

Protocol

Title: SelecTing Approaches for Rapid Reviews (STARR) Decision Tool project

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Background:

Rapid reviews are of increasing importance within health technology assessment (HTA) due to the need for timely evidence to underpin the assessment of new technologies. Financial constraints within HTA have also contributed to the increase in rapid reviews. There are many rapid review methods available (1) although there is little guidance as to the most suitable methods (2). Rapid review methods need to be chosen to fit the needs of the review, each of which may have different challenges. Collaboration between those producing rapid reviews and commissioners/policy-makers is crucial when choosing methods to ensure that the needs of commissioners/policy-makers are met and limitations associated with the chosen methods are understood. A recent paper outlines issues to consider when selecting rapid review methods (3). Four important aspects to consider when selecting rapid review methods include: interaction with commissioners/policy-makers, scoping and searching the evidence base, data extraction and synthesis methods and reporting of rapid review methods. Preliminary work in ScHARR has resulted in the development of a decision tool for reviewers to use to select the most appropriate rapid review approaches for HTA. The aim of the decision tool is to outline broad high-level options for the overall rapid review process rather than outlining detailed methods. The decision tool is being used locally within ScHARR and internationally (4) and informal feedback has suggested that it is very useful and has the potential to benefit all those working in systematic reviewing. Based on feedback the decision tool has been updated and is attached as Appendix 1.

Aims and objectives

The aim of the proposed study is to validate the decision tool by achieving consensus using the Delphi method among those involved in rapid reviewing. This will ensure that the most important broad high level options to consider when choosing rapid review approaches are included in the decision tool.

Methods:

Methodology

The Delphi method is a well-recognised method for gaining consensus among a group of experts (5-7). The Comet Initiative DelphiManager platform (http://www.cometinitiative.org/DelphiManager/) will be used for this study. A modification of the standard Delphi exercise will be used and include three iterations with participants, each subsequent iteration building on the responses from the previous iteration. The draft Delphi questions for the first iteration are shown in Appendix 2. These questions will be further developed with input from the project advisors and the team at DelphiManager. These draft questions will then be pilot tested on five systematic reviewers in two UK universities with expertise in rapid reviews and revised accordingly based on their responses. It is anticipated that three rounds of questions will be required with three weeks between rounds. Participants will be able to provide open ended feedback questions.

For rounds 2 and 3, participants will presented with their scores and how they compare with summaries of ratings from all participants. Modifications to questions will be considered by the researchers after each Delphi round based on the answers from participants. Questions may be omitted after each round or additional questions added depending on responses. Data analysis will be undertaken by the applicants and be in two parts: 1) stage-wise: using participants who responded to a particular round to understand their perceptions and 2) across stages: using participants who have responded to the rounds under consideration to understand change in perceptions. Both rounds depend on responsers so efforts will be made to encourage participation, such as weekly reminders. An overall response rate will be calculated as well as summary statistics for each question. Individual participants score change and overall score change for each round will be calculated and presented to respondents. Consensus will be defined as at least 70% of participants rating an item as 'critically important' (scores 7 to 9). The qualitative data from the free text questions will be analysed through thematic analysis. If there is very little change after round 2 a third round will not be undertaken.

Participants:

Following the pilot test approximately 60 participants will be invited to take part. The participants will be identified from i) searches of electronic databases for authors who have published rapid reviews and ii) experts who have undertaken research in this area identified from specialist websites iii) invitations to key systematic review forums, such as the Cochrane Rapid Reviews Group. Participants will be chosen to ensure that reviewers are included with a breadth of expertise working for a wide range of institutions in countries worldwide and will be considered as one stakeholder group. All participants will be invited to participate via e-mail. They will receive an information sheet on the study electronically (Appendix 3) and be asked to give consent via a tick box on the introductory page of the Delphi platform when they register. Information will be provided regarding handling and use of data and it will be made clear that participants can withdraw at any time. Their data will be deleted at the time of withdrawal. Anonymity will be maintained throughout, with the identity of participants known only by the researchers. No payment will be given to participants and we do not anticipate any potential harm to participants.

