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A guide to synthesising qualitative research for researchers undertaking health technology assessments and systematic reviews

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A guide to synthesising qualitative research for researchers undertaking health technology assessments and systematic reviews

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Contents

1 Foreword

NHS QIS has a leading role in improving the quality of healthcare for the people of Scotland. We support NHS boards and their staff by providing advice and guidance on effective clinical practice; supporting implementation improvement, and assessing the performance of NHSScotland.

Advice on the clinical and cost effectiveness of new and existing technologies is one aspect of the work of the organisation, primarily through activities to support the Scottish Medicines Consortium and Scottish Health Technologies Group. The process of health technology assessment (HTA) is used to develop this advice and as such the needs, views and perceptions of patients are recognised as a key element of these analyses. Methods to synthesise qualitative research evidence on patient views are therefore increasingly being explored and used.

NHS QIS has adopted the following definition of HTA, which is based upon those used by the Canadian Agency for Drugs and Technologies in Health (CADTH) and the European Network for Health Technology Assessment (EUnetHTA):

> 'An HTA is an evaluation of the clinical effectiveness, cost effectiveness and broader impact of drugs, medical technologies and health systems, both on patient health and the healthcare system. During the assessment, data from research studies and other sources are systematically gathered, analysed and interpreted in a transparent and robust manner. The findings from this process are then summarised to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value for NHSScotland.'

A health technology is any intervention that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. This includes the pharmaceuticals, devices, procedures and organisational systems used in healthcare (International Network of Agencies for Health Technology Assessment).

This report has been developed in collaboration with colleagues at the University of Stirling to provide those producing and using HTAs with a guide to the methods used to synthesis qualitative research. The guide provides an overview to the main methods with links to further information as an introduction to this specialist area rather than a step-by-step guide. We hope this will provide those new to HTA or new to the inclusion of patient and public needs and preferences, with sufficient information to know when to seek specialist expertise in the use of qualitative research evidence.

We also hope that this report proves a useful introductory text to synthesising qualitative evidence for other purposes, and for students and those trained in quantitative disciplines who wish to know more about this area of research.

2 Executive summary

There is growing consensus that the needs, preferences and experiences of patients should be taken into account in the development and evaluation of new health technologies or service delivery models. It is also acknowledged that such a patient-centred approach should also be extended to HTAs and systematic reviews.

There are several ways of ensuring that the views of patients can be incorporated into HTA and systematic reviews. One way is through identifying and bringing together (synthesising) the relevant research evidence from a variety of individual qualitative studies. While the results from one qualitative study may be difficult to generalise, a syntheses of all the relevant qualitative studies on the same topic can identify a range of common themes as well as any divergent views. Qualitative studies typically use focus groups and/or interviews to gather experiential data from patients and other health service users. Such information can be particularly useful in understanding the barriers and facilitators to the delivery or implementation of new technologies in practice. Qualitative studies, by highlighting the patient perspective, can also help to explain why health and/or social care interventions may be more (or less) effective in some population groups than others.

While methods for the synthesis of quantitative research in healthcare are well established, the synthesis of qualitative research studies is still an emerging methodology and there are currently a range of methods which could be used within HTA and/or systematic reviews. In this report, we describe the most frequently cited methods used to identify and synthesise qualitative evidence and provide examples of how they have been applied in health and/or social care settings. We also discuss the debates and issues surrounding the synthesis of evidence from qualitative studies, such as quality assessment of included papers. We therefore provide a guide for those developing or using HTA reports on the appropriateness of the methods for different types of review and where to find more detailed guidance on how to undertake such syntheses.

3 Introduction

3.1 What is qualitative research and qualitative data?

Qualitative research has developed out of a wide set of disciplines and traditions (eg anthropology, sociology) with a range of underpinning philosophies and no single approach or definition[1]. While the underpinning philosophy may differ, qualitative research does have some common characteristics. It generally refers to research methods that seek to explore people's experiences and understandings through analysing textual data from speech or observation[2]. In particular, it aims to explore and understand the 'hows' and 'whys' of a particular experience or social phenomena. Traditionally, qualitative studies have tended only to focus on such issues and have remained distinct from quantitative studies, although in recent years the 'mixed methods' approach has become more common with both qualitative and quantitative methods being used to answer a research question.

The most common qualitative data collection methods in health research are observation, unstructured and semi-structured interviews and focus groups. (Some people also consider data from surveys, especially from open-ended questions, as qualitative, particularly if the survey's aim was to understand experiences or phenomenon.) Data collected from qualitative methods are therefore textual and rich in meaning. Primary qualitative research studies have specific aims, often underpinned by a particular philosophical or theoretical stance (eg feminist theory, social theory, post modernism) and these can be analysed in a number of ways (eg using grounded theory or phenomenology). Qualitative data analysis generally involves inductive reasoning processes (hypothesis generating) to interpret and structure the data/findings[3]. Influences on the qualitative data analysis process include: the way in which the data were collected; the understanding and interpretations the researcher(s) has of the data; and the theoretical or philosophical 'lens' with which the researcher(s) approaches the data[3]. All these influences need to be considered when synthesising qualitative research and assessing its validity.

3.2 What is a research synthesis?

A research synthesis is a general term used to describe the 'bringing together' of a body of research on a particular topic. The aim is usually to describe, analyse and draw conclusions on the research evidence, and is often used to make decisions about the effectiveness of healthcare interventions. Within the context of HTAs, research syntheses can be of quantitative evidence, qualitative evidence or a combination of the two. Syntheses of quantitative evidence often use rigorous protocols and processes which aim to ensure that they are transparent, systematic and reproducible (eg Cochrane reviews). Common terms and synonyms used to describe such a synthesis include systematic review, meta-analysis[a], and systematic literature review. Quantitative synthesis seeks to focus on an estimate of an effect and reduce uncertainty in that estimate. Synthesisers of quantitative research often use statistical pooling of numerical data (meta-analysis) to estimate the effects of an intervention or treatment. The type of quantitative evidence that is most relevant to HTA

a This term generally refers to the method of combining quantitative data from studies.

includes those that assess the effectiveness of interventions, the 'gold standard' being the randomised controlled trial (RCT), and epidemiological studies such as cohort studies[4]. Primary studies included in reviews of quantitative data tend to use designs and methods which are relatively homogenous. There is little underlying emphasis placed on a philosophical stance and the main aim of intervention studies is to quantify the effects (be it efficacy or effectiveness, benefit or harm) of intervention X versus intervention Y on outcomes A, B and C. The outcome data in such studies are numeric and can be extracted and summarised, for example, using the researchers' own summary statistics as reported in their study paper.

