Manuscript Submission: Journal of Advanced Nursing

Article Type: Original Research – qualitative

FINAL DRAFT Last edit: 9 Sept 13

Word Limit: 5000 Current count: 4351

FULL TITLE

The 'active ingredients' for successful community engagement with disadvantaged expectant and new mothers: a qualitative comparative analysis.

RUNNING HEAD

The 'active ingredients' for successful community engagement with disadvantaged expectant and new mothers: a qualitative comparative analysis.

AUTHORS

Ginny BRUNTON RM RGN1, Alison O'MARA-EVES2, James THOMAS3

- ¹ Research Officer, EPPI-Centre, Social Science Research Unit, Institute of Education, University of London and Clinical Midwife, Cambridge University Hospitals NHS Foundation Trust, Cambridge UK
- ² Research Officer, EPPI-Centre, Social Science Research Unit, Institute of Education, University of London
- ³ Professor in Health and Social Policy, EPPI-Centre, Social Science Research Unit, Institute of Education, University of London

ACKNOWLEDGEMENTS

We would like to acknowledge the co-authors of the original systematic review, which informed this work: Angela Harden, Farah Jamal, Josephine Kavanagh, Tihana Matosevic, David McDaid, and Sandy Oliver.

CONFLICT OF INTEREST STATEMENT

All authors have completed the unified competing interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare (1) no financial support for the submitted work from anyone other than their employer; (2) no financial relationships with commercial entities that might have an interest in the submitted work; (3) no spouses, partners, or children with relationships with commercial entities that might have an interest in the submitted work; and (4) no non-financial interests that may be relevant to the submitted work.

FUNDING STATEMENT

This report refers to independent research commissioned by the National Institute for Health Research (NIHR). Any views and opinions expressed herein

are those of the authors and do not necessarily reflect those of the NHS, the NIHR, the Public Health Research programme or the Department of Health.

KEYWORDS

Community health, maternal child health, qualitative comparative analysis, research methodology, systematic reviews, health visiting, midwifery practice, nursing practice

ABSTRACT

Aims

To explore which components of community engagement strategies are implicated in effective interventions targeting disadvantaged pregnant women and new mothers.

Background

Adaptive experiences during pregnancy and the early years are key to reducing health inequalities in women and children worldwide. Nurses and midwives are well placed to address such disadvantage, often using community engagement strategies. But such interventions are complex, and a need exists to understand which aspects of community engagement are aligned with effectiveness.

Design

Qualitative comparative analysis of trials data included in a recent systematic review meta-analysis.

Methods

Two reviewers agreed relevant conditions from 24 included maternity or early years interventions studies examining four models of community engagement. Effect size estimates were converted into 'fuzzy' effectiveness categories and truth tables were constructed. Using fsQCA software, Boolean minimisation identified solution sets. Random effects multiple regression and fsQCA were conducted to rule out risk of methodological bias.

Results/Findings

Studies focused on antenatal, immunisation, breastfeeding and early professional intervention outcomes. Peer delivery (consistency 0.833; unique coverage 0.625); and mother-professional collaboration (consistency 0.833; unique coverage 0.208) were moderately aligned with effective interventions.

Community-identified health need plus consultation/collaboration in

intervention design and leading on delivery were weakly aligned with 'not effective' interventions (consistency 0.778; unique coverage 0.291).

Conclusion

For disadvantaged new and expectant mothers, peer delivery or collaborative delivery models could be used to design interventions. A need exists to design community engagement intervention evaluations in other areas of maternity and early years care, and to further evaluate models of empowerment.

SUMMARY STATEMENT

Why is this research or review needed?

- Adaptive experiences during pregnancy and the early years are key in the development of reducing health inequalities in women and children worldwide.
- Nurses and midwives are well placed to address health inequalities in these populations, often using community engagement strategies.
- However, interventions seeking to impact on disadvantaged populations'
 health are complex, and a need exists to understand which conditions of
 community engagement are aligned with effectiveness.

What are the key findings?

- Studies focused on antenatal, immunisation, breastfeeding and early professional intervention outcomes.
- Peer-led or peer-professional collaboration on intervention delivery was aligned with effective interventions
- Empowerment-based strategies appeared less often, and were weakly aligned with non-effective interventions

How should the findings be used to influence policy/ practice/ research/ education?