Data confidentiality and storage

The DelphiManager platform is a bespoke piece of software written in C# 4.0 using MVC 4. The data is stored in a MySQL database. The system itself is hosted on the main Clinical Trials Research Centre (CTRC) server which is hosted in the University of Liverpool data centre. Physical access to the University of Liverpool datacentre is restricted to authorised personnel. The CTRC server sits behind the University firewall and uses a 256 bit SSL certificate. Only authorised CTRC Information Systems (IS) team members have access to the server. Access to the DelphiManager software instance is set up by the IS team and then password protected administrator accounts are managed by the study team. Any data entered into the individual instance of DelphiManager can be extracted by the study team administrators. Data are extracted as a CSV file from DelphiManager. All data will be encrypted in DelphiManager and decrypted when downloaded. The study data will be archived for three months by DelphiManager after completion of the study. This archive is stored on a secure network drive that only CTRC IS staff members have access to. After this the data will be deleted. Steps will be taken to ensure that DelphiManager conforms with data protection and information governance process recommended by the University of Sheffield.

Outputs

The findings from this research will be used to finalise the decision tool and will be published in peer reviewed journals such as the Journal of Clinical Epidemiology. This protocol will be published as part of the HEDS Discussion Paper Series

(<u>https://www.sheffield.ac.uk/scharr/sections/heds/discussion-papers</u>) and potentially in a peer reviewed journal. A webpage has been developed within the ScHARR webpages with details of the study and progress updates

(https://www.sheffield.ac.uk/scharr/sections/heds/sys_rev/rapid).

Ethics

This study has ethics approval from the ScHARR Ethics Committee (application number 017096).

Financial support

This project is funded by the ScHARR Research Stimulation Fund.

Project timetable:

The research project will last seven months (March -September 2018), key tasks and dates are listed below.

Programming of DelphiManager platform	April 2018
Pilot test of questions	May 2018
Initial iteration	May 2018
2 nd iteration	June 2018
3 rd iteration	July 2018
Write up of results	August 2018
Publication submission	September 2018

References

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Appendix 1. SelecTing Approaches for Rapid Reviews (STARR) Decision Tool

The purpose of the STARR decision tool is to guide the reviewer in selecting possible approaches to conducting their rapid review.

1. Interaction with commissioners

Ensure clear communication with review commissioners. It is important that there is a common understanding as to the purpose of the review, the questions to be answered, and the trade-off between time and review scope. Points to consider:

- Review focus: Why is the review being commissioned? What is the primary decision question for the review?
- Restricting the scope: Can the scope be limited e.g. by geographical context, setting, year of publication, type of study?
- Breadth versus depth: Would the commissioner prefer a brief overview of a wide range of studies or a more in-depth analysis of a smaller selection of relevant studies?

2. Understanding the evidence base

Assess the volume and type of evidence available. This will help inform discussions with commissioners about the review scope, which rapid review methods are most appropriate and the feasibility of the review in the given timescales. Points to consider:

- Volume and type of evidence: Have you considered the expected volume and type of evidence? Potentially useful options to determine this include:
 - Scoping searches (e.g., brief searches of MEDLINE, PubMed, Google Scholar)
 - Use of existing systematic reviews
 - Expert advice
- Final review searches: Can the total number of citations to screen be reduced by narrowing the search, such as using fewer databases, applying focussed terms or search filters? What is an acceptable trade-off between volume of citations and impact on comprehensiveness?