Synthesis of qualitative evidence is, by contrast, more exploratory and may seek to expand understanding of a phenomena or patient experience. Evidence from primary qualitative studies can also be synthesised but there are many different approaches and methods to the identification of studies for inclusion and their synthesis (see later sections). Some approaches use similar, but not identical, methods to quantitative synthesis in terms of searching for relevant primary studies, applying inclusion criteria and assessing the quality of the research. However, the synthesis of qualitative studies can be more complex than the synthesis of quantitative studies. As mentioned previously, qualitative research studies have specific aims, often underpinned by a particular philosophical stance and findings are presented in a different ways. The researcher(s) has to interpret their study data and there is recognition that there may be no universal truth. The degree and type of interpretation can therefore be a major issue for a reviewer trying to synthesise data from several different primary studies. For example, 10 studies looking at the experiences of access to emergency contraception may generate 20–30 themes derived from the participants' findings, some of these themes may be similar but others may not be. Also, some of these researchers may have analysed their data using feminist theory whilst others have taken a less theoretical approach. Thus, the interpretation and presentation of data in these 10 studies may be very different, even if the participants overall are actually saying similar things. The range of approaches to analysis of individual study data means that there is no easy way to extract and combine data on the themes from several studies. By comparison, different quantitative studies often collect data on, for example, outcome A in a similar way so findings can then be combined meaningfully across studies. Importantly, synthesis of qualitative studies usually involves the reviewer(s)[b] providing their interpretation of the original author's interpretation of their participants' views. As such, qualitative synthesis can produce 'third order' findings that is, an interpretation of an interpretation of an interpretation[5-7].

Syntheses and systematic reviews of quantitative literature are conducted and reported using a structured approach which is well documented and recognised[8-11]. In contrast, the methods for synthesising the qualitative literature are still evolving even although over the last decade there has been a noticeable increase in the number of publications reporting synthesis of qualitative studies and a corresponding increase in publications outlining the different approaches which could be used and how to integrate the qualitative literature into

b That is, the person undertaking the synthesis of qualitative studies.

systematic reviews[8,12-16]. Although the syntheses of qualitative literature within the context of HTA and medical research are a relatively recent development, the potential of this process has been recognised in other disciplines since the 1980s, for example, within education[7] and nursing[17].

3.3 Why do a synthesis of qualitative studies?

Various factors have encouraged this recent interest in the synthesis of qualitative studies, particularly in relation to HTA. In particular, there is a now a policy imperative for person-centred services so the needs, preferences and experiences of patients must be central to any discussion about the use of new technologies, treatments and/or service redesign[18]. For example, The HTA Handbook[4] suggests the synthesis of qualitative evidence can be used in HTA in several ways (Box 1).

Box 1: Use of qualitative synthesis in HTAs

In HTAs qualitative synthesis can:

- contribute to decision-makers having the best possible evidence base
- help to assess core patient aspects in relation to a given HTA
- be used to assess whether there is a need for primary research
- be used to gain new insight into relevant patient and/or organisational aspects
- be used to make a generalisation.

Members of the Cochrane Collaboration Qualitative Methods Group have also identified possible ways in which qualitative research can contribute to a systematic review of effectiveness (Box 2).

Box 2: How qualitative research can contribute to Cochrane intervention reviews[14]

Qualitative research can contribute to Cochrane intervention reviews by:

- informing reviews by using evidence from qualitative research to help define and refine the question, and to ensure the review includes appropriate studies and addresses important outcomes
- enhancing reviews by synthesising evidence from qualitative research identified while looking for evidence of effectiveness
- extending reviews by undertaking a search to specifically seek out evidence from qualitative studies to address questions directly related to the effectiveness review
- supplementing reviews by synthesising qualitative evidence within a standalone, but complementary, qualitative review to address questions on aspects other than effectiveness.

Importantly, there is also now explicit recognition of the benefits of using qualitative research in the development and evaluation of complex interventions[19].

Although the synthesis of qualitative research has been be used to integrate study findings from individual qualitative studies[20] and can be used alongside or within quantitative reviews[8], it is important to be aware that not everyone accepts that it is possible, or even appropriate, to synthesise qualitative studies. For example:

> 'Some qualitative researchers argue that the synthesis of qualitative studies is impossible and meaningless. Others support the notion of qualitative synthesis, but there is no emerging consensus on appropriate guidance for the systematic review of qualitative evidence for health and social care'[10].

3.4 The authors' perspective as synthesisers of qualitative literature

The authors of this report take the position that it is possible and appropriate to synthesise qualitative studies, whilst acknowledging some of the challenges and assumptions in doing so. The authors started by undertaking reviews of quantitative evidence, primarily to determine the effectiveness of interventions. Ring and Jepson, two of the report authors, have since undertaken qualitative reviews as 'standalone' projects, as well as using them to understand the results of quantitative reviews. Whilst aware of the differing philosophical stances underlying the various approaches to qualitative synthesis, the authors have adopted a pragmatic approach to their work in this area. The authors also believe that qualitative studies have an important role to play in understanding how factors facilitate or hinder the effectiveness of health technologies.

4 Practical steps and other challenges associated with synthesising qualitative studies

4.1 Terminology

Synthesis of qualitative studies is an emerging methodology and there are many approaches that can be used. Within the literature a wealth of terms are used to describe these different approaches and this can be daunting for those new to the field as they seek to make sense of the situation. This is especially challenging as terms often appear quite similar, for example 'meta-synthesis', 'meta-ethnography', 'meta-narrative', 'meta-study' and 'meta-interpretation', but may have different meaning. Some of these terms just relate to the actual synthesis of the data from the studies, whereas others refer to the whole process of the synthesis, including identification of studies, inclusion and exclusion criteria, assessment of quality and synthesis of the data from the primary qualitative studies. While some authors are explicit in defining their terms, aims and scope, this is not always the case. As such, readers should not assume that authors using the same or similar term, share the same definition or understanding of that term.

'Meta-synthesis' is one frequently used but potentially ambiguous term. For example, it has been defined as 'a method of synthesising qualitative accounts to construct adequate interpretive explanations from multiple studies'[21]. Paterson et al. specifically outline meta-synthesis as a process contributing to their interpretive meta-study approach[22]. However, on other occasions, meta-synthesis is used more broadly as an overarching term for a variety of approaches[20,23,24], sometimes extending to include the use of quantitative methods to aggregate qualitative findings. Meta-synthesis has also been used loosely within the literature as a qualitative equivalent for the quantitative term 'meta-analysis'. Given that 'the roots' of meta-synthesis are 'multi-facted'[23] and that the synthesis of qualitative studies is increasingly being conducted in the context of HTAs and systematic reviews, such difference in meaning is not surprising. In recognition that the term 'meta-synthesis' can be defined by some as having a specific interpretive meaning but be regarded by others more broadly – sometimes even being used interchangeably with other terms which place less emphasis on interpretation – the authors have therefore avoided using this term, where possible.

