**The Title Registration and Protocol Checklist – An Elaboration and Explanation**

When reviewing the title registration and protocol, we will cross check the following elements:

1. **Has the on-call QIMG convenor been notified of the intention to register a review and has a QIMG convenor been involved in supporting the Title Registration and Protocol development?**

Writing qualitative evidence syntheses (QES) is a relatively recently recognised skill, particularly within the constraints of the Cochrane processes. Each protocol should be assigned a Cochrane QIMG co-convenor who will guide the review through the registration process, securing peer review as and when appropriate. Contact the on-call QIMG convenor in the first instance and they will try to assign the most appropriate convenor to the topic and nature of the review.

1. **Is this a priority review to conduct an exemplar qualitative evidence synthesis?**

While the CQIMG convenors will try to support all qualitative evidence syntheses associated with Cochrane Review Groups (CRGS) certain reviews have been prioritised for methodological development or strategic purposes. If your review has been pre-identified in this way then this will accelerate the process of peer review – without compromising the rigour of the review process.

**3a. Is it an integrated quantitative/qualitative protocol with a joint team and if so is it clear how the reviewers will work together to undertake and integrate the two reviews?   OR**

Managing an integrated quantitative and qualitative review project is a particularly complex process. In addition to the requirements for each review component there is an additional requirement for integration. Consider will the reviews be conducted sequentially or in parallel and how long will the integration process take? Is it already obvious at the stage of the protocol the point at which quantitative and qualitative data might be brought together e.g. commonality of outcomes with themes or commonality of intervention components with themes?

**3b. Is the intention that an additional qualitative evidence synthesis will be undertaken and then integrated with an existing Cochrane effectiveness review(s) published in the library.  If so, what links exist or have been made between the qualitative and quantitative review teams and is there agreement in place that a qualitative evidence synthesis is warranted/desirable at the present time?**

Although superficially it may seem easier to undertake a qualitative evidence synthesis to complement a pre-existing Cochrane effectiveness review the challenges of integration should not be underestimated. It is important that opportunities to maximise the value of integration are identified and exploited as early as the protocol stage. Which characteristics of the Cochrane Effectiveness review does the qualitative evidence synthesis hold the potential to illuminate? Does the QES help to explain why an intervention is not as effective in a “real world setting” as it has been demonstrated to be under experimental conditions? Does the qualitative evidence offer insights into barriers and facilitators for implementation? Does qualitative evidence shed light on areas not explored by the Effectiveness review, for example, outcome considered important by patients but overlooked by health professionals? Does the qualitative evidence perhaps hold the potential to highlight some incongruity of different perspectives e.g. clinicians and managers, clinicians and patients, patients and carers etcetera?  Close liaison with the authors of the Cochrane Effectiveness Review will help the QES team to tap into knowledge identified during the course of the review that may not have been explicitly articulated in the published version of the review.

**4. Are the review questions appropriate for a qualitative evidence synthesis?**

Qualitative evidence syntheses may address several types of review question. According to the Cochrane QIMG Supplementary Guidance on Question Formulation (Harris, 2011) qualitative research can help to address one or more of the following issues in relation to the effectiveness of an intervention:

* Perceptions of health issues
* Social and cultural beliefs
* Understanding of the intervention
* Patient/carer perceptions of the disease or condition
* Patient/carer perceptions of treatment and their preferences
* Health professional preferences for particular treatment options
* Acceptability of the intervention
* Accessibility factors
* Opinions about acceptable/important outcomes

While this can never be an exhaustive list it will be helpful if your protocol can align itself with these recognised processes OR can articulate a justification for a type of question if not present on this list.

**5. Has a scoping search been undertaken to establish the nature and type of available qualitative evidence to inform decision-making about the choice of sampling and synthesis method?**

Typically evidence to address a qualitative review question will comprise a mix of contextually thick and conceptually rich data and thinner descriptive reports. The relative distribution of evidence for your review will determine your subsequent choice of sampling and synthesis method. It is therefore very important that you gain an initial view of the likely characteristics of your evidence base. Generally speaking, if your evidence is comprised mainly of thin descriptive studies your choice of synthesis will gravitate towards more aggregative approaches such as meta-aggregation or thematic synthesis. Alternatively if the evidence is comprised of thick descriptive reports accompanied by interpretation your synthesis method may involve a more interpretive approach. If studies are primarily homogeneous (in terms of population, phenomenon of interest, method of investigation, discipline of research team etcetera) then it is correspondingly less likely that each study will make a unique contribution. You might therefore seek to construct a sampling frame that accommodates the main types of variation identified from the studies and then to ensure that you have sampled from within each of the supporting bodies of evidence. If studies show significant variation at the mapping stage you may decide to review every study in the expectation that this will yield substantive insights between subsets of the population, the timing of the disease etcetera.

