# Chapter 6: Mixed methods synthesis: a worked example

## Josephine Kavanagh1,Fiona Cambell2, Angela Harden3 and James Thomas1

### 1 EPPI-Centre, Social Science Research Unit, Institute of Education

### 2 School of Health and Related Research, University of Sheffield

### 3 Institute for Health and Human Development, University of East London and Newham University Hospital Trust

## Abstract

The issue of integrating both qualitative and quantitative data has grown in importance. Systematic reviews of complex social and public health interventions increasingly address questions that go beyond ‘what works’ and ask ‘what works - for whom - and under what circumstances?’ Answering these broader questions requires the inclusion of qualitative studies in research synthesis which address the understanding, attitudes, behaviours and experiences of the targets of interventions. While there is a strong body of research on methods for reviewing quantitative and qualitative evidence, methods to enable the synthesis of the two remain less well developed.

A mixed methods approach to research synthesis developed by researchers at the EPPI-Centre is described here. Three distinct stages of the review process support the integration of two epistemologically diverse traditions. The first stage is a traditional systematic review of effectiveness (with or without meta-analysis); the second a synthesis of qualitative research which addresses questions of intervention need, implementation, acceptability and appropriateness; and, finally a cross-study synthesis which brings the findings of both earlier syntheses together. Methods for stage one are well established and reported. For stage two of the mixed-methods framework a thematic synthesis is proposed by the authors. Thematic synthesis builds upon the techniques of grounded-theory and meta-ethnography. It involves: the coding of text ‘line by line’; the development of descriptive themes; and, the generation of ‘analytical themes’. Implications for interventions are derived from the analytical themes and are linked to the findings of the effectiveness review in the final cross-study synthesis. This final stage is a comparative analysis which juxtaposes the findings of both syntheses to identify appropriate and acceptable interventions which match the needs and experiences of those targeted by interventions.

The mixed methods approach is illustrated in a case example of a systematic review dietary and physical activity interventions for weight management in pregnancy. This review found that important factors that influence maternal weight gain were not addressed by the intervention studies, such as: the difficulty women encounter when seeking to use gym facilities when pregnant; and, the conflict between lay health beliefs held by the wider family and healthy eating messages.

## Introduction

Earlier chapters have described a range of methods for qualitative evidence synthesis, summarising how qualitative synthesis can contribute to evidence-informed policy and practice decision making across a number of fields. In this chapter we describe an approach to integrating both quantitative and qualitative research in systematic reviews using a mixed methods approach. This approach combines the statistical meta-analysis of the findings from trials to answer questions about ‘what works?’ with, the thematic synthesis of the findings from qualitative research to address questions of experience, process and context. The methods described in this chapter were developed by researchers at the Evidence for Policy and Practice Information and Co-ordinating (EPPI) Centre, in the Social Science Research Unit at the Institute of Education, University of London in the UK (Harden and Thomas, 2005; Oliver et al., 2005; Thomas et al., 2004), and have since been endorsed and adopted by other researchers and research groups around the world (e.g. Chalmers, 2005; Ely et al., 2007; Roberts and Noyes, 2009). The resulting systematic reviews are a type of mixed methods systematic review which have been defined as reviews that combine “the findings of qualitative and quantitative studies within a single review in order to address overlapping or complementary questions” (Harden and Thomas, 2010, p750). In this chapter we describe in more detail the origins and theoretical underpinnings of the method, outline the steps involved and provide a worked example to illustrate the method in action. The review used as the worked example was led by a team at the University of Sheffield in the UK and was conducted independently of the team who developed the mixed methods approach. We end the chapter with some reflections on the strengths and challenges of this approach to integrating qualitative and quantitative research in systematic reviews.

**Origins and theoretical assumptions**

The mixed methods approach to integrating qualitative and quantitative research in systematic reviews described in this chapter was developed within an EPPI-Centre programme of work on evidence-based health promotion and public health funded by the English Department of Health. Initially, policy makers sought systematic reviews addressing intervention effectiveness. However, questions about ‘what works?’ were soon supplemented with questions about ‘what works – for whom – and under what circumstances’, as well as questions about health needs, appropriateness and acceptability. Answering these questions required the inclusion of what is often described as ‘qualitative’ research, and in particular, research which reported the perspectives and experiences of the population groups that health promotion and public health interventions are targeted at. We began to use the term ‘views’ studies as a shorthand to describe these largely qualitative studies, because they shared a central characteristic – the primary focus being one which privileges the views and experiences of participants themselves to uncover their worldview. Including qualitative research in systematic reviews of effectiveness posed a significant challenge to the EPPI-Centre team, who embarked on this work in 1999, in that no standard method or template for the quality assessment and synthesis of qualitative research alongside trials in systematic reviews had yet emerged.

The teams’ starting point for the synthesis of qualitative research and its integration with quantitative research was to adapt the standard systematic review model designed to answer questions of effectiveness - developed and promoted with great success by, for example, the Cochrane Collaboration - and to draw on methods already established for data analysis in primary qualitative research. In their adaptation of the standard systematic review model the team worked with several key principles: transparency (to be explicit about the methods used to integrate different types of studies); error avoidance (to use strategies to enhance the rigor of our reviews); user involvement (to consult and negotiate with policy makers at several points throughout the review process to ensure that the review would be relevant as well as scientifically robust); matching and adapting review methods according to the study type under review; a complementary rather than competing view of qualitative and quantitative research; and a commitment to learning from the experiences of the intended targets of the policies and practices under review.