Differences in terminology are also apparent in the 'categorisation' and naming of the various methods used to synthesise qualitative studies. There is currently no single agreed approach. For example, Finlayson & Dixon identify four methods for synthesising qualitative research (meta-ethnography, grounded formal theory, cross-case analysis and meta-study)[24] whereas others identify nine[8,25]. Even where authors identify the same number of methods for synthesising qualitative studies, variations can still occur, for example some authors consider ecological triangulation to be a method of synthesis but others do not[8,25]. Sometimes too, the different methods to qualitative synthesis are categorised by their individual names[8,24-25], for example meta-ethnography. On other occasions, broader groupings are used, for example overarching categories such as theory building, theory explication and descriptive study[26].

Differences in naming and categorising the various methods used to synthesise qualitative studies have arisen for several reasons. One reason is the

epistemological position of authors and whether they regard such synthesis as focusing exclusively on studies using qualitative research methods and/or involve aggregation of qualitative data. Therefore a number of alternative approaches of categorising the different methods have been proposed[14,20,27] which recognise that reviewers may be linking qualitative findings to quantitative ones and even quantifying qualitative data. Another reason for terminology differences is that whilst it may be helpful to regard the different methods as 'discrete entities'[26] this is not possible as there is overlap[28] with a 'number of superficially distinct approaches [which] exhibit strong underlying similarities'[27]. Additionally, researchers may also adopt more than one method for the synthesis of qualitative studies, for example, using meta-ethnography and grounded theory within the one investigation[29].

Synthesising qualitative research is a complex area. The variety of terms, differences in qualitative primary studies and the discipline of those conducting such reviews, have contributed to discussion, debate and contention over the best methods of synthesis. Readers wanting to know more about such issues are referred to this wider body of knowledge where various authors describe in-depth the associated theoretical issues for example as described by Downie[30].

Only a few examples of how the names and/or categorisation of the different methods of synthesising qualitative research can vary are highlighted in this section. Such examples serve merely to illustrate the complexities associated with this area of research – it is not the authors' intention to criticise the work of others. The authors' purpose was to raise awareness among readers that various approaches to synthesising qualitative literature exist, nomenclature may vary and consideration needs to be given to the approach most suited to the purpose of the synthesis and the reviewer's philosophical position.

4.2 Deciding on the research question

One of the first challenges for a reviewer conducting a synthesis of qualitative studies is to understand which of the many methods is most appropriate for their study. The research question and aims will guide a reviewer's choice of method for synthesising the qualitative data. A reviewer may need to consider:

1. What is the exact nature of the planned synthesis? For example, is the aim to explore aspects of a condition such as living with depression; or is it about evaluating people's experiences of a service such as treatments for depression?
2. What is the context for the research such as the relevant policy and practice?
3. Who is the synthesis aimed at (eg policy makers, healthcare professionals, and/or patients).
4. What is the reviewers' philosophical approach to qualitative research and synthesis?

In many cases, synthesis of qualitative studies will start with a relatively well-defined research question(s). However, depending on the philosophical approach of the person undertaking the qualitative synthesis this may not always be the case – some qualitative synthesisers may modify their initial research question in response to their literature searching and screening[13].

In qualitative research, very few primary studies are likely to have exactly the same research question or focus as that of the planned synthesis, nonetheless

there may be a large number of primary research studies containing some relevant data. For example, a review of studies may be commissioned to answer the research question 'What are the experiences of pregnant women who are recommended by health professionals to reduce their alcohol consumption?' Primary studies may have focused more on women's experiences of drinking alcohol in pregnancy, which is only one aspect of the recommendations by a health professional. The dissonance between the research question of the synthesis and that of the primary researcher's question is less evident in quantitative reviews, where the primary research and synthesis questions may be similar. For example, a quantitative review and a primary study may both want to answer the research question, 'Does cranberry juice reduce urinary tract infections?'

4.3 Study inclusion

Similar to quantitative reviews, there are a number of decisions which will help shape the search strategy and subsequent decisions about which primary studies to include or exclude. Some researchers use a similar approach to systematically identifying and appraising qualitative evidence as they would for a quantitative synthesis. This is particularly evident for reviews of qualitative evidence undertaken alongside reviews of quantitative evidence (eg Cochrane reviews), but there have been debates as to whether this approach is appropriate given the differences in primary data[31].

Use of inclusion criteria within a synthesis of qualitative studies varies depending on the reviewers' underlying philosophical approach. For example, for those conducting a qualitative study synthesis alongside a systematic review of quantitative studies, inclusion criteria are likely to be well defined and explicit. Many reviewers of quantitative evidence devise their inclusion criteria based on the Population, Intervention, Comparison and Outcome (PICO) model[9] which has been adapted for qualitative studies by including the phenomena of interest (P) and context (C)[10]. By comparison, those conducting a standalone synthesis of qualitative studies using grounded theory may decide to include studies based on 'conceptual robustness' and theoretical saturation[32], perhaps adopting a more iterative approach to literature searching and screening. Nonetheless, for studies to be considered appropriate for inclusion, reviewers need to be aware of the following issues:

- The population group and context
- The topic being researched, eg a disease, intervention, service or model of care
- The underlying phenomenon or experience that is being explored such as attitudes, beliefs, knowledge, experience, understanding, facilitators, barriers, perceptions and acceptability
- The type of qualitative data to include and whether to include studies which have a different focus to the review aims.

Context can be an issue for qualitative reviews as well as quantitative reviews[c] as experiences and common understandings may differ according to where and when the research took place. For example, attitudes towards alcohol drinking

c For example, those reviews which focus on interventions to change behaviour which are heavily influenced by attitudes, beliefs and context.

may be different in non-Muslim and Muslim countries; medication use in long-term conditions may vary between countries depending on whether healthcare is publicly or privately funded. The issue of context may need particularly careful interpretation with regard to the applicability of the findings.

Reviewers must also consider whether included studies will use only traditional, participatory qualitative data collection methods such as interviews and focus groups or whether a broader range of evidence will be used. The reviewers' approach to the synthesis of qualitative research may determine the type of data collection methods that are eligible for inclusion. For example, a synthesis on domestic violence included studies predominantly using grounded theory and phenomenological research methods[33] whereas a review on the diffusion of innovation included studies from diverse research traditions (and both qualitative and quantitative research)[34]. A study by Ring and Jepson on the barriers and facilitators to asthma action plans excluded data from interviewer administered questionnaires[35] because such data was considered to lack the necessary conceptual depth.