**6. Are the proposed methods and processes consistent with QIMG guidance?**

At present the Cochrane QIMG is seeking to identify the widest range of synthesis methods that might usefully contribute to qualitative evidence synthesis within a Cochrane framework. The following Table seeks to locate the main methods of synthesis according to their methodological readiness for incorporation with Cochrane Effectiveness Reviews. It is important to recognise that this relates only to fitness for a specific purpose and is not a reflection of the value of the synthesis method in general. A brief explanation is provided for each assessment.

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| --- | --- | --- | --- | --- | --- |
| **Ready** | | **Minor Methodological Issues to be resolved** | | **Substantive Outstanding Methodological Issues** | |
| **Method** | **Explanation** | **Method** | **Explanation** | **Method** | **Explanation** |
| **Thematic Synthesis** | Most accessible form of synthesis. Accommodates translation to actionable points relatively smoothly. May be limited in interpretive ‘power’ | **Framework Synthesis** | Appears well-suited to qualitative and integrative synthesis. Requires work on how to identify, select and justify choice of framework. | **Critical Interpretive Synthesis** | Interpretive synthesis method that problematises the literature. May serve a targeted explanatory function but unclear how it meets Cochrane purposes. |
|  |  | **Meta-Aggregation** | Simple method of synthesis that draws upon primary author interpretations. Unclear if it can be used independently of JBI tools and software. May be limited in interpretive ‘power’ | **Meta-Ethnography** | Primarily interpretive synthesis method leading to creation of new high order constructs. May not satisfy requirements for an audit trail. Unclear how findings translate into actionable points. |
|  |  |  |  | **Meta-Narrative** | Seeks to characterise development of concepts through different paradigms. Unclear how this might contribute to Effectiveness review |
|  |  |  |  | **Realist Synthesis** | Seeks to explain what works for whom under which circumstances. Unclear how use of non-research forms of data can be accommodated within Cochrane model.. |
|  |  |  |  |  |  |

**7. Will the search for qualitative evidence be limited to studies related to included trials or will a wider search be performed for additional qualitative evidence that is unrelated to included trials?**

Within the Cochrane QIMG documentation we distinguish between qualitative data presented alongside trials, qualitative data linked to trials but separately published in “sibling studies”, qualitative data related to trials but not directly linked (“kinship studies”) and independent qualitative accounts. There is a clear trade-off between quantity of data and relevance to the included effectiveness studies. While some qualitative data may be identified while searching for and identifying randomised controlled trials there seems little value in restricting a qualitative synthesis to this source of data. Qualitative data identified in this way may simply serve as “footnotes” to illuminate specific issues identified from individual trials e.g. the content of the intervention or specific implementation issues. Of more value to a qualitative synthesis are sibling studies with the inherent advantage that they share context with the trial evidence. Systematic procedures for locating this type of evidence have been proposed (Booth et al, 2013). Where such evidence is not plentiful a team may expand their inclusion to include studies that may illuminate the original study while not being directly linked (e.g. early ancestors of the trial performed in a different context) (Booth et al, 2013). Finally a team may decide to search more broadly for qualitative studies, reviewing the two bodies of literature, quantitative and qualitative, separately, and bringing findings together at the analysis stage. In this case sibling studies may add particular insights but are not a major feature of the review method. Whichever type of qualitative evidence the review team intends to include their protocol should demonstrate that they have explored the methods and resources required to deliver against this intention.