The systematic review and synthesis of qualitative research *and* its integration with quantitative research are not without controversy and epistemological conundrums. Some qualitative researchers oppose the synthesis of qualitative findings outright arguing that combining findings from different studies would divorce findings from their original research context. Other qualitative researchers support the synthesis of findings across multiple studies but argue that the traditional systematic review framework is a ‘quantitative’ enterprise that is not appropriate for the review of ‘qualitative’ research (e.g. Dixon-Woods et al., 2006). There are echoes of the paradigm wars in this position whereby the qualitative and quantitative research paradigms are seen as incommensurable because of fundamental epistemological differences. From this view there is little point in integrating qualitative and quantitative research. As Guba (1987, p31) notes, one paradigm precludes the other ‘just as surely as the belief in a round world precludes belief in a flat one’. However, as Creswell (2010, p54) argues, the ‘paradigm debate’, which asserted that work undertaken in different paradigms cannot be mixed, has diminished in recent years and there are now a range of “paradigm stances” that researchers can adopt when mixing methods such as a the complementary strengths stance (whereby the paradigms are seen as different rather than incompatible, but because they are different they should be kept separate in mixed methods research) or an alternative paradigm stance (whereby a single paradigm provides the foundation for integrating the research, and this foundation may be found in, for example, pragmatism or a transformative-emancipatory perspective). Our starting paradigm stance for mixed methods systematic reviews was a complementary strengths one.

In a recent critical overview of methods for qualitative research synthesis Barnet-Page and Thomas (2009) constructed a useful typology of synthesis methods based on their epistemological foundations. The typology divides synthesis methods into two broad camps: idealist, that err more toward social constructivist viewpoints; and realist, that assume the existence of an external reality, albeit with the acceptance that research can only ever be a representation of that reality. Idealist approaches are characterized by being flexible in their approach to identifying and assessing the quality of the literature they contain, and are more likely to aim to locate it within its disciplinary context. Examples of idealist approaches are critical interpretive synthesis (Dixon-Woods et al., 2006b) and meta-narrative mapping (Greenhalgh et al., 2005). Realist approaches follow methods that are similar to the traditional systematic review with pre-specified search strategies and predetermined inclusion and quality criteria. In addition, they are less likely to use the paradigm within which the primary research was conducted as part of their analysis. The epistemological foundation of our approach to the synthesis of qualitative research is towards the realist end of the idealist-realist continuum.

**Steps in a mixed methods approach**

The mixed methods approach has three distinct elements or stages which enable learning to be integrated from two epistemologically diverse traditions. The first element is a traditional systematic review of intervention effectiveness (with or without meta-analysis); the second a synthesis to address related question of process, context of meaning using qualitative research; and, finally a cross study synthesis (figure 1). As noted above, a key principle underpinning this mixed methods approach are that it should maintain the existing principles of systematic reviews, remaining question driven, transparent and where possible and appropriate, select, appraise, and synthesise all research evidence relevant to the question(s).

- Insert figure 1 about here -

***1) The effectiveness synthesis***

The first synthesis aims to address questions about the effects of interventions and to estimate the balance of benefit and harm from the intervention(s) under review. The effectiveness synthesis follows established methods for systematic reviews of intervention effects incorporating statistical meta-analysis when appropriate. These methods have been described in great detail elsewhere, and are not repeated here (e.g. Egger et al., 2001; Higgins and Green, 2009; Lipsey and Wilson, 2001). Following exhaustive searching, systematic screening, quality appraisal and data extraction the effect sizes from trials are pooled. Variation (heterogeneity) may be explored using sub-group analyses on a limited range of categories, specified in advance (e.g., study quality, study design, setting and type of intervention). Exploratory narrative analysis may also be used to compare characteristics of interventions showing harmful effects, no effects, or positive effects. Such an analysis can reveal several potential explanations for heterogeneity in effects, but these must be viewed as speculative since it is difficult to avoid data dredging with this type of analysis.

***2) The qualitative synthesis***

The second synthesis aims to address different questions, albeit, questions related to effectiveness such as those about intervention context, implementation, appropriateness, acceptability and need. In EPPI-Centre reviews these questions have frequently been framed around the perspectives and experiences of the intended recipients of interventions under review. Thematic synthesis - a synthesis method developed within EPPI-Centre reviews (Thomas and Harden, 2008) - has often been used in the centre’s reviews to synthesise the qualitative (and other types of research) which examine perspectives and experiences. Other researchers adopting our mixed methods approach have used other qualitative synthesis methods such as meta-ethnography.

Thematic synthesis (box1) builds upon some of the principles and techniques from meta-ethnography (Noblit and Hare, 1988) and grounded theory (Strauss and Corbin, 1998), and has been facilitated through the use of the web-based systematic review software EPPI-Reviewer (Thomas et al., 2010). The term ‘thematic synthesis’ has been employed to acknowledge that this synthesis method builds upon methods for thematic analysis for primary qualitative research. The “raw data” for this synthesis are the text from study reports that are labeled by the authors as “findings” or “results.” These data are to some extent interpretative, however as described earlier a primary focus of ‘views’ studies is to privilege the views and experiences of the research participants .

- Insert box 1 about here -

The data for the synthesis are entered verbatim into a qualitative analysis software package and subjected to thematic synthesis. Thematic synthesis is conducted in three main stages: (1) the coding of text “line by line,” (2) the development of “descriptive themes,” and (3) the generation of “analytical themes”. The starting point for the first two stages of the analysis is the findings of the studies themselves without necessarily any direct reference to the questions of the review. The review questions do, however, drive the third stage when analytical themes are generated, and this is a crucial step in the preparation for the third cross-study synthesis. From the analytical themes, a set of implications for interventions can be derived which helps to link the findings of the qualitative synthesis to the effectiveness synthesis. In the worked example provided implications for policy and intervention development were reached through a consensus method involving the reviewers and stake-holders (patient groups, commissioners of review, and experts).