The number of studies included within a synthesis of qualitative studies is also an issue of debate. While the included studies need to provide depth of insight into the research question, too many may hinder the data analysis process[23,26] so a balance is needed between too many and too few. Whether reviewers include all relevant texts or a sample depends on the reviewer's philosophical position and the purpose of the review. So, for example, a reviewer conducting a synthesis of living with diabetes may choose to sample only those studies which provide the most 'rich description' or 'conceptual clarity'[8]. Readers requiring further information on sampling in the synthesis of qualitative studies should refer to the relevant literature, for example publications by Finfgeld[26] and Dixon-Woods[13]. In practice, the number of included studies is usually relatively small, for example eight[35,36] or 13 studies[33]. What is expected in most syntheses (whether qualitative or quantitative) is that reviewers explicitly and transparently state their criteria for including studies.

4.4 Literature searching

It is widely acknowledged that searching for qualitative studies is a more complex and difficult task than searching for quantitative studies[37,38]. Established methods used for searching and identifying quantitative research do not necessarily translate into effective searches for qualitative studies. There are several reasons for difficulties in searching for primary qualitative studies.

First, although qualitative studies are now indexed as well as other study designs, such as RCTs, this was not always the case (for example, 'qualitative research' was introduced as a MeSH term in MEDLINE only in 2003). Databases also differ in the terms they use to index qualitative studies (in CINAHL, the term used is 'qualitative studies'). The danger of using only indexed terms is that potentially relevant studies may be missed during the search, because inappropriate index terms have been used[32] or papers were published prior to any adequate indexing.

Second, the focus or aim of the research is not always explicit in the title of the primary qualitative research, for example, 'Being serious about humour in healthcare'[39] and 'Courage as a process of pushing beyond the struggle'[29]. Identifying the research focus of a qualitative study is especially difficult when a paper's title consists of a participant quote and/or there is no abstract.

Third, as mentioned previously, the focus of a primary qualitative study might be different from the focus of the qualitative review, therefore, the abstract, title and index terms may not provide details of potentially relevant data. Thus relevant papers may not appear in any search. One way of addressing this problem is to hand-search relevant journals and/or review reference lists of included studies for additional items. Finally, qualitative research is also published in books as well as journals and therefore extra consideration needs to be given to searching this source.

Any search for qualitative studies must take these difficulties into consideration. As with searches for quantitative studies, a search strategy needs to devised and refined (see Section 4.4.1), but this is an area of qualitative reviews that is least developed and tested[40]. Regardless of the approach taken to searching for literature (systematic and comprehensive versus selective or theoretical), it is important to detail how the searches were derived and undertaken and include such details in subsequent publications of the review.

4.4.1 Devising a search strategy and undertaking a search

The process of devising a search strategy to identify qualitative studies can be similar to, or share some similarities with, the process for identifying quantitative studies. There have been several papers published on how to search and locate qualitative studies in the specific electronic databases including MEDLINE[41], EMBASE[42], PsycINFO[43] and CINAHL[44]. Another study reported that a search using broad-based terms was as effective as a complex (free text) one in locating qualitative research examining patients' experiences of living with a leg ulcer[40]. Unlike clinical studies (eg RCTs) where there is a register of trials (the Cochrane Central Register of Controlled Trials), there is no such database for qualitative research. Before beginning to devise a search strategy for a review, it is important to consider the comprehensiveness of the search and time constraints.

Searching for studies is informed by a reviewer's philosophical approach to qualitative synthesis. Some approaches (such as those which mirror the quantitative systematic approach) aim to be comprehensive and identify all the potentially relevant studies. Other approaches to sampling may be more purposive, where the aim is to reach theoretic saturation rather than identify all the relevant studies[14]. Meta-ethnography, grounded-theory approaches and realist synthesis (see Sections 5 and 6) may all use theoretical sampling approaches.

The use of theoretical or selective rather than systematic sampling creates a number of problems. In particular, if the reviewer wants to locate a synthesis of qualitative studies within the paradigm of conventional systematic review methodology, it could be asserted that such reviews are neither transparent or reproducible; they are more (or less) traditional literature reviews of the type that have always been done[13].

Searches need to be developed both for the topic area (eg experiences of breast cancer care) and the types of studies to be included (eg RCTs or qualitative studies). Search strategies, particularly for quantitative studies are usually designed to maximise their sensitivity, specificity and precision (often referred to as 'optimal' search strategies)[45]. Sensitivity is the proportion of articles retrieved that are relevant (meeting inclusion criteria); specificity is the proportion of irrelevant articles (not meeting inclusion criteria) that are not retrieved; and precision is the proportion of retrieved articles that meet inclusion criteria[45].

Optimal searches can necessitate the casting of a wide net in order to identify every possible study and are often very time consuming as they can result in identifying large numbers of non-relevant studies.

It is very difficult to have a search which is highly sensitive and specific, especially when trying to identify complex topics in certain areas. Thus, the researcher may need to decide whether to try and identify every study (which is very time consuming) or whether to aim to have a very specific search which is likely to miss some studies (ie be less than 100% sensitive). Some papers have evaluated the search strategies for identifying qualitative studies across one or more electronic databases[40,46]. One study reported that strategies that attempt to maximise the number of potentially relevant records (high sensitivity) are likely to result in a large number of non-relevant studies (low specificity)[46]. As with identifying quantitative studies it is necessary to search a range of other sources for both published and unpublished studies, such as citation lists, reference lists and the internet. Hand-searching a few relevant journals for studies may also be useful especially if relevant data may be 'buried' within the text of a paper and the study would not be retrieved through electronic searches. For example, in a synthesis of qualitative research focusing on older people's attitudes to sport and exercise, hand-searching the Journal of Aging and Physical Activity (over a time-limited period) could be a useful complement to electronic database searching but will require additional time.

4.5 Selection of studies and data extraction

Once the searches for qualitative studies have been undertaken, the search results are commonly downloaded into a reference manager software (eg Reference Manager, EndNote, Refworks) to enable them to be assessed for relevance. The next step is deciding on which studies to include or exclude, which may depend on the approach used to synthesise the studies. Some approaches have clear inclusion and exclusion criteria whilst other approaches are more iterative (eg realist synthesis). While topic relevance is clearly a reason for inclusion or exclusion, some researchers also exclude studies on the basis of quality (see Section 4.6). Sources of guidance on systematic reviews, such as the Cochrane handbook[9], recommend that two people assess studies for inclusion and exclusion as it adds to the validity and transparency of the review. The authors of this report believe that, regardless of the approach used to analyse, it may be useful to log decisions made at this stage, either through the use of a diagrams such as recommended by Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) (www.prisma-statement.org) or by recording decisions in a transparent way that enables a reader to understand the analytical and decision processes[28]. If there is debate about which studies to include, these can be resolved in discussion with a third reviewer. In some cases, authors of the original studies may need to be contacted for further information before decisions regarding a paper's inclusion can be made.

Data can be extracted in a number of ways. Some people use software packages such as NVivo to organise and extract the data so it can be synthesised relatively easily. To increase accuracy of data extraction, it is also useful to have two people working on this part of the process.