**8. Does the review team have the requisite skills to conduct a qualitative evidence synthesis and then integrate the qualitative/quantitative findings?**

Generally speaking the more interpretive the review method the greater the experience of qualitative research required to conduct the review successfully. This informs overall strategies such as the choice of synthesis method and specific stages such as the choice of the instrument for quality assessment. In addition further advanced skills are required to integrate quantitative and qualitative findings. A review team should have identified: subject experts, trained information specialists (preferably with experience of searching for qualitative evidence), systematic review methodologists and qualitative researchers (preferably with experience of qualitative evidence synthesis).

**9. Are the resources and timeframes appropriate?**

Qualitative evidence synthesis will require separate stages of searching, data extraction, quality assessment, synthesis and analysis. Typically the timeframe will be comparable to that for an Effectiveness review and the human resource requirements will also be comparable. Time may be reduced by sampling purposively from the population of qualitative studies and by limiting the activities that are performed in parallel by multiple reviewers. However this may have a negative impact on quality and on the subsequent prospects of publication in peer reviewed journals. Generally you should not assume that the qualitative evidence synthesis component will take a shorter period of time unless you can identify unequivocal opportunities for time saving. Bear in mind any dependencies e.g. if required to complete the effectiveness review before undertaking the QES, and the additional requirements for integration. Also if resources are to be shared across component reviews (e.g. a reviewer is to participate in both the quantitative and qualitative reviews) this may impact negatively on the availability of resources and this extend the critical path for a combined review. Sample planning timetables are available (Booth et al, 2011)

**10. Is the CRG supportive of registration?**

All Cochrane Methods Groups, CQIMG included, are reliant on good working relationships with the Cochrane Review Groups. CRGS may demonstrate different levels of co-operation regarding the production of qualitative synthesis from energetic support through to passive or even overt resistance. Such positions vary according to the perceived value, or otherwise, of the qualitative evidence synthesis, when ranged against the conflicting demands of Effectiveness Reviews in general, and on its likely contribution to the specific issue being examined. The Cochrane QIMG convenors are currently building up links with, and a knowledge of, particular CRG members with a view to optimising working relationships and increasing mutual understanding of the issues involved.

**11. Is the title registration/protocol complete, coherent and transparent?**

**This is not a Methods Group-specific requirement but reflects attention to good science. The protocol should meet the accepted requirements of the Cochrane Style Guide** at www.cochrane.org/style/home.htm**. This includes such features as:**

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| --- |
| Proofread the Cochrane Protocol carefully in accordance with the Cochrane Style Guide Basics. |
| If additional subheadings have been added, the appropriate Heading Style has been selected using the drop down box on the RevMan toolbar. |
| Used either UK or US English consistently throughout the review (e.g. either ‘randomised’ or ‘randomized’) |
| Explained all acronyms and abbreviations, e.g. World Health Organization (WHO). |
| Written numbers up to and including nine as words, and numbers 10 or higher as numerals (excluding those at the start of a sentence and numbers appearing in tables or figures). |
| Reference citation IDs are in the correct format (first author or group abbreviation and year of publication, e.g. Smith 1983 or UKPDS 1990) |
| Included each journal title in full, with no abbreviations. |
| Checked how each reference is displayed to remove unnecessary punctuation. |
| Where applicable, listed the first six authors before using ‘et al.’ |
| Written the page numbers correctly (e.g. 354-7). |
| Included the date accessed in any references to web pages. |
| Other published versions of this review |
| Included references to any previous or derivative published versions of this Cochrane Protocol. |

**References**

Booth, A., Papaioannou, D., & Sutton, A. (2011). *Systematic approaches to a successful literature review*. Sage.

Booth, A., Harris, J., Croot, E., Springett, J., Campbell, F., & Wilkins, E. (2013). Towards a methodology for cluster searching to provide conceptual and contextual “richness” for systematic reviews of complex interventions: case study (CLUSTER). *BMC medical research methodology*, *13*(1), 118.

Harris J. Chapter 2: Using qualitative research to develop robust effectiveness questions and protocols for Cochrane systematic reviews. In: Noyes J, Booth A, Hannes K, Harden A, Harris J, Lewin S, Lockwood C (editors), *Supplementary Guidance for Inclusion of Qualitative Research in Cochrane Systematic Reviews of Interventions.* Version 1 (updated August 2011). Cochrane Collaboration Qualitative Methods Group, 2011. Available from URL: <http://qim.cochrane.org/supplemental-handbook-guidance>

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