***3) Cross-study synthesis***

The analytical themes and associated implications for interventions are the starting point for the integration of the “qualitative” and “quantitative” phases of the review. The integration is carried out in two main stages. First, all of the interventions evaluated by the trials are assessed for the extent to which they address or incorporate the implications for interventions derived from the qualitative synthesis. The results of this analysis can be charted within a conceptual and methodological matrix which plots the implications for interventions against the trials. This enables the identification of interventions that match or address the implications for interventions derived from the qualitative synthesis; those that represent a mis-match; and research gaps.

This kind of comparative analysis, which juxtaposes the findings from the first synthesis against the findings of the second, identifies appropriate and acceptable interventions which capture the needs and experiences of those targeted by interventions. The analysis also reveals aspects of those needs and experiences that have been ignored (or were unknown) by those developing and evaluating interventions.

The cross-study synthesis can be pushed one step further in situations when there are sufficient numbers of well-evaluated interventions that either match or do not match the implications for interventions derived from the qualitative synthesis. In these situations, the effect sizes of those interventions that address and those that do not address the implications for interventions can be compared. Standard statistical tests can be conducted to test whether interventions that did address the implications for interventions had a bigger effect size than those that did not. Caution is, however, advised in interpreting the findings of these tests; the method might be considered to be a good way of generating hypotheses for future interventions to test, rather than for determining critical policy or practice decisions.

**A worked example**

We have chosen to illustrate the stages and methods of a mixed methods systematic review using a systematic review of dietary and physical activity interventions for weight management in pregnancy. This review was conducted by researchers from Sheffield University in the UK, and was commissioned to provide evidence to support public health guidance produced by the National Institute of Health and Clinical Excellence (NICE) in England. This review aimed to systematically review evidence of the effectiveness, acceptability and feasibility of dietary and physical activity interventions for weight management in pregnancy. It is an excellent example of how a mixed methods approach can provide policy makers with evidence of how the contextual factors which surround intervention delivery can influence intervention effectiveness. For example researchers sought to examine how the intervention setting, intervention provider, or personal and social beliefs and views of pregnant women (and their families and health care providers) about diet, physical activity and weight management in pregnancy might influence intervention effectiveness.

In this section we describe the background to the review and how the team conducted the review focusing in particular on the decision-making that went on throughout the process of developing the questions for the review; drawing up the review protocol and other preparatory work; searching for relevant studies; appraising quality; extracting data; and synthesis.

***Background to the review and question development***

Excessive weight gain in pregnancy is an important public health concern in the UK and elsewhere. For example, in the UK approximately 20 per cent of pregnant women are obese, and 43 per cent gain excessive weight (Kanagalingam et al., 2005). Women who are overweight or obese have an increased risk of a range of complications during pregnancy and childbirth, including: miscarriage, pre-eclampsia, thromboembolism, gestational diabetes, post-partum haemorrhage, induction of labour, instrumental birth and caesarean section. Furthermore, it has been reported that overweight and obesity in pregnancy can be directly or indirectly associated with over half of all maternal deaths in the UK (Lewis 2007). There are also increased risks to the fetus of macrosomia, congential anomaly and intrauterine death (Lewis 2007). Given the identifiable health risks to both mother and child of being overweight or obese during pregnancy, a clear evidence-based policy about the best ways to manage weight gain prior to and in pregnancy for all women whether of normal weight, overweight, or obese was required. Synthesising trials testing the effectiveness of interventions to prevent excessive weight gain would form a key part of the evidence-base.

It was important, however, to also consider the complexities in the epidemiological evidence and the social context of obesity, weight gain and eating. The observed relationship between pregnancy, obesity and health risks is not completely clear: some research suggests that other determinants, such as socioeconomic status and ethnicity, may be confounding the reported association of excessive weight in pregnancy and poor perinatal outcomes (Sheiner et al., 2004). Obesity is a socially constructed issue and eating is a social activity (Crossley, 2004). Further, social inequalities may contribute to differing perceptions of obesity, food and nutrition. A recent study of middle- and low-income women’s experiences of motherhood and food noted that weight loss is valued differently by different classes of women; that being a mother means putting the needs of the family above the self; and that one-size-fits-all health promotion-based weight loss approaches discretely focused on food, bodies and eating are ‘disembodied and disengaged from the social contexts in which people live their lives’ (Warin et al., 2008: p.98). These findings illustrate important differences in the way in which diverse groups of women may approach weight gain over the childbearing year. These differences may influence the success of dietary or physical activity interventions for pregnant women.

Understanding more about diverse groups of women’s experiences of maintaining their weight during pregnancy through the inclusion of qualitative research in the review was hypothesized by the review team and review commissioners to be able to add depth to understanding why interventions are effective and how to ensure that they are delivered in an acceptable and appropriate manner. This understanding was also anticipated to contribute to the development of interventions yet to be evaluated which address women’s understanding of what helps and hinders healthy weight management in pregnancy.

The questions of the review were therefore posed as:

1. What is the effectiveness of interventions to prevent excessive weight gain in pregnancy?
2. What are the perspectives and experiences of pregnant women around weight, diet and physical activity?
3. What factors may influence intervention effectiveness?

A quantitative approach was applied to question one whilst question two was asked from a qualitative perspective drawing on the views of women. Question three combines both qualitative and quantitative perspectives.

### *Preparatory work and protocol development*

The review team decided to adopt the mixed methods approach to reviewing developed by the EPPI-centre for a number of reasons. The team viewed the approach as well explained and transparent making it ideal for them to pick up and use easily. There was flexibility in the method as it allowed for the inclusion of a range of ‘quantitative’ and ‘qualitative’ studies. The opportunity the method presents to create a dialogue between the qualitative and quantitative studies also made this approach appealing especially in relation to addressing the third question of the review.