4.6 Quality appraisal of included studies

Quality appraisal of qualitative studies is not as straightforward as for

quantitative studies where there are several validated methods of assessing quality. Indeed, there is currently little consensus as to what are the essential criteria for a high-quality qualitative study and over 100 quality appraisal tools are available[14]. The issue of what constitutes quality in qualitative research is a much contested area and part of a bigger debate over the nature of knowledge generation[47]. Different disciplines may place a higher value on some aspects of study design such as the theoretical perspective or analytical strategy and there are concerns about excluding less well-conducted studies on the grounds of quality as they may still provide important new insights into a phenomenon[5,48-50]. Some view qualitative checklists as reductionist and over prescriptive in nature suggesting that, 'if we succumb to the lure of "one size fits all" solutions we risk being in a situation where the tail (the checklist) is wagging the dog (the qualitative research)'[51]. Thus, there is a concern that checklists are being used to reduce qualitative research to a list of technical procedures.

Questions have also been raised over whether qualitative research can be judged using the same criteria as applied to quantitative research – for example, reliability, validity and generalisability[52]. There are two opposing views on these issues and more detailed discussion is provided in the literature, for example, the paper by Mays et al.[52]. Additionally there is debate over whether there is consistency in judgements made when assessing studies. Dixon-Woods et al.[50] compared three different approaches to qualitative appraisal: unprompted judgement based on expert opinion; a UK Cabinet Office quality framework[53]; and CASP (a Critical Appraisal Skills Programme tool)[54]. They found that the tool-based approaches did not appear to have a higher level of agreement than those using unprompted judgement[54]. Another commonly used quality appraisal tool is Popay et al.'s criteria[55]. Further discussion of the range of checklists (and additional advice and support) is available through the Cochrane Qualitative Collaboration Methods Group and is recommended reading[56-57] for anyone considering synthesising qualitative research studies.

Additionally, different approaches to synthesising qualitative research (such as meta-ethnography, thematic analysis) have their own approach to quality assessment and a discussion of these is presented in a paper by Barnett Page et al.[25]. For example, they note that framework, meta-narrative and thematic synthesis all have specific approaches to quality assessment, whereas other approaches such as meta-ethnography or grounded theory are 'less committed to the concept' of quality appraisal[25].

Organisations which produce systematic reviews, and/or incorporate qualitative evidence into reviews, such as the Evidence for Policy and Practice Information and Co-ordinating Centre (EPPI-Centre), the Centre for Reviews and Dissemination (CRD), the Cochrane Collaboration and the Joanna Briggs Institute (JBI), all assess the quality of qualitative studies. Their different approaches and/or suggested quality tools are outlined in Appendix 1. The EPPI-Centre and JBI both have quality checklists embedded in reviewer software. So, in terms of whether quality assessment should be part of the process of synthesising qualitative studies, there is currently debate and a range of possible options which should be considered by reviewers. In the experience of Ring and Jepson, while they have not used quality assessment as a basis for excluding potential studies from synthesis, they have found the process of quality appraisal useful as it has facilitated their systematic and critical review of included studies, thereby enabling a deeper understanding of their included texts.

5 Specific methods for synthesis of the qualitative studies

5.1 Context and background

There are multiple ways for synthesising qualitative studies and the method adopted depends on many factors including the reviewer's philosophical position and the purpose of the review. In Sections 5 and 6, the authors provide an overview of the various methods which could be used to synthesise qualitative research including within, or alongside, HTA and systematic reviews. These methods have been identified after review of an extensive, but not exhaustive, body of literature from a range of diverse sources including journal papers and guidance documents. The authors adopted an iterative approach to identifying their information sources. They started by identifying existing reference documents describing methods for synthesis of qualitative studies and seminal theoretical texts, for example on meta-ethnography[7]. Using the key terms identified from these sources, the authors then searched databases such as MEDLINE and CINAHL to identify individual research studies using the methods identified in the reference and theoretical texts. The references lists of relevant papers were also reviewed to identify other possible sources and the Internet was also searched.

Where possible in this section, the authors illustrate the theoretical concepts and issues with practical worked examples. As the synthesis of qualitative studies is an ongoing area of debate and discussion, readers should note that the authors present their own interpretation of this complex body of literature. Although the authors discuss the different methods for the synthesis of qualitative research separately, in practice they overlap and are inter-related. There are several reasons for this. One reason is that qualitative research is increasingly being used to better understand clinical issues either through interpretation of, or integration with, quantitative research. In such cases, those conducting a synthesis of qualitative studies may utilise a pragmatic approach, adapting the principles of a specific method(s). An example of this is the study by Ring and Jepson, which used the principles of meta-ethnography and thematic synthesis to integrate qualitative findings with those from an earlier systematic review of RCTs[35]. The authors present several methods which could be used in the synthesis of qualitative research. Other methods also exist but Sections 5 and 6 focus specifically on those methods appearing most often in the published health and social care literature[d]. As mentioned previously, there is no agreed approach to the naming and/or categorisation of the different methods which could be used to synthesise qualitative studies. For pragmatic reasons, methods featured in Section 5 are presented alphabetically – the order is not intended to suggest a hierarchy of importance and/or frequency of use in the literature. Methods outlined are:

- critical interpretive synthesis
- grounded theory synthesis
- meta-ethnography

d On this basis, 'ecological triangulation' (see Barnett-Page & Thomas for details)[25] is not specifically featured in this document as the supporting references while freely available on the internet are of an unknown date.

- meta-interpretation
- meta-study
- meta-summary
- qualitative cross-case analysis
- thematic synthesis.

Most of these methods are detailed at length by leading authors in these fields. Readers should therefore refer to key texts by authors such as Noblit & Hare[7] and Sandelowski & Barroso[58] for further information.

5.2 Critical interpretive synthesis

This method, which has the potential to generate theory, was developed by Dixon-Woods et al. as a means of conducting an interpretive synthesis of all types of evidence in a specific field[49]. Although the term 'interpretive synthesis' appears in the literature much earlier, for example by Jensen & Allen in the 1990s[59], the focus in this section is specifically critical interpretive synthesis and the work of Dixon-Woods et al.[49].

Critical interpretive synthesis applies to the whole process of the review, not specifically the synthesis element[25]. Dixon-Woods et al.[49] propose critical interpretive synthesis as a model 'sensitised to the kinds of processes involved in a conventional systematic review while drawing on a distinctively qualitative tradition of enquiry'. Critical interpretive synthesis is therefore adapted from, or influenced by, other approaches especially grounded theory and meta-ethnography (see Sections 5.3 and 5.4) and is an iterative process. Dixon-Woods et al. apply their model to a study of access to healthcare by vulnerable groups[49]. For example, they note their approach was useful as it was 'neither possible nor desirable to have a precise review question' at the outset of their investigation so their research question was refined in response to the outcome of their literature search[49]. A summary of the key processes involved in critical interpretive synthesis is shown in Box 3.