- Decision-makers should consider using either peer delivery or collaborative delivery models when planning similar interventions.
- A fairly narrow range of topics within maternity and early years care suggests a need to design community engagement intervention evaluations in other areas.
- Future research to evaluate empowerment models of community engagement is needed.

INTRODUCTION

New motherhood is a crucial time for women and children. Adaptive experiences during pregnancy and the early years are key in the development of good social, physical and emotional health in women and children worldwide (Cohen et al. 2005, Department of Health (DH) 2010, Safe Motherhood 2010). Within developed countries, more disadvantaged groups of expectant and new mothers may find it particularly difficult to be healthy. These include women of lowincome, at risk of health problems, living in areas of deprivation or of ethnic minority status. Their health status can lag behind that of more advantaged groups due to their social, economic, and environmental conditions (Marmot et al. 2010). Tackling health inequalities amongst disadvantaged groups has been a focus of policy interest worldwide (Crombie et al. 2005, DH 2004); and giving all children the best start in life has been identified as one of the key priority areas in which to address health inequalities in the UK (Marmot et al. 2010).

Health care professions are well placed to support disadvantaged mothers in giving children the best start possible. Nurses and midwives have long recognised that they are in a strong position to assess, recognise and impact health inequalities in the populations with whom they work. As part of this, nurses and midwives endeavour to embody the principle of 'working with', rather than 'doing to' (Royal College of Nurses (RCN) 2012, Royal College of Midwives (RCM) 2001, RCM 2012). Strategies that promote community engagement are especially encouraged for those working with disadvantaged groups (McNeill et al. 2012, UCL Institute of Health Equity 2013, Crombie et al. 2005, DH 2006a, DH 2006b). Nursing and midwifery services value, and are oriented toward, patient-centred care and seek to encourage shared decision-making in the planning of care (Manley et al. 2011, RCM 2011). For example, models of peer-delivered care in maternity and early years services have been widely implemented, especially amongst pregnant women and new mothers (Dale et al. 2008, Lewin et al. 2010, Renfrew et al. 2012).

However, interventions which seek to impact women and children's health in challenging and diverse social environments are complex. Women can be engaged in many ways, including coalitions, volunteering, and advocacy. The extent of women's involvement in such interventions as community members also ranges widely across a continuum of empowerment (Milton et al. 2012, Popay 2006, Popay et al. 2007). For example, women may identify a health need in their community and lead on the design of an intervention (Barnes et al. 1999, Davidson et al. 1994). This deeper level of community engagement can be viewed as coming from the 'social justice/empowerment' model of health improvement (O'Mara-Eves et al. 2013 in press). Where community members are not involved in identifying a health need but simply lead or collaborate on delivery of an intervention, as in peer breastfeeding models (Arlotti et al. 1998), their contributions lean more toward a utilitarian model of engagement (O'Mara-Eves et al. 2013 in press). Other interventions target the middle ground between these two theoretical poles. For example, community members may be consulted or collaborate with others on designing an intervention (Shafer et al. 1998). Such distinctions echo a continuing discussion amongst academics and policy-makers about whether to build interventions from the 'ground up' or from the 'top down' (O'Mara-Eves et al. 2013 in press).

These three broad models of engagement (i.e., empowerment, peer- or lay-delivery, and collaboration/consultation in design) were all shown to be effective in a recent systematic review (O'Mara-Eves et al. 2013 in press). However, in order to run the statistical models, the studies had to be grouped in terms of the models of engagement as mutually-exclusive categories. In reality, most interventions had aspects of multiple models of engagement; for example, a peer-led intervention might also seek the views of the community in designing the intervention. As such, the statistical models in the systematic review—whilst informative about the broader theories of change—overlook some of the complexities of community engagement interventions. It is therefore unclear whether any of the aspects of community engagement strategies are particularly important 'active ingredients', or whether it is a combination of these factors, which contributes to an effective intervention.

Thus questions remain about which components or conditions of community engagement work to improve the health of women and children in pregnancy and the early years. It is not clear which conditions of community engagement are aligned with effectiveness, or whether combinations of these conditions are necessary for effective interventions. The data provided by our recent systematic review allowed a secondary analysis of existing data. It was anticipated that understanding which conditions and combinations of conditions of community engagement are linked to effectiveness would help practitioners and policymakers develop better (more appropriate, targeted, relevant) services, in collaboration with the disadvantaged women and children with whom they work.