A protocol was developed by the reviewers in close dialogue with a wider consultation team including review commissioners, content experts, policy makers and consumers. This ensured that the review scope was defined collaboratively and addressed the issues that were important to various stakeholders. The protocol facilitated consultation with relevant stakeholders on the search strategy so that all the relevant search terms, databases and key journals that would assist in a comprehensive search for relevant research could be defined. The consultation team was also asked to identify relevant papers they were aware of.

The protocol was written according to standard systematic review headings with sub-headings to describe separate methods and processes for the effectiveness part of the review and the qualitative part. For example, we set up distinct sets of inclusion criteria for trials and for qualitative studies (Box 2).

- Insert box 2 about here -

***Search***

A comprehensive search of both published and unpublished ‘grey literature’ was undertaken to identify relevant studies and background information. Eleven databases were searched and the citation list of relevant review articles and included papers were also searched. The searches were undertaken in early December 2008 and a second search, updating the first was conducted in August 2009.

The search strategy was not restricted by study design which facilitated the identification of the diverse range of study designs required for the review. More commonly systematic reviews include a search filter to identify specific study designs such as a randomized controlled trials (in reviews of clinical effects) or qualitative studies (in qualitative systematic reviews). Searches were limited by year of publication (1990-2008), corresponding with the introduction of the concept of excessive gestational weight gain by the IOM (1990) when it published recommended guidance for gestational weight gain. Where possible limits were applied to retrieve studies in humans and English language citations only.

The search strategy combined terms for pregnancy and terms for body composition, obesity and weight change. This set of “population” terms was then combined with terms for diet, exercise, physical activity advice and monitoring, giving four separate sets of results for each database. In addition a bibliographic search of all the included studies was carried out and experts in the field were also consulted to identify any additional literature.

The search results were screened independently by one reviewer and all excluded references were checked by a second reviewer. Where insufficient information was present in the title and abstract to determine eligibility, full papers were retrieved for further consideration. This process was more time-consuming because of the search for qualitative studies. Frequently there was insufficient information from the title to indicate whether an article reported a qualitative research study or whether it was simply an opinion piece. Consequently relatively few qualitative papers could be excluded at the initial title sifting stage. All potentially eligible studies were obtained and re-assessed for inclusion. The inclusion of any studies which were unclear was resolved through discussion.

The search and screening process resulted in the identification of 5 trials and 8 qualitative studies.

### *Quality appraisal*

The selection of appropriate tools to judge quality of included studies and how to incorporate the quality assessment in the analysis of data remains an area of ongoing debate and research. Different tools were used to assess the quality of trials and the qualitative studies. The internal validity of each included trials was assessed using the Cochrane Collaboration’s tool for assessing risk of bias.16 This tool was used because it assesses aspects of trial design that have been empirically shown to influence the validity and reliability of the trial outcomes. The tool assesses six key methodological domains; sequence generation, allocation concealment, baseline comparability, intention to treat analysis and loss to follow-up and selective outcome reporting.

The use of assessment tools to critically appraise qualitative studies is also an area of evolving methodology (Noyes et al 08). Qualitative studies encompass a wide breadth of research methodologies limiting the applicability of generic appraisal criteria (Dixon-Woods et al 2004). In this example the reviewers adopted the quality assessment tool for qualitative studies included in the NICE Methods Manual (National Institute for Health and Clinical Excellence, 2006). This tool drew on a range of qualitative checklists and designed questions exploring the theoretical approach adopted, methods of sampling, rigour in data collection, exploration of the role of the researcher in the review, description of the context, reliability of methods and analysis, rigour of data analysis, richness of data, coherence of findings and consideration of relevant ethical issues.

### *Data Extraction*

Separate data extraction forms were developed for the trials and qualitative studies in consultation with clinical experts and each was piloted. For the trials, data on study methods, characteristics of participants, interventions and relevant outcomes were independently extracted by two reviewers from included trials. Any differences in data extraction were resolved by discussion. Data extraction of the qualitative studies was undertaken somewhat differently. Each study, after being read initially to confirm that it fulfilled the inclusion criteria, was then subjected to repeated independent readings during which it was appraised and its findings summarized on the data extraction form. Consideration was given to the ways in which the methodologies used shaped understandings about the subject of interest (in this case barriers and facilitators affecting healthy weight management in pregnancy).

* Add Box 3 about here -

### *Data Synthesis*

The data synthesis was conducted in three stages according to the mixed methods framework described above.

1. Effectiveness synthesis

Firstly, where possible and if appropriate, the results of the RCTs were statistically synthesized in a meta-analysis to assess the effectiveness of the interventions in the controlled trials. Meta-analysis was undertaken using Cochrane Collaboration Review Manager 5.0 software. The mean difference was used to estimate the pooled mean difference in weight gained between intervention and control groups, using a random effects model. Statistical heterogeneity between trials was assessed using the chi2 test, its corresponding P-value and the I2 test.18 Sensitivity analyses were performed excluding poor quality trials. Sub-group analyses were performed grouping trials into pre-specified categories. Subgroup analyses according to baseline BMI status or type of intervention (e.g. impact of using regular weight monitoring with feed back to participants) did not demonstrate any difference in the effect of the intervention. The small number of studies limited the exploration of the effects of different features of the interventions.

The main finding of this synthesis was that there was no significant evidence that dietary interventions with or without additional support to increase physical activity were effective in reducing gestational weight gain (figure 2).