Box 3: A summary of the key processes involved in critical interpretive synthesis (from Dixon-Woods et al.[49])

- Identification of an initial review question (which is modified as the study progresses)
- Literature searching and sampling
- Determining quality of possible papers
- Extracting data and/or summarising included papers
- Analysing included papers, eg 'developing a critique, generating themes and [producing] new theoretical conceptualisation'.

5.3 Grounded theory synthesis/formal grounded theory

Grounded theory was initially developed as an interpretive method for primary research, especially for investigations of social phenomenon[60]. Grounded theory synthesis (sometimes known as the constant comparative method) uses an

inductive approach for data analysis and has been used as a method of theory building[26]. Barnett-Page & Thomas[25] provide a comprehensive overview of the background to grounded theory and its use in the synthesis of qualitative studies.

The most frequently cited examples of the synthesis of qualitative research using grounded theory appear within the nursing literature and focus on topics such as domestic violence[33] and aspects of caring[61-62]. Such papers provide useful guidance on how these researchers conducted their studies. Whilst grounded theory has been used to synthesise 'like methods or like materials'[33], it has also been used to analyse studies with different epistemological perspectives such as phenomenology and concept analysis[62]. Grounded theory synthesis has a place in qualitative synthesis; however its potential within the context of HTA is yet to be fully explored and currently other methods especially meta-ethnography are used more widely.

5.4 Meta-ethnography

Meta-ethnography is based on the 1980s work of Noblit & Hare in education[7]. In recent years, based on the significant increase in published papers using the principles of this approach, meta-ethnography has emerged as a leading method for synthesising qualitative healthcare research. For example, it has been used in understanding long-term conditions such as diabetes[63], chronic fatigue syndrome[64] and medicine taking[65]. In the context of HTA, meta-ethnography could be used to aid interpretation of findings from quantitative studies, perhaps as a 'parallel synthesis' with findings 'juxtaposed alongside' those from a systematic review of trial-based evidence[14].

The process of meta-ethnography involves seven steps (see Box 4) which should result in production of a new 'third order' interpretation by bringing together findings from individual interpretive accounts[7,25,52]. To provide this new insight, meta-ethnography utilises the participant findings and author interpretations reported in the original studies. As such, qualitative studies used in meta-ethnography are generally conceptually rich. To synthesise these qualitative studies and produce a new third order interpretation, meta-ethnography uses a variety of methods including 'reciprocal translation analysis' and 'line of argument synthesis'[7]. These methods are detailed in theoretical texts[7,25,52] and in seminal worked examples[5,63] so, readers are referred to such sources.

Box 4: The seven steps of meta-ethnography (from Noblit & Hare)[7]

1. Getting started (the search)
2. Confirming initial interest (literature screening)
3. Reading studies and extracting data
4. Determining how studies are related (identifying common themes and concepts)
5. Translating studies (checking first and/or second order concepts and themes against each other)
6. Synthesising translations (attempting to create new third order constructs
7. Expressing the synthesis.

Meta-ethnography is one approach to synthesis that can have an important role to play in HTA reviews. For example, Ring and Jepson used meta-ethnography to obtain new insight and meaning into the barriers and facilitators to asthma action plan use[35] - insight which enabled a better understanding of the trial interventions which an earlier systematic review identified as effective in promoting action plan ownership and use[66]. Although it is over 20 years since meta-ethnography was first identified[7] and a considerable number of researchers have since applied meta-ethnography to healthcare issues, this is still an evolving method. Those wishing to undertake a qualitative synthesis and who want more detailed information about how Noblit & Hare's principles[7] have been applied in practice should refer to these published examples[5,63].

5.5 Meta-interpretation

Within the context of healthcare, meta-interpretation has been used infrequently. An early definition (from the 1990s) is that 'meta-interpretation is a study in which findings from multiple qualitative research projects are synthesised and new translations of the phenomenon under investigation are generated to create a more theoretically dense conceptualisation'[29]. Finfgeld's model of meta-interpretation, which was procedurally guided by meta-ethnography with grounded theory providing the epistemological and methodological basis, focused on the courage used by those managing life with persistent threats to their wellbeing, and is perhaps the most frequently cited example of meta-interpretation in healthcare[29].

Subsequently, a more specific method of meta-interpretation has been proposed by Weed[67-68] within the discipline of sports science. The 'fundamental features' of Weed's model[67-68] – outlined in Box 5 – enable the synthesis of qualitative research in a way that 'maintains an interpretive epistemology congruent' with the original studies[67-68]. Weed's model of meta-interpretation appears to be currently untried in a health-specific context although some aspects of Weed's model such as the 'celebration of differences in the studies being synthesised' are in common[68] with Paterson et al.'s meta-study approach[22] (see Section 5.6) which has been used in healthcare. For those undertaking qualitative synthesis within the context of HTA and systematic reviews, they may opt to use other more established approaches. Readers wanting to know more about Weed's model and its fundamental features are referred to the descriptions and illustrations in his writing[67-68].

Box 5: The seven fundamental features of meta-interpretation as described by Weed[67-68]

1. The role of the synthesiser as an active interpretive agent
2. A recognition that the synthesis will be 'an interpretation' rather than 'the interpretation' of collection of studies
3. An ideographic approach to the development of exclusion criteria
4. An iterative approach to the theoretical sampling of studies for synthesis
5. A focus on 'meaning in context'
6. Interpretations as the 'raw data' for synthesis
7. A transparent audit trial demonstrating the integrity and trustworthiness of the synthesis.

5.6 Meta-study

Meta-study involves critical interpretation of existing qualitative research[22]. Before synthesis of the qualitative literature can take place and a new interpretation obtained, three analytical phases are completed – 'meta-theory, meta-method and meta-data analysis'[69]. These three phases (defined in Box 6) can be briefly summarised as respectively, the 'analysis of theory', 'analysis of methods' and the 'analysis of findings'[25]. These three analytical processes, which can be conducted concurrently 'provide a unique angle of vision from which to deconstruct and interpret' a body of qualitative literature[22]; for example, they can help to identify a study's underlying theoretical assumptions. Once these analytical processes have been completed, meta-synthesis is then required to 'bring back together ideas that have been taken apart' and create a new interpretation of the phenomenon under investigation[22].

A comprehensive guide to meta-study is available and readers requiring more information are referred to this seminal text[22]. Although meta-study was derived from a sociological and anthropological perspective[70], it has been used within healthcare especially nursing. The most notable example is the study by Thorne et al. of living with chronic illness[70]. It has also been used more recently, for example to investigate aspects of specialist and advanced nursing practice[71] as well as information and shared decision-making in healthcare consultations[72]. Researchers using meta-study may also adopt other approaches within the analytical processes, for example using meta-ethnography during meta-data analysis[72].