3. Data extraction and synthesis methods

Consider presentation of evidence. The complexity of the evidence base should be taken into account and an assessment made as to how much data should be extracted and presented and in what format. Points to consider:

- Existing systematic reviews: Could existing reviews be used for any of the following? This may depend on their closeness to your review question, search dates, and methodological quality.
 - Undertaking a review of reviews
 - Extracting data from existing reviews, supplemented by a search for more recent studies (i.e. a review update)
 - Evidence tables from existing reviews used as a data extraction template

- Most important outcomes: What are the most important outcomes for review commissioners? Prioritisation of key outcomes may help ensure the review is feasible within the timescales.
- Synthesis approach: Do the data and timescales support the use of meta-analysis? If not, consider other methods to highlight key findings.
- Data presentation: What is the most useful way to present the findings to the commissioner? Consider a brief narrative summary and the use of evidence tables and/or graphical representation of the evidence. It may be important to highlight gaps in the evidence to inform future research.

4. Reporting of rapid review methods

Clearly report rapid review methods used. It is crucial that the reader understands what methods have been used and the impact this may have on the findings. Points to consider:

- Description of methods: Have you clearly reported and justified the rapid review methods used, highlighting differences from standard systematic review methods and enabling the rapid review to be updated if required in the future?
- Discussion of limitations: What are the potential limitations and biases of the chosen rapid review methods?

Appendix 2 Draft Delphi questions for round 1

Information for participants

Welcome to the STARR Decision Tool Delphi Survey Homepage.

We are a team of University of Sheffield researchers with an interest in rapid review methodologies. We want to identify the most important things to include in a decision tool to aid reviewers with choosing rapid review approaches. While there is a considerable amount of literature available outlining various rapid review approaches, there is little published guidance on how to decide which rapid review methods to choose. We have reviewed literature on different ways of developing rapid review methods, developed and published a decision tool (https://www.sheffield.ac.uk/scharr/sections/heds/sys_rev/rapid).

The decision tool has recently been revised in an effort to outline broad high level options to consider when selecting rapid review approaches. We want to get the views of a wide range of reviewers on what they believe is most important to include in the decision tool. We will use this to further develop and refine the decision tool.

We know we will not get consensus on every component and are interested in the written comments you make so we can understand more about why people have different views. Please feel free to provide feedback in the comment box provided. You will be asked to rate the importance of each item presented.

Our aim is to develop a practical decision tool to help reviewers plan their rapid review. We don't anticipate that the decision tool will cover every option open to a reviewer as we hope to keep it concise and user friendly.

Thank you for taking part in the survey.

Draft questions for STARR Decision Tool Delphi

Question	Question
number	
Overall use of tool	
1.	How important is it to have a decision tool to help in the selection of rapid
	review approaches?
Interaction with commissioners	
2.	How important is the section: Interaction with commissioners in the decision
	tool?
3.	How important is the description of the section: Interaction with commissioners?
4.	How important is the sub-section: Review focus?
5.	How important is the sub-section: Restricting the scope?
6.	How important is the sub-section: Breadth versus depth?
Understanding the evidence base	
7.	How important is the section: Understanding the evidence base in the decision
	tool?
8.	How important is the description of the section: Understanding the evidence
	base?
9.	How important is the sub-section: Volume and type of evidence?
10.	How important is the sub-section: Final review searches?
Data extraction and synthesis methods	
11.	How important is the section: Data extraction and synthesis methods in the
	decision tool?
12.	How important is the description of the section: Data extraction and synthesis
	methods?
13.	How important is the sub-section: Existing systematic reviews?
14.	How important is the sub-section: Most important outcomes?
15.	How important is the sub-section: Synthesis approach?
16.	How important is the sub-section: Data presentation?
Reporting of rapid review methods	
17.	How important is the section: Reporting of rapid review methods in the decision
	tool?
18.	How important is the description of the section: Reporting of rapid review
	methods?
19.	How important is the sub-section: Description of methods?
20.	How important is the sub-section: Discussion of limitations?

Appendix 3 Participant information sheet

1. Research Project Title: SelecTing Approaches for Rapid Review (STARR) Decision Tool project

2. Invitation paragraph

You are being invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.'