- Insert figure 2 about here -

1. Synthesis of qualitative research

Secondly, thematic analysis of the findings from the qualitative studies was conducted. As noted earlier, each of the five studies were read and re-read to enable the reviewer to familiarize themselves with the studies. Findings were summarized on the data extraction form and consideration was given to the ways in which the methodologies used shaped understandings about the subject of interest (in this case barriers and facilitators affecting healthy weight management in pregnancy). After repeated readings and summarizing of the findings, common themes were identified and supporting quotes drawn from the qualitative studies. One reviewer undertook this process.

Women expressed many different views and attitudes to diet, physical activity and weight gain in pregnancy. Three themes emerged in the analysis of these studies relating to women’s views of weight management in pregnancy: contradictory messages, pregnancy as a time of transition and change and a perceived lack of control (figure 3).

- Insert Figure 3 about here –

1. Cross-study synthesis

The final step was to bring the findings of the synthesis of the qualitative and quantitative systematic reviews together in order to discover to what extent interventions addressed the factors that influence gestational weight gain.

We constructed a methodological and conceptual matrix to integrate the findings of the two syntheses. The potential implications of the views of pregnant women, their partners, families and health professionals for interventions were presented alongside the content and findings of the interventions evaluated by the trials. Matches and gaps were identified. Potential mismatches were explored but not found.

* Insert box 4 about here -

An example of a match was the implication from the qualitative research that interventions address the contradictory nature of advice and information on healthy eating and physical activity during pregnancy. This was addressed by all the interventions evaluated by the trials. Despite this, however, the interventions were not shown to be effective. Drawing on the findings of the qualitative synthesis, one explanation might be the powerful influence on women’s behaviour of their peer support system which may undermine the messages of health professionals. Interventions at a community level may support interventions that are targeting the behaviour of individual pregnant women.

 An example of a gap was that the interventions included in the trials did not seek to address the wider, social factors that might contribute to poor weight management. Pregnancy was a time of change and transition for women. Some described it as a time when they felt a loss of control over their bodies, a time of transition, after which normal patterns of dietary limitation and exercise would resume. Facilitating behaviour change may be more effective amongst women where a sense of control is felt and interventions delivered in such a way as to re-establish a sense of control. All of the interventions evaluated by the trials assumed compliance with the underlying values implicit within them – i.e. that weight gain and overweight is not good. For some women these may be attitudes that are hard to accept, pregnancy may be a time when they feel comfortable, able to eat with fewer limitations and overweight being more socially acceptable. As such health messages may not have been accepted and adopted by participants.

The pattern of convergence and divergence between the interventions and the factors identified in the qualitative studies may explain the mixed results seen in the outcomes of the interventions studies. No clear pattern of effectiveness emerged and this would suggest that other important factors are influencing maternal weight gain in pregnancies which are not being sufficiently addressed in the interventions reviewed here.

**Strengths and challenges of the approach**

The EPPI-Centre method of integrating qualitative and quantitative findings offered a transparent and coherent approach that we could adopt readily despite little experience of integrating qualitative and quantitative studies in previous systematic reviews. The final stage of the analysis, incorporating results into a matrix with the results from each arm of the review juxtaposed facilitated in depth analysis about the implications of the findings and how they illuminated the hidden complexities of why interventions might and might not work within different contexts. This analysis was also positive in informing recommendations about the direction for future research.

The added value that the mixed methods approach brought to the review did come at a cost. A mixed methods approach to review is resource intensive. Traditional systematic reviews usually involve one type of study and one type of synthesis whereas the mixed methods approach reported here involves three (‘sub-‘) syntheses and two main study types. The resources available to conduct our review were limited and we had tight timescales in which to deliver. This was a challenge, especially given the fact that mixed methods reviews are a fairly recent development and the team conducting the review were applying the methodology for the first time. We had to make pragmatic decisions about how to make the review manageable within the resources available.

Although our review included international studies, it had a UK focus. We therefore included only qualitative studies from the UK as we considered the strengths of qualitative research to be in identifying the specific contextual factors shaping women’s perspectives and experiences in the UK. All of our trials, however, were conducted in the US. This placed limits on the reach of the analysis. Ideally, for a fuller analysis of what works for whom in what context and it would have been useful to extend our inclusion criteria to qualitative studies conducted in other countries. A further useful source of information on reasons for why the interventions may not have achieved the anticipated outcomes would be to include trial authors insights as reported in, for example, the discussion sections of trial reports.

Although further worked examples of this approach are needed, overall the University of Sheffield team found that integrating qualitative and quantitative research within a mixed methods review framework offered several benefits. The approach has been well explained and the steps involved are in the main explicit and easy for others to pick up and use. There is flexibility in the approach as it is question driven and be tailored to accommodate the inclusion of a range of ‘quantitative’ and ‘qualitative’ studies and a range of synthesis methods within its different ‘sub-syntheses’. The opportunity the method presents to create an explicit dialogue between the qualitative and quantitative studies is a particularly attractive feature of the approach. As the other chapters in this book demonstrate, considerable effort has gone into developing methods for the synthesis of qualitative research over the past decade. In the context of trying to produce a more nuanced understanding of the effects of interventions, methods for integrating qualitative syntheses with effectiveness syntheses are much less well-developed. The methods and approach described in this chapter are therefore an important contribution.

**Conclusion**

The mixed methods approach described in this chapter illustrates the value of drawing together the findings of a qualitative thematic synthesis with those of an effectiveness review. The framework for this approach is explicit and the review processes can be picked up with ease as illustrated in the worked example. Identifying the recurring themes and issues that emerge from people’s views and experiences of the policies and practices under review creates knowledge about the need, appropriateness and acceptability of interventions. This approach increases understanding of why complex interventions may or may not work in different contexts, and can inform the development of future interventions and research. **References**

Barnett-Page E, Thomas J (2009) Methods for the synthesis of qualitative research: a critical review. *BMC Medical Research Methodology*, 9:59. doi:10.1186/1471-2288-9-59.