Box 6: The three analytic phases involved in meta-study[69,70]

Have been defined by Thorne[70] as:

- Meta-theory: examination of the theories that led researchers to identify relevant research topics; frame research questions in certain ways; and determine such factors as inclusion criteria, 'angle of vision', and 'interpretive lens'.
- Meta-method: thoughtful examination of the manner in which the methodological approach used to gather and interpret data shapes the findings that emerge from a particular study.
- Meta-data analysis: re-interpretation of the actual findings from the original qualitative studies in light of data and findings from other studies.

5.7 Meta-summary

Qualitative meta-summary is an approach for 'quantitatively oriented aggregation of qualitative findings that are themselves topical or thematic summaries or surveys of data'[58,69,73]. Meta-summary therefore includes quantitative processes such as the identification of the frequency of individual findings[58,73]. Integrative meta-summaries can be conducted on their own, or in association with more traditional qualitative synthesis, and can include qualitative and quantitative descriptive findings[58,73]. Given that meta-summary reflects a quantitative perspective and can be used with survey data, which is often excluded from some qualitative synthesise as it lacks conceptual depth and richness, this approach has a potential role in HTA and systematic reviews. Qualitative meta-summary techniques are shown in Box 7 and readers are

referred to Sandelowski & Barroso's handbook for details[58]. Although meta-summary has been applied in a study of factors associated with adherence and non-adherence in anti-retroviral therapy in human immunodeficiency virus (HIV)-positive women[73], this approach is still relatively underutilised in the healthcare context.

Box 7: Techniques used in qualitative meta-summary[58,73]

Leading authors in this field[58,73] have identified these as:

- Extracting findings, separating them from other elements of the research report
- Editing findings to make them accessible to readers
- Grouping findings in common topical domains
- Abstracting and formatting findings
- Calculating frequency and intensity size effects (ie 'this constitutes a quantitative transformation of qualitative data… [with the purpose of] extracting more meaning from the data and verifying …patterns or themes' [58].

5.8 Qualitative cross-case analysis

Cross-case analysis is a method of synthesis which uses tables and/or matrices to summarise data across both qualitative and quantitative studies[27,52,74]. Qualitative cross-case analysis can be informed by various theoretical approaches, such as Miles and Huberman's approach to data analysis[75]. A report by Mays et al. provides an excellent overview of qualitative cross-case analysis including related theory as well as strengths and limitations of the method so readers are referred to this source for more details[52]. To date, qualitative cross-case analysis has not been widely used in the context of health or social care. McNaughton appears to use this method to conduct a synthesis of 14 studies reporting on the practice of home visiting by American public health nurses[76]. The aim of this synthesis was to examine 'the original author's description of research findings and to find common themes and relationships among the [varying] research reports'[76]. Full details of how the principles of Miles & Huberman's data analysis[75] can be applied for the purpose of synthesising qualitative studies are provided in McNaughton's paper, for example through the use of coding[75-76].

5.9 Thematic synthesis

Thematic analysis is another method used for analysing qualitative data, particularly (but not exclusively) alongside quantitative data synthesis. It was first used and developed by researchers from the EPPI-Centre to address questions around 'what works', primarily in relation to health promotion interventions. The researchers synthesised qualitative research and quantitative research separately then integrated their findings[77]. Most recently, this method has been used in synthesising findings from multiple qualitative studies in systematic reviews. Thomas and Harden developed a new approach called thematic synthesis which draws on the principles of primary qualitative research and other established methods[78]. It identifies the recurring themes or issues in the primary literature, analyses these themes and draws conclusions in

systematic reviews. The purpose of this method is to develop analytical themes through a descriptive synthesis and find explanations relevant to a particular review question. This method was developed to address specific review questions about need, appropriateness and acceptability of interventions, as well as effectiveness. People's views and experiences are taken into account, and hypotheses that could be tested against the findings of qualitative studies are generated.

The process of thematic synthesis involves three steps which overlap to some degree (see Box 8) and is illustrated in a published review on health promotion[78].

Box 8: The stages of thematic synthesis (from Thomas[78])

- Free line-by-line coding of textual findings from primary studies.
- Organisation of free codes into 'descriptive' themes.
- Generation of 'analytical' themes – using the descriptive themes, reviewers produce a new interpretation which goes beyond the original studies.

The development of descriptive and analytical themes using coding invokes reciprocal translation and constant comparison. As such, this method shares some characteristics of meta-ethnography and grounded theory.

Thematic analysis, as described above, has been used in multiple reviews[36,79-85] in the following topic areas: health promotion[36,79,84]; chronic kidney disease[81]; organ transplantation[85]; the patient-doctor relationship[83]; practice-based learning[82]; and lay understandings of cancer risk[80]. There is also a worked example of thematic analysis in relation to lay views on infant size and growth available[86]. Most recently, it has been used in synthesising findings from multiple qualitative studies in a systematic review of children's views of obesity[87].

6 Other methods of synthesising research evidence

This section outlines two methods which are not necessarily specific for synthesising qualitative data (although qualitative evidence can form part of the synthesis) but may be of use to people undertaking HTAs.

6.1 Realist synthesis

Realist synthesis (also known as realistic synthesis or realist review) is a relatively new 'approach to reviewing research evidence on complex social interventions which provides an explanatory analysis of how and why they work (or don't work) in particular contexts or settings'[88-90]. Realist review and synthesis 'can combine theoretical thinking and empirical evidence' in a form that can be of value to decision and policy makers[88]. As such, realist synthesis is associated with evidence-based policy and practice but has a potential role in the synthesis of qualitative studies. The process of realist synthesis involves several stages, which can be iterative, and was developed in response to the more rigid, traditional approach to systematic reviews[88]. A brief description of the key steps in realist synthesis is outlined in Box 9 and readers wanting to know more about this method are referred to the relevant seminal texts[88-90].

There are a number of published reviews which have used realist synthesis[91-97] for a wide range of topics. These include prevention of childhood obesity[91], school feeding programmes[92], housing/homelessness and mental health[93,96], practice development[94-95], and internet-based medical education[97]. Again, readers are referred to these sources for further details of how to undertake a realist synthesis to answer a research question.

Box 9: Key steps in a realist synthesis (from Pawson[88-90])

1. Identifying the scope of the review
2. Search and appraise the evidence
3. Extract and synthesise the findings, eg using constant comparison, identification of contradictory evidence
4. Draw conclusions and recommendations – this includes production of a conceptual summary.

6.2 Narrative synthesis

Like meta-synthesis, narrative synthesis is a term that can have different meanings. For example, while some may consider a conventional literature review or a general descriptive discussion to be a narrative synthesis, others see it as being a way of synthesising quantitative studies where meta-analysis is not possible (eg where there is too much heterogeneity). In recognition of the 'lack of consensus regarding the constituent elements of a narrative synthesis and how best to promote trustworthiness in the process'[74,98-99], guidance for conducting narrative synthesis has been developed[98] and readers are referred to this important source and related supporting texts[74,98-100].

