense check by the Lead/Principal HCS. After feedback is incorporated, the draft should be sent to the SME for review, allowing them a full working week for the review process.
- 11.2. The Lead Author should then integrate the SME's comments and, if necessary, organise a meeting with the SME to finalise the consultation draft. Ideally, this meeting should also include the Lead/Principal HCS and the Supporting Author, if available.

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- 11.3. Final sign-off must be obtained from the relevant SME/Commissioner before the draft is sent for consultation. The template email named 'Literature Review Draft approval for consultation' should be used to seek agreement on the draft. The email with the approval from the SME should be saved in the 'consultation' folder.
- 11.4. Once approved and before being sent for consultation, the draft should be sent to the Information Officer to check for accessibility and branding. Ensure that the email with the approval for consultation from the Information Officer is saved in the 'consultation' folder.

Recommendations for practice and further research

- 11.5. For literature reviews, recommendations for practice are not often provided. It is the responsibility of the SMEs to make recommendations based on the review findings and confidence assessments. However, for some journal articles, recommendations for practice may be required. In this case, they must be developed in consultation with the SME.
- 11.6. When providing implications for further research, these can be categorised as general and specific.
 - General implications for research: These recommendations are aimed to the wider academic and professional community, focusing on gaps within the existing knowledge and areas where conflicting data is identified in the literature review.
 - Specific implications for research: These are the recommendations the commissioner or SME would like to pursue further through primary research
- 11.7. Despite identifying two types of implications for further research, the final report does not need to establish this distinction and can report all under the 'Implications for further research' section. The distinction is made for internal purposes only.
- 11.8. All implications for research, both general and more specific, will be documented in the Research Repository file. The recommendations the commissioner would like to pursue further through primary research will be documented in the Research Themes file.
- 11.9. The Lead Author is responsible for reporting the recommendations for practice to the Research Service Project Management Team and cc'ing the Lead/Principal HCS.

How to reference in the final report

- 11.10. For literature reviews not intended for publication in a peer-reviewed journal, the Vancouver referencing system should always be used. If the review is intended for a journal, the journal's preferred referencing system must be followed.
- 11.11. When using the Vancouver system:
 - Including authors' names in the main text should be avoid. For example, instead of using phrases like "Sanz et al. (2024) identified...", use phrasing such as "Two qualitative studies identified..."

- Organisations can be cited within the text (e.g. The World Health Organisation recommended...).
- Reference numbers should be placed after punctuation. For example, "One study found that the in-board design of the bedroom negatively impacted all users,¹ while another study found it only negatively impacted the patient user group.² Or: it was identified that privacy in rooms improve wellbeing,^{4,6,8} sleep quality, ^{9,12} and satisfaction with the environment.²

Appendixes in the final report

- 11.12. The final report should include the following appendices:
 - Appendix A. <u>Search terms and search strategies</u> These are available in file named '[Review Name] Search Strategy'
 - Appendix B. List of excluded reports with reasons for their exclusion after the second screening See section X on how to create these tables.
 - Appendix C. PRISMA flow diagram [Review Name] Prisma Diagram file
 - Appendix D. A table summary detailing the main characteristics of all the included reports See section X on how to create these tables.
 - Appendix E. Critical appraisal assessment tables See section X on how to create these tables
 - Appendix F. <u>Evidence grading assessment tables</u> [Review Name] Evidence Assessment Table file.

How to Create a Table for Excluded Reports

- 11.13. The 'A Excluded' tab in the Review Tool contains three tables:
 - Table 1: Reports excluded during the second screening through the database search.
 - Table 2: Reports excluded during the second screening through the citation search.
 - Table 3: Reports excluded due to concerns about methodological quality.
- 11.14. In the 'Appendix 3' Word document, Table 1 should be pasted. If applicable, the second table should be merged with the first, and the same should be done for the third table. The tables contain IDs that need to be replaced with Vancouver-style references. To achieve this, the EndNote library for the Review should be opened, and each reference ID manually searched. The corresponding reference should then be dragged and dropped into the table. Once all references are added, they should be sorted alphabetically, which can be done automatically.

Consultation

11.15. The consultation draft will be sent to the consultation groups/members for a two-to-four-week consultation period, depending on the complexity of the review. For rapid reviews, if

- applicable, the consultation period should be 1 to 2 weeks. The draft should be accompanied by the Final Report Evaluation Tool. If the review is an update, any changes should be clearly highlighted.
- 11.16. Following the agreed consultation period, the Lead Author will collate all comments, if any, into one document using the RN Consultation Template and name it '[Review Name] Report Consultation Response'. This should be saved in the folder [ProjectName]>Project Stage>Write up.
- 11.17. The Lead Author and allocated SME will review all comments from the consultation and draft suitable responses to these comments. Any amendments should be discussed and agreed upon. The Supporting Author should be involved if available.
- 11.18. If amendments are required, the Lead Author will then make the amendments and send the report back to the SME/ Commissioner for final sign-off using the email template 'Final Version Sign-Off'.
- 11.19. Any edits made during the consultation and sign off process including decisions made and by whom and rationale, must be reflected retrospectively in the relevant confidence evidence tables.

Final Literature Report and Publication

- 11.20. The Lead Author must ensure that a copy of the final formatted word document is tagged as 'Final Version'. This version should be shared with the Lead/Principal HCS for final approval before sending it to the Information Officer for the final checks.
- 11.21. Following approval from the Information Officer for publication, the Lead Author is responsible for conducting a final read-through to check for any errors.
- 11.22. The Lead Author should send the final versions of the literature review report and protocol to the Information Officer for uploading to the NHSScotland Assure website. Once uploaded, the Lead Author should inform the Website Content Owner, who will include the links to the publications. Further instructions on how to add and modify website content can be found in Folder [xxx].