Campbell F, Johnson M, Messina J, Guillaume L, Goyder E. Diet and/or physical activity interventions for the prevention of excessive weight gain in women during pregnancy. A systematic review. 1-215. 2010. London: National Institute for Health and Clinical Excellence.

Confidential Inquiry into Maternal and Child Health (CEMACH). CEMACH obesity in pregnancy project, 2009. Available at: <http://www.cemach.org.uk/Programmes/Maternal-and-Perinatal/Maternal-Obesity.aspx>.

Chalmers, Iain (2005) If evidence-informed policy works in practice, does it matter if it doesn't work in theory? Evidence & Policy: A Journal of Research, Debate and Practice, Volume 1, Number 2

Creswell J (2010) Mapping the developing landscape of mixed methods research. In A Tashakkori, C Teddlie (Eds) Mixed Methods Handbook (Second Edition). New York: Sage Publications.

Crossley, N. "Fat is a Sociological Issue: Obesity Rates in Late Modern, 'Body Conscious' Societies." *Social Theory and Health* 2(3) (2004): 222-253.

Dixon-Woods M, Shaw RL, Agarwal S, Smith JA (2004) The problem of appraising qualitative research. Qual Saf Health Care 13: 223-225

Dixon-Woods M, Bonas S, Booth A, Jones D, Miller T, Sutton A, Shaw R, Smith J, Young B (2006a) How can systematic reviews incorporate qualitative research? A critical perspective. *Qualitative Research* **6**: 27-44.

Dixon-Woods M, Cavers D, Agarwal S, Annandale E, Arthur A, Harvey J, Katbamna S, Olsen R, Smith L, Riley R, Sutton AJ (2006b) Conducting a critical interpretative synthesis of the literature on access to healthcare by vulnerable groups**.** *BMC Med Res Methodol* 2006, **6:**35.

Egger M, Davey-Smith G, Altman D (eds*)* (2001) *Systematic Reviews in Health Care: Meta-analysis in context*. London: BMJ Publishing.

Ely, J. W, Osheroff, J. A, Maviglia, S. M, Rosenbaum, M. E (2007). Patient-Care Questions that Physicians Are Unable to Answer. J Am Med Inform Assoc 14: 407-414

Fox P, Yamaguchi C. Body image change in pregnancy: a comparison of normal weight and overweight primigravidas. *Birth: Issues in Perinatal Care* 1997;35-40.

Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O, Peacock R (Jul 2005) Storylines of research in diffusion of innovation: a meta-narrative approach to systematic review., *Social Science & Medicine*, 61 (2), 417-30

Gross H, Bee P (2004) Perceptions of effective advice in pregnancy - The case of activity. Clinical Effectivness in Nursing 8:161-169

 Guba, E.G. (1987). What have we learned about naturalistic evaluation? Evaluation Practice, vol. 8 (1), 23-42.)

Harden A, Thomas J (2005) Methodological issues in combining diverse study types in systematic reviews. International Journal of Social Research Methods 8:257-271

Harden A, Thomas J (2010) Mixed methods and systematic reviews: examples and emerging issues. In A Tashakkori, C Teddlie (Eds) Mixed Methods Handbook (Second Edition). New York: Sage Publications.

Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.0.2 [updated September 2009]. The Cochrane Collaboration, 2009. Available from [www.cochrane-handbook.org](http://www.cochrane-handbook.org).

Kanagalingam MG, Forouhi NG, Greer IA, Sattar N. (2005) Changing in booking body mass over a decade: retrospective analysis from a Glasgow maternity hospital. BJOG 112: 1431-3.

Lewis, G (ed) 2007. The Confi dential Enquiry into Maternal and Child Health (CEMACH). Saving Mothers’ Lives: reviewing maternal deaths to make motherhood safer - 2003-2005. The Seventh Report on Confi dential Enquiries into Maternal Deaths in the United Kingdom. London: CEMACH

Lipsey M, Wilson D (2001) *Practical Meta-analysis*. Thousand Oaks, California: Sage.

National Institute for health and Clinical Excellence. Public health guidance:development process and methods. 2006. London: National Institute for health and Clinical Excellence. ([http://www.nice.org.uk/media/2FB/53/PHMethodsManual110509.pdf](https://mail.ioe.ac.uk/owa/redir.aspx?C=70f03a7c30c24760a0bb0545afe25caf&URL=http%3a%2f%2fwww.nice.org.uk%2fmedia%2f2FB%2f53%2fPHMethodsManual110509.pdf)) Accessed 12.04. 2011.

Noblit GW, Hare RD: *Meta-Ethnography: Synthesizing qualitative studies*. Newbury Park: Sage; 1988.

Noyes J, Popay J, Pearson A, Hannes H, Booth A (2008) Qualitative research and Cochrane reviews. In JPT Higgins and S Green (Eds) Cochrane Handbook of Systematic Reviews of Interventions. Chap 20. John Wiley & Sons, Chichester

Oliver S, **Harden A**, Rees R, Shepherd J, Brunton G, Garcia J, Oakley A (2005) An emerging framework for integrating different types of evidence in systematic reviews for public policy. Evaluation 11:428-466.

Roberts A, Noyes J (2009) Contraception and women over 40 years of age: mixed-method systematic review. Journal of Advanced Nursing 65(6), 1155–1170. doi: 10.1111/j.1365-2648.2009.04976.x

Sheiner E, Levy A, Menes TS, Silverberg D, Katz M, Mazor M. Maternal obesity as an independent risk factor for caesarean delivery. 2004; 18(3):196-201.