In the context of systematic review and synthesis of findings from multiple studies, narrative synthesis has a place in HTA reviews. For example, it could be used prior to meta-analysis. Although narrative synthesis can involve statistical

summary, its 'defining characteristic is that it adopts a textual approach to synthesis'[74], relying primarily on the use of words and text to summarise and explain the findings[98-99].

Popay et al. identify four main elements to the process of narrative synthesis[98] (Box 10) and acknowledge that researchers are likely to proceed through these stages iteratively. The guidance on narrative synthesis in systematic reviews focuses on the effects of interventions and the factors influencing intervention implementation[98]. Two methodological papers demonstrating the practical application of this guidance are available reviewing intervention effectiveness and implementation in the area of domestic smoke alarms[99-100].

Box 10: The four main elements of narrative synthesis (from Popay[74,98])

- Developing a theory of how the intervention works, why and for whom
- Developing a preliminary synthesis of findings of included studies
- Exploring relationships in data
- Assessing the robustness of the synthesis.

The tools and techniques which could be used in narrative synthesis, for example textual description of the original studies, are comprehensively described elsewhere. Some methods of narrative synthesis such as translating data through thematic analysis[98] have echoes of other approaches to qualitative synthesis. Whereas other techniques, such as those for exploring relationships within and between studies using funnel and forest plots, are traditionally more associated with quantitative rather than qualitative synthesis. Narrative synthesis can be applied to studies gathering qualitative data using methods such as focus groups and interviews[100]. Ultimately whether narrative synthesis is used depends on the research questions which need answered and the researcher(s) epistemological position that is, whether they wish to conduct a synthesis more grounded within the philosophy of the qualitative paradigm.

7 Conclusions

Incorporating qualitative research specifically within HTAs and systematic reviews is a relatively recent development but researchers in a range of disciplines have been synthesising qualitative studies for some time. There is a considerable body of knowledge in this area, both theoretical guidance and practical worked examples. The literature relating to the synthesis of qualitative literature is however complex, especially as several different approaches exist and terminology is often used interchangeably and inconsistently. This is perhaps not surprising as the field is still evolving and those synthesising qualitative research may approach the studies from differing epistemological stances. For example, a researcher synthesising qualitative studies to inductively understand a social phenomenon may adopt a different method from one synthesising qualitative studies with the purpose of better understanding the effects of an empirically-tested clinical intervention. Alternatively, a researcher planning to synthesise qualitative research primarily as a means of generating theory may use a different approach from one who intends to apply the results to answering a specific clinical question. In addition, it is not uncommon for researchers to use the principles of more than one method for synthesising qualitative studies within a single study. Nonetheless, at the time of writing, there are certain methodologies which already appear to be leading the field in healthcare. In particular, these are: meta-ethnography for the synthesis of qualitative studies; thematic synthesis for the integration of qualitative findings with those from quantitative systematic reviews; and realist synthesis to combine a range of evidence.

This document only provides an outline of possible methods. Those wishing to undertake a synthesis of qualitative studies within the context of an HTA or systematic review – as well as commissioners and funders of such research – might wish to consider the aim(s) and objective(s) of their review and the outcome required, and select the method(s) accordingly. Finally, researchers are also advised to familiarise themselves with the theoretical and practical guidance associated with the approach(es).

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10 Appendix 1

Methods of quality assessment used by organisations producing HTA

EPPI-Centre	
Underlying approach Different tools are used, but all focus on 'review specific assessments' which consider appropriateness of the methodology used in an individual study for answering the reviews question[e]. **Quality criteria** One tool developed by member of the EPPI-Centre uses eight criteria which cover: i) methods (the rigour of study sampling, data collection and analysis) ii) findings (the grounding/support of study findings by data and the breadth and depth of the findings themselves) iii) the use of methods/approaches to privilege participant's views. A framework is used by EPPI-Centre[f].	**Scoring** Weight of evidence (WoE) approach: A = (methodological quality) B = (methodological relevance) C = (topic relevance) D = Judgement of overall WoE Total of A-C.
CRD	
Underlying approach Gives examples of five checklists[8]. **Quality criteria** Popay *et al*.[55] CASP[54] UK Cabinet Office quality framework[53] Long & Godfrey[101] Walsh & Downe[102]	**Scoring**
Cochrane Collaboration	
Underlying approach Provides an overview and suggests two framework tools and further reading[14]. **Quality criteria** They assert[56] that quality appraisal involves: (i) filtering against minimum criteria, involving adequacy of reporting detail on the data sampling, collection and analysis (ii) technical rigour of the study elements indicating methodological soundness (iii) paradigmatic sufficiency, referring to researchers' responsiveness to data and theoretical consistency. EPPI-Centre framework JBI framework (see next section) UK Cabinet Office quality framework[53]	**Scoring**

e http://eppi.ioe.ac.uk/cms/Default.aspx?tabid=177

f URL: http://eppi.ioe.ac.uk/eppireviewer/login.aspx

JBI	
Underlying approach No details provided in JBI manual[10] **Quality criteria** There is congruity between the stated philosophical perspective and the research methodology. There is congruity between the research methodology and the: (i) research question or objectives (ii) methods used to collect data (iii) representation and analysis of data (iv) interpretation of results. There is a statement locating the researcher culturally or theoretically. The influence of the researcher on the research (and vice-versa) is addressed. Participants and their voices are adequately represented. The research is ethical according to current criteria or, for recent studies, there is evidence of ethical approval by an appropriate body. A statement on the ethical approval process that was followed should be in the report. Conclusions drawn in the research report do appear to flow from the analysis, or interpretation, of the data.	**Scoring** Scored: yes, no, unclear. Not clear how criteria are subsequently used in the review.

11 Abbreviations

CADTH	Canadian Agency for Drugs and Technologies in Health
CASP tool	Critical Appraisal Skills Programme tool
CRD	Centre for Reviews and Dissemination
EPPI-Centre	Evidence for Policy and Practice Information and Co-ordinating Centre
EUnetHTA	European Network for Health Technology Assessment
HIV	Human immunodeficiency virus
HTA	Health technology assessment
JBI	Joanna Briggs Institute
NHS QIS	NHS Quality Improvement Scotland
PICO	Population, Intervention, Comparison and Outcome
PRISMA	Preferred Reporting Items for Systems Reviews and Meta-analysis
RCT	Randomised controlled trial
WoE	Weight of evidence

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The Scottish Health Council, the Scottish Intercollegiate Guidelines Network (SIGN) and the Healthcare Environment Inspectorate are key components of NHS QIS.

HEI Healthca re Envir onment Inspectorate

SIGN
Scottish Intercollegiate Guidelines Network

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