General Protocol for the production of evidence syntheses for the HS&DR programme

This general protocol outlines the approach that will be taken to undertake evidence syntheses for the HS&DR. The specific topics to be undertaken are yet to be agreed, therefore this document will describe the general process we will establish to undertake the work.

Background

The production of evidence syntheses will be undertaken by the Evidence Synthesis Group. This group will comprise the director, senior staff members, skilled research fellows and information specialists with methodological expertise, access to input from external experts, and administrative support. For each evidence synthesis topic, a team will be established drawing on the pool of skilled staff available and links to relevant expert advice. Each team will include research fellows and information specialists, with advisory input from both content and methodology experts as appropriate.

Developing a scope

For each topic, we will develop an initial scope in partnership with the commissioner, taking account of available time and resource and likely availability of evidence as well as commissioning and NHS needs. A clear, unambiguous and agreed scope will be vital to enable high quality, useful output within tight timelines.

A variety of approaches and outputs may be appropriate for individual evidence syntheses, ranging from (a) rapid identification and critique of existing evidence syntheses in a briefing format, through (b) scoping reviews that map the research evidence and identify both opportunities for synthesis and gaps in the evidence base, (c) rapid reviews within tight confines, to (d) full systematic reviews. The approach most suitable to each particular topic will be agreed at the outset.

To ensure a consistent and thorough approach is taken in this initial scoping, we will utilise a standard specification form for each topic. The form will be divided into three sections: the first section, to be completed by the HS&DR programme will detail the topic, providing the rationale for the work (the motivation for the topic and how the findings will be used), the research questions to be addressed, and the timescale for completion; the second section, to be completed by the ESG, will describe the approach to be taken, confirming or clarifying the research questions to be addressed and the methods that will be used, and detailing the time and resources required; the third section will detail the final outcome of the scoping process approved by the HS&DR programme directors.

Developing a protocol

On completion of the initial scope, a protocol will be developed which will set out the approach and methods to be used and address any relevant issues identified during scoping. The draft protocol will be approved by HS&DR, and then if appropriate registered on PROSPERO (PROSPERO is an international database of prospectively registered systematic reviews in health and social care. It currently includes systematic reviews of the effects of interventions and strategies to prevent, diagnose, treat, and monitor health conditions, for which there is a health related outcome).

The protocol will be developed in consultation with key stakeholders appropriate to each topic. Access to wider expertise will be particularly important in developing the protocol and interpreting results to ensure relevant and accessible outputs. Experience suggests that specialist topic expertise, especially in the early stages of the review process, is highly beneficial; it provides essential background to set the work in an appropriately informed policy and practice context and provides quality assurance from the start. If appropriate, patient and public involvement will be obtained for specific topics. The aim of this involvement will be to assist in defining and refining the research question(s) to be addressed and ensuring relevant and important outcomes are considered, highlighting areas and issues from a patient and public perspective.

The protocol will include a project timetable with key milestones and deadlines specified to ensure quality and timeliness of delivery. The key elements of the evidence synthesis documented in the protocol will be as follows:

Research question(s)
A clear research question, or set of questions, will be stipulated and set in the context of the background to the topic.

Literature searching
CRD's information specialists conduct extensive peer-reviewed literature searches for systematic reviews but are also familiar with supporting rapid evidence syntheses. In rapid reviews the comprehensiveness of the search needs to be balanced against the limited time and resources available. Ways of streamlining the search process include: restricting the number of databases used; limiting the search for grey literature; including methodological search filters in strategies; and introducing language and date restrictions.

Text mining technology will be particularly relevant for searching and screening in scoping reviews to rapidly assess the volume and scope of literature in complex areas. There are two ways of using text mining that are particularly promising for assisting with screening in systematic reviews: one aims to prioritise the list of items for manual screening so that the studies at the top of the list are those that are most likely to be relevant ('screening prioritisation'); the second method uses manually-assigned include/exclude decisions in order to 'learn' to apply such categorisations automatically ('semi-automatic classification'). We plan to utilise both methods in order to identify the most relevant studies as early as possible in the review process, thus shortening the time it takes to find eligible studies. We will also utilise text analytics to help to devise search strategies, identifying potentially important terms on which to search, and others which it may be prudent to avoid. Finally, automatic document clustering can be used to group similar 'clusters' of studies (based on the words in their titles / abstracts), thus offering a very quick snapshot of the areas and issues covered by a set of citations.

Data management
We will use Endnote® and EPPI-Reviewer software. Endnote is a bibliographic software tool which we use to record and manage references, and to streamline document management and production of reference lists. EPPI-Reviewer is a web-based software program for undertaking research synthesis, developed for all types of review including meta-analysis, framework synthesis and thematic synthesis; it also includes technologies for text mining.

Study selection, data extraction and quality assessment
To ensure explicit and objective processes, clear criteria will be used to select relevant studies. Depending on the topic, these criteria may be broad or narrow, but will ensure the boundaries of the review are clearly defined. The key information required from each included study will be pre-specified and data will be extracted using EPPI-Reviewer software. All studies will be assessed critically to determine the quality of the evidence and the strength of the study results. The key elements of quality will be specific to each project and study design and will be explicitly stated; there are a range of tools available which can be adapted to the individual research questions.

Synthesis Methods

Having identified and critically appraised the relevant evidence, the synthesis will bring together and combine the findings of individual studies. There are a variety of methods which can be used, depending on the question to be addressed and the evidence available. All evidence syntheses will provide a clear descriptive summary of the studies, assessing the strength of the evidence and the consistency of the findings; differences between studies will be explored along with possible explanations for any observed inconsistencies.

Given the anticipated areas of research, it seems likely that a combination of methods may be required, to integrate the quantitative estimates of effect with a qualitative understanding of the mechanisms which may influence this. When used appropriately, formal statistical pooling using meta-analytic techniques can provide a powerful and precise estimate of effect, however it is not always feasible or meaningful. A narrative synthesis framework can be used to summarise and interpret studies which are so diverse (either in focus or methodology) that combining results would not be meaningful. Understanding the mechanisms behind the effects can be done by synthesising qualitative research which explores patient experience or identifies factors that impact on implementation.

Evidence synthesis will be undertaken following established and agreed principles; we will utilise the methods appropriate to the specific research question(s) formulated for each topic including quantitative (narrative synthesis and meta-analysis), qualitative, mixed methods, and applied health economics.

Outputs

The format and content of the output will also depend on the topic. The choice of output and dissemination activities will be informed by the key findings of the research, taking account of the needs and preferences of the target audience(s). All outputs will summarise the available evidence and provide a concise critique of the quality of the evidence and strength of the findings. We will ensure that relevant audiences can acquire, access and apply the findings to support their decision making.

Project management, supervision and quality assurance

The programme of work will be overseen by the director who will provide senior project management with support from the other senior staff members. The director will be involved in all the evidence syntheses and will call upon the expertise of the other co-applicants as appropriate for each topic.

For each individual topic, supervision and content and methodological expertise will be provided by senior staff; experienced research fellows will be responsible for the day to day running of projects. We will follow CRD's established principles to minimise bias and assure quality. Literature searches conducted by CRD's information specialists are peer-reviewed within the team. Independent checking of both study selection and data extraction will be undertaken. There will be regular project team meetings and monitoring to ensure project milestones are met.