Strauss AL, Corbin J: Basics of Qualitative Research: *Techniques and Procedures for Developing Grounded Theory* Thousand Oaks, CA: Sage; 1998.

Thomas J, Brunton J, Graziosi S (2010) *EPPI-Reviewer 4.0: software for research synthesis.* EPPI-Centre Software. London: Social Science Research Unit, Institute of Education.

Thomas J, Harden A, Oakley A, Oliver S, Sutcliffe K, Rees R, Brunton G, Kavanagh J (2004) Integrating qualitative research with trials in systematic reviews: an example from public health. British Medical Journal 328: 1010-12.

Thomas J, Harden A (2008) Methods for the thematic synthesis of qualitative research in systematic reviews *BMC Medical Research Methodology* 8:45

Warin M, Turner K, Moore V, Davies M. Bodies, mothers and identities: rethinking obesity and the BMI. 2008; 30(1):97-111.

Warriner S. Women's views on being weighed during pregnancy. *BR J MIDWIFERY* 2000; 8(10):620-623

Figure 1: A mixed methods approach to conducting a systematic review of diverse study types (adapted from Harden et al., 2004 and Oliver et al., 2005)

Box 1: Steps in a thematic synthesis (based on Thomas and Harden, 2008)

|  |
| --- |
| **Stages one and two: coding text and developing descriptive themes**The first stage of a thematic synthesis involves the identification of themes across the included studies. This aims to be a fairly descriptive activity, remaining ‘close’ to the data and encapsulating the studies’ findings in a framework that relates the themes they contain to one another. The following, analytical stage, aims to draw conclusions from the findings of stage one, in the light of the conceptual framework of the review and its review questions.**Identifying the ‘findings’**The first task in stage one is to identify the ‘findings’ of the primary studies. Findings can appear almost anywhere in a paper or report (and it is possible to conceptualise the whole report as ‘findings’). As we are usually concerned with identifying what people think, feel or believe about a given phenomenon, we often look for sections in papers that report what participants say (both individually and corporately). Thematic syntheses can also use the conclusions of primary reports, depending on their given objectives. We acknowledge, however, that all thematic synthesis is essentially an interpretation of primary reports, which are themselves authors’ interpretations of what study participants were saying. Once the ‘findings’ have been identified, they are entered verbatim into standard software for undertaking qualitative analysis (e.g. NVivo or Atlas TI) or specialist reviewing software (e.g. EPPI-Reviewer).**Line-by-line coding**Using a method familiar to those involved in analysing primary research, each line of text from the primary studies is then assigned one or more codes than encapsulate its meaning. As soon as codes begin to be applied to a second study, the task of *conceptual translation* has begun: a key characteristic of the synthesis of qualitative research. This involves identifying concepts that studies have in common, though they may be expressed in different words. Noblit & Hare outline two aspects of this: *reciprocal* and *refutational* translation, in which concepts are identified as supporting, or dissenting from one another. The use of line-by-line coding ensures that a link between the descriptive codes and the primary studies on which they are derived is maintained, and also that they are used consistently across studies.**Developing descriptive themes**Either as part of the process of generating descriptive codes, or once it is complete, reviewers then organise their emerging findings into *descriptive themes*. This involves developing an overarching conceptual framework that groups conceptually similar codes and may appear similar to a the development of a theory about how study participants perceive the phenomena under discussion. Though this framework is the interpretation of the reviewers who generated it, it should nevertheless aim to summarise what the primary studies said, rather than drawing new and original conclusions. In some reviews, the synthetic activity will stop at this point, since the descriptive themes answer the review questions satisfactorily; some reviews require an additional, more analytical, stage. |
| **Stage three: generating analytical themes**The final activity in a thematic synthesis is the (optional) generation of analytical themes. These themes explicitly take the synthesis ‘beyond’ the content of the primary study, and generate new interpretive conclusions. They are generated in an iterative process. First, each area – and possibly each theme – in the descriptive synthesis are considered *in the light of the review’s research questions*. Reviewers ask the question ‘how does this theme address / answer this question?’ and record the result as a statement. (In the first review in which we generated this method, these statements were the barriers to, and facilitators of, healthy eating among children.) A second thematic analysis is then applied to these statements to draw out the cross-cutting *analytical themes* that they contain. These themes and statements are the final product of a thematic synthesis and can later be used to interrogate trials in the mixed-methods synthesis. |

Box 2: Inclusion criteria for studies in a mixed methods review of weight management interventions in pregnancy

|  |  |
| --- | --- |
| **Quantitative Studies** | **Qualitative Studies** |
| Inclusion Criteria* RCTs (including cluster randomised trials)
* Published in English
* Women aged 18 or over, pregnant or planning a pregnancy; normal weight overweight or obese
* Interventions which included dietary and/or physical activity interventions
 | Inclusion Criteria* Qualitative studies providing evidence regarding the views of pregnant women, their partners and families, service providers, including practitioners delivering antenatal services, regarding diet, physical activity and weight management in pregnancy
* Qualitative studies were taken to be studies which used techniques such as in-depth interviews, focus groups, observation, reflective diaries and case-study methodologies to explore participants experiences
* Qualitative evidence collected within RCTS included in the effectiveness part of the review as well as relevant stand-alone qualitative studies.
 |
| Exclusion Criteria* Women with underlying medical conditions
* Women expecting more than one baby
* Underweight women (BMI <18.5 kg/m2)
* Studies conducted in a non-OECD countries
 | Exclusion Criteria* Studies conducted outside of the UK
 |

Figure 2: Results of the statistical meta-analysis of trials in a mixed methods review of weight management interventions in pregnancy