12. Actions Following Publication

Set up alerts

12.1. Some literature reviews may need to be reviewed within an agreed period of years. If this is the case, alerts can be set up at regular intervals (e.g., every few months) to identify whether any key evidence has emerged.

Update research repository Literature Reviews

12.2. The Lead Author is responsible for emailing the Research Service Project Management Team,³ specifying the general and specific implications for research for the review project and indicating the completion date of the project (this is the final sign-off).

Quality assurance

12.3. It is the responsibility of the Lead Author to ensure that all files related to the review are stored in the correct folder. Use the Folder Structure.xlsm to perform the quality check.

13. Communication

13.1. This Version is for internal communication only. This will be distributed within the HCS Technical Team. This will be saved in the following folder xxx/ and Q-pulse.

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Appendix A Systematic and Scoping Reviews

Systematic Literature Reviews

In a systematic literature review, a difference from a scoping review, the question is more specific, clearly defined and addresses specific research objectives, such as evaluating the effectiveness of interventions, identifying relationships between variables, exploring qualitative insights like perceptions and experiences. It is particularly suited for when decision-makers require concrete answers, informed by the best available evidence to guide practice recommendations.

Systematic literature reviews are more suitable if the field is more mature and has substantial research. However, in some cases, a systematic literature review may identify that the available evidence is insufficient to provide comprehensive insights or conclusive answers for some questions. In such cases, the review may conclude that the current evidence is insufficient to support definitive conclusions, highlighting the need for further research and providing recommendations for future studies.

Note: In academia, the term 'systematic literature review' often refers to reviews that include only qualitative or quantitative data from empirical studies. When qualitative and quantitative data from empirical studies are combined in a literature review, it is known as a mixed methods review. When reviews incorporate various types of evidence, such as empirical studies (qualitative or quantitative), grey literature, and expert opinion (such as interviews, consultations, articles based on expert insights, editorial papers, and so on), they are referred to as 'integrative systematic review'. To avoid confusion, for our reviews we used the term 'systematic literature reviews' regardless of the type of data or evidence considered. However, if the study is to be published in a journal, the title of the literature review should align with the terminology preferred in academia.

Scoping Review

A scoping review aims to map the existing literature on a broad topic to identify the types and sources of evidence available, key concepts, and gaps in research. It is particularly useful for emerging fields or complex, multifaceted topics where the scope of the research is not well-defined or with limited research available.

To determine if a scoping literature review is appropriate for the topic, consider whether the review aims align with the following objectives of a scoping review:

- Evidence mapping: identify the types of available evidence in a given field.
- Concept clarification: clarify key concepts/ definitions in the literature.
- Methodological exploration: examine how research has been conducted on a certain topic or field.
- Characteristic Identification: key characteristics or factors related to a concept.

- Systematic review precursor: Assess the feasibility and inform the development of a subsequent systematic review.
- Gap analysis: identify and analyse knowledge gaps.

If the review topic meets one or more of these objectives, then a scoping review would be appropriate.

Note: Scoping reviews do not include a critical appraisal of the methodological quality/ risk of bias of included reports. Recommendation for guidance should not be provided based on the findings from a scoping review.

When to conduct a scoping review as a precursor to a systematic literature review

- When the initial search indicates that the available studies are highly varied in their
 designs, methodologies, populations, interventions, or outcomes, it can be challenging
 to synthesise the evidence in a meaningful way. A scoping review helps to map out this
 diversity and categorise the studies, which can reveal patterns and guide the
 development of a more focused and feasible systematic review.
- When the research field is new or emerging, and the exact reviews questions are not well-defined, a scoping review can help clarify the key concepts, definitions, and the scope of available research. This process can help refine research questions and develop a more targeted systematic review.
- When there is a need to explore a broad area to understand the range of existing literature, a scoping review provides an overview that can identify gaps and inform the formulation of specific, focused questions for a systematic review.
- When there is uncertainty about the extent, range, and nature of research conducted in a particular area, a scoping review can help to map out what has been studied or published in the literature, the types of evidence available, and the key characteristics of the research landscape. This mapping can reveal gaps and areas where more a systematic review can be conducted.

Appendix B Key Characteristics Across Review Types

Stages	Systematic Literature Reviews	Rapid Reviews	Scoping Reviews
Authors	Two authors	One author	One or two authors
Search	 All relevant databases Citation search Grey literature search (if applicable) 	 Conducted in general databases. Specialised database searches limited to 1-2 sources. Citation searching and grey literature may be restricted. 	 All relevant databases Citation search Grey literature search (if applicable)
Study Selection		One author screen titles and abstracts and full texts of eligible studies.	
Data Extraction	 Lead Author extracts data using a piloted form. Supporting Author checks all extracted data. 	Data extraction may be limited to essential items; existing systematic reviews can be used.	 Lead Author extracts data using a piloted form. Supporting Author checks 30% of the data extracted.
Critical appraisal	 Lead Author conduct the critical appraisals Supporting Author does 30% check. 	No critical appraisals required	No critical appraisals required

SOP Literature Reviews

Stages	Systematic Literature Reviews	Rapid Reviews	Scoping Reviews
Confidence Assessments	Collaboration among Lead, Supporting Author, Lead/Principal HCS, and at least one SME.	 SME consultation if time allows. Use proxy indicators for the methodological quality criterion. 	No confidence assessments performed.
Consultation	• Yes	Not required	• Yes
Publication	• Yes	Not required	• Yes