3. What is the project's purpose?

Rapid reviews are of increasing importance within health technology assessment (HTA) due to the need for timely evidence to underpin the assessment of new technologies. There are many rapid review methods available although there is little guidance as to the most suitable methods. Preliminary work at the School of Health and Related Research at the University of Sheffield has resulted in the development of a decision tool to aid in the selection of methods. The purpose of the proposed study is to validate the decision tool by achieving consensus using the Delphi method among those involved in rapid reviewing within HTA.

4. Why have I been chosen?

You have been chosen as you have been identified through your publications as someone who either produces rapid reviews within HTA or is involved in rapid review methods work.

5. Do I have to take part?

It is up to you to decide whether or not to take part and you can withdraw at any time. If you do decide to take part you will be sent a link to the Delphi survey and you will be asked to provide consent when accessing the survey online, you can still withdraw at any point during the survey, though data that you contribute will be kept up to the point of withdrawal.

6. What will happen to me if I take part?

If you are interested in taking part, please register via the link to the survey in the e-mail you have been sent inviting you to take part in the survey. On registration, you will be asked to provide consent and provide some basic details including your contact details, your experience in rapid reviews. The survey will not take more than half an hour of your time and will be open for completion for three weeks. You may be sent up to four reminders to complete the survey while it is open. We expect the Delphi process to have three rounds. We hope that you can take part in all three rounds although you are free to withdraw after any of the rounds. The first round will ask you to rate the importance of each item presented. In rounds two and three, you will be presented with the overall outcome alongside each item, and you will be asked to rate these again. The data from the survey will be stored by The University of Liverpool during the Delphi process and will be sent in full to the research team in Sheffield after each round. All transfer of data will be encrypted. You will be informed once the Delphi process (all rounds) has been completed. If you do not want to be invited to further surveys please contact the study team and we will not contact you again in regards to this project.

7. What do I have to do?

All you have to do is answer the questions. You can withdraw consent at any time.

8. What are the possible disadvantages and risks of taking part?

The only possible disadvantage to taking part in this research is the time commitment for answering the questions. It is expected that the survey (all three rounds) will require no more than two hours of your time.

9. What are the possible benefits of taking part?

Whilst there are no immediate benefits for those people participating in the project, it is hoped that this work will help to establish best practice in the field of selecting rapid review methods and enable the development of a better, more efficient process and provide focus for further research developments.

10. What happens if the research study stops earlier than expected?

If the research study stops earlier than expected, you will be informed.

11. What if something goes wrong?

If you have a complaint you should inform Professor Eva Kaltenthaler. However if you feel your complaint is not being handled to your satisfaction then you can contact Professor John Brazier, Dean of the School of Health and Related Research, Regent Court, 30 Regent Street, Sheffield S1 4DA; telephone: 0114 2225453; e-mail: j.e.brazier@sheffield.ac.uk.

12. Will my taking part in this project be kept confidential?

All the information that we collect about you during the course of the research will be kept strictly confidential. All comments made during the Delphi iterations will be anonymised. You will not be able to be identified in any reports or publications unless you wish to be acknowledged.

13. What will happen to the results of the research project?

The results from this research study will hopefully be published in a peer reviewed journal such as Journal of Clinical Epidemiology. We hope to submit the paper in August 2018. You will not be identified in any report or publication. The anonymised data collected during this project may be used for subsequent research.

14. Who is organising and funding the research?

This study is funded by the University of Sheffield School of Health and Related Research (ScHARR) and being organised by Eva Kaltenthaler, Katy Cooper, Marrissa Martyn-St James, Abdullah Pandor and Ruth Wong from ScHARR.

15. Who has ethically reviewed the project?

This research project has been ethically approved via ScHARR's ethics review procedure.

16. **Contact for further information**

If you require further information, please contact Eva Kaltenthaler, ScHARR, Regent Court, 30 Regent Street, Sheffield S1 4DA; telephone: 0114 2220810; e-mail: e.kaltenthaler@sheffield.ac.uk

Thank you for taking part in this research project!