THE STUDY

Aims

The aim of this study was to explore which combinations of community engagement conditions are found in effective interventions targeted at disadvantaged pregnant women and new mothers. To that end, four different community engagement conditions as identified by O'Mara-Eves et al. (2013) were examined:

- 1) community-initiated, in which members identified the health need to be addressed:
- 2) consultation on design of the intervention;
- 3) collaboration on delivery of the intervention; and
- 4) leading on intervention delivery.

Communities were defined as a group of people united by at least one but perhaps more than one common characteristic, including geography, ethnicity, shared interests, values, experience or traditions (Brenner & Manice 2011). Engagement was seen as any involvement along a continuum, from empowerment such as in (1) above, to consultation, collaboration or simply being informed about an intervention. Disadvantaged groups were those seen as

experiencing (or at risk of experiencing) health inequalities. These could include low-income populations, ethnic minority groups, those living in socioeconomically deprived areas, or those at risk because of particular health needs (e.g. at-risk youth, groups with disabilities).

Design

To address this aim, a secondary analysis of data extracted from trials included in a recent systematic review was undertaken, using qualitative comparative analysis (QCA).

Ethical considerations

Relevant ethics approval for the original systematic review was obtained through the funder and the authors' institutions.

Sample/Participants/Data collection

The studies included in this analysis were drawn from a larger recent systematic review of community engagement in public health and health promotion interventions delivered to disadvantaged groups (O'Mara-Eves et al. 2013). To identify studies for inclusion in the meta-analysis of the original review, we searched the following sources without language restriction for systematic reviews (SRs) of public health interventions: Cochrane Database of Systematic Reviews (CDSR) and Clinical Trials Register (CCTR), Campbell Library, York Centre for Reviews and Dissemination Database of Reviews of Effectiveness (DARE), the National Institute of Health Research Health Technology Assessment (NIHR HTA) programme website and database, and the EPPI-Centre's Database of Public Health Effectiveness Reviews (DoPHER). Through the identified SRs, we collated a database of primary studies that appeared to be relevant, and screened the full-text documents of those primary studies against out inclusion criteria. In parallel, we searched the NHS Economic Evaluations Database (EED) and the EPPI-Centre's Trials Register of Public Health Interventions (TRoPHI) for additional primary studies. We also contacted key authors and conducted citation searching.

Full-text reports of all systematic reviews on public health topics identified through these sources were retrieved; their summary tables were then scanned to locate relevant trials. A secondary screening of titles and abstracts eliminated studies published before 1990 and from non-OECD countries. All full-text reports of relevant trials were subsequently retrieved, screened and included if they:

- (1) Reported primary research;
- (2) Were not a Master's thesis;
- (3) Included intervention outcome and/or process evaluations;
- (4) Focused on community engagement as the main approach;
- (5) Contained a control or comparison group;
- (6) Characterised study populations/reported differential impacts of social determinants of health captured by the PROGRESS-Plus framework. The PROGRESS-Plus categories include place of residence, race/ethnicity, occupation, gender, religion, education, socioeconomic position, and social capital, plus other variables describing ways in which people may be systematically disadvantaged by discrimination (including sexual orientation, disability, social exclusion, and challenging life transitions such as teenage pregnancy) (Kavanagh et al. 2009); and
- (7) Reported health or health-related (including cost) effectiveness outcomes and/or process data.

Due to the large number of studies identified for inclusion in the map of community engagement interventions (n=319; see full report for details), we narrowed the scope of health topics included in the meta-analysis to the policy objective areas identified in the recent review of health inequalities, 'Fair Society, Healthy Lives' (Marmot et al. 2010). This led to a final review sample of 131 studies.

For the current qualitative comparative analysis, a sub-set of 24 trials relevant to the priority area identified by Marmot et al. (2010) of reducing health inequalities by ensuring the 'best start in life' were included in analysis. These included interventions focused on antenatal care, breastfeeding, child illness prevention, and parenting.

As part of the systematic review process, studies were coded according to study characteristics, such as population, health topic, intervention type, community engagement type, provider, location, and outcome. All included studies were assessed for methodological quality according to previously established criteria (Higgins and Green 2009): equivalent group allocation, attrition, and avoidance of selective reporting of outcomes.