Figure 3: Overview of themes from the synthesis of qualitative research in a mixed methods review of weight management in pregnancy

|  |  |
| --- | --- |
| **Theme** | **Description** |
| Contradictory messages | \*Advice and information from health professionals, peers and family often seen as contradictory and confusing (“There’s no black and white about what you should and shouldn’t do so I don’t, I can’t follow it at all’ (Gross & Bee 2004, pg 165))\* Women reported strong encouragement from peers to rest and to increase their intake of certain food types such as milk and cheese. \*Professionals were often reluctant to initiate discussion around weight management due to fear of ‘victimising’ women.  |
| Pregnancy as a time of transition and change | \*Needs of unborn child take precedence over mothers\*Decline in physical activity and increase in eating – these behaviour patterns reinforced by social networks and environment\*Changing body image: positive (“..now I have a wonderful excuse to be big” (Fox and Yamguchi 1997, pg 38)) and negative (‘fat’, ‘bloated’ and ‘frumpy’) |
| Perceived lack of control | \*Weight gain as inevitable (‘It’s just one of those things that you expect happens when you are pregnant, you almost hand your body over to these people and you just accept whatever they say or do to you without really questioning it’. (Warriner, 2000, p621))\*Restricted access to gym and normal physical activities\*Physical demands of pregnancy restricted activity and influenced dietary patterns |

**Box 3: Qualitative data extraction form**

|  |  |
| --- | --- |
| **Review Details** |  |
| Author, year |  |
| Reference ID |  |
| Publication type (ie full report or abstract) |  |
| Country of corresponding author |  |
| Language of publication |  |
| Sources of funding |  |
| Study design |  |
| Authors’ objective(s) of review |  |
| **Methodological Characteristics** |  |
| Population |  |
| Setting |  |
| Inclusion / exclusion criteria |  |
| Method of recruitment |  |
| Method of data collection |  |
| Method of data analysis |  |
| Theoretical assumptions / definitions of concepts |  |
| **Clinical Issues** |  |
| Measures |  |
| Comparators |  |
| Definition of outcomes |  |
| **Results** |  |
| Total number of participants |  |
| Participants’ baseline characteristics (age, gender, ethnicity, co-morbidities, previous drinking levels) |  |
| Duration of study |  |
| Findings 1 |  |
| Findings 2 |  |
| Authors’ comments on strengths/weaknesses of review |  |
| **summary** |  |
| Authors’ overall conclusions |  |
| Quality assessment of review |  |
| Generalisability to UK |  |
| Reviewer’s comments |  |

Box 4: Synthesis Matrix

|  |  |
| --- | --- |
| **Potential barriers and facilitators to healthy weight management in pregnancy** | **Extent to which these were addressed in the trials** |
| Diet and Exercise - factors external to the individual |  |
| Access to adequate and relevant information and advice was somewhat ad-hoc. Information from health professionals was often vague or contradictory | All of the intervention studies except Kardel & Kase (1997) addressed this factor by delivering interventions that provided clear and consistent advice to pregnant women often using different methods to reinforce health messages.  |
| Women accessed information and advice relating to weight management from 3 main sources; health care professionals, family and friends, and the media | None of the studies sought to influence the other sources of information that influence women’s behaviour in pregnancy. Nor did they describe methods of supporting women who may be hearing conflicting messages from differing sources. |
| There were practical barriers to exercise with women finding that gyms did not encourage participation by pregnant women. | The focus of the interventions was at the level of the individual and did not seek to influence beliefs regarding pregnancy and the need to maintain exercise as a part of effective weight management in pregnancy in the wider community  |
| A lack of exercise provision actually targeting pregnant women with midwifery support | Four studies offered exercise classes as part of the intervention (Hui et al., 2006, Kinnunen et al., 2007, Claaesson 2007, and Gray Donald 2000).  |
| Diet and exercise factors specific to the individual |  |
| Appetites and food preferences were disrupted in pregnancy | Apart from Guelinckx et al., (2008) all of the interventions offered tailored advice which may have incorporated women’s preferences |
| For some who were already overweight before pregnancy, pregnancy was a time when they felt it was legitimate to be overweight and their self esteem was higher as a result.  | Individually targeted interventions will not challenge the cultural values surrounding body shape, though they may assist women in making informed choices and in resisting unhelpful discourses.  |
| Women’s attitudes and behaviours in relation to diet and physical activity during pregnancy are associated with – pre-pregnancy attitudes and behaviour to diet and exercise | Only one case report described an intervention for overweight women trying to get pregnant (Galletly et al.,.,. 1996). All of the other interventions specifically targeted interventions during pregnancy. |
| For some women pregnancy is a time when women feel it is legitimate to relax on self-imposed dietary limitations and weight gain can be dealt with later. | This was not reported in the interventions described. |
| For some women weight gain in pregnancy is regarded as a norm and excessive weight gain can be addressed once they are no longer pregnant. | Use of regular monitoring of weight and plotting of weight on graphs combined with stepped care would challenge this view  |
| Women’s experiences of and attitudes to body image fluctuate during pregnancy. | It may be difficult to map the timing of interventions effectively onto the fluctuating subjectivities of pregnant women. |
| Conflicting lay beliefs A perception that eating was a way of protecting the baby and a woman should be ‘eating for two’ | The interventions will have addressed the mothers lay beliefs but not the beliefs of important significant others who will give conflicting messages. |
| There were many barriers to exercise in pregnancy including physical discomfort experienced by women, important lay messages about the need for rest and pregnancy offering a legitimate reason for not being active. Perceived risks associated with exercise might be appropriate (facilitator) or inappropriate (barrier) compared to guidance. | The barriers to exercise were only partially addressed by the interventions. They conveyed messages about the safety of exercise in pregnancy and some offered classes for women to attend.  |