Data analysis

Descriptive frequencies of characteristics of studies were computed. To identify which combinations of the four conditions of community engagement are found in effective (and ineffective) studies, qualitative comparative analysis (QCA) was undertaken. QCA is a method used to explore complex causality, by investigating which combinations of particular conditions (e.g. provider and/or location and/or printed information) are more often found in effective (and non-effective) interventions (Ragin et al. 2006). Given that interventions targeting social determinants of health are necessarily complex (Medical Research Council 2008), this method is well-suited to examine the components of effective interventions in maternity and early years interventions. Transforming effect sizes into 'fuzzy sets' allowed us to investigate more flexibly the effectiveness of the interventions, given that a) some studies had larger effect sizes than others; and b) the differences in underlying population incidence rates of each outcome meant that while the effect sizes might be statistically significant, clinical significant effects across health topics under study would vary widely.

A modified five-step method for QCA was undertaken (Rihoux & Ragin 2009; Thomas et al. in preparation). These steps are as follows:

Building the data table

A series of four mechanisms of community engagement were identified as the conditions to be tested; studies were given a value of '1' if they met each condition or '0' if they did not. To determine which condition or combination of conditions was associated with effective interventions, we selected four mutually exclusive conditions related to the degree of community involvement:

- (1) community members defined the need;
- (2) consultation or collaboration with community members on the design of the intervention :
- (3) community members leading on the intervention delivery; or
- (4) members of the community collaborating with others (i.e. health service providers) on intervention delivery.

The outcome in this dataset of studies is an indicator of the effectiveness of the intervention. The original metric used in the meta-analysis was an effect size estimate that compared the health behaviours of participants in the intervention group to those in the control group at immediate post-test (i.e., directly after the intervention finished). The effect size estimates were then calibrated for use in the QCA analyses by converting them into a fuzzy set that allows for degrees of membership. Effect sizes for constructing the fuzzy set were calibrated as follows in Table 1:

Table 1. Effect size: effective set membership determination

Study effect size	Membership in 'Effective' set	Fuzzy set value
> .50	In (full)	1.00
.30 > d ≥ .50	More in than out	0.66
0< d ≤ .30	More out than in	0.33
0	Out (non)	0

Constructing the truth tables

Studies were assigned to a configuration set depending on their combination of conditions. Possible configurations of the three conditions are illustrated in Table 2.

Table 2. Possible configurations and set labels of the four conditions

Conditions				
Empower-	Lay-	Collaborated	Consulted	
ment	delivered	on Delivery	on Design	Configuration set label
1	1	1	1	Empower*Lay*CollabDeliv*ConsultDesign
1	1	1	0	Empower*Lay*CollabDeliv*~ConsultDesign
1	1	0	1	Empower*Lay*~CollabDeliv*ConsultDesign
1	1	0	0	Empower*Lay*~CollabDeliv*~ConsultDesign
1	0	1	1	Empower*~Lay*ConsultDesign*ConsultDesign
1	0	1	0	Empower*~Lay*CollabDeliv*~ConsultDesign

1	0	0	1	Empower*~Lay*~CollabDeliv*ConsultDesign
1	0	0	0	Empower*~Lay*~CollabDeliv*~ConsultDesign
0	1	1	1	~Empower*Lay*CollabDeliv*ConsultDesign
0	1	1	0	~Empower*Lay*CollabDeliv*~ConsultDesign
0	1	0	1	~Empower*Lay*~CollabDeliv*ConsultDesign
0	1	0	0	~Empower*Lay*~CollabDeliv*~ConsultDesign
0	0	1	1	~Empower*~Lay*CollabDeliv*ConsultDesign
0	0	1	0	~Empower*~Lay*CollabDeliv*~ConsultDesign
0	0	0	1	~Empower*~Lay*~CollabDeliv*ConsultDesign
0	0	0	0	~Empower*~Lay*~CollabDeliv*~ConsultDesign

^{*} and ~ not

Truth tables were constructed and assessed for both positive (i.e. 'effective intervention') and negative (i.e. 'not effective intervention') outcomes. The resultant tables were checked for the spread of studies across the different configurations available and whether both positive and negative occurrences of the outcome were well covered or not.

Resolving contradictory configurations

Two reviewers assessed the dataset for any contradictory configurations (i.e. sets of studies in which identical configurations of conditions lead to the same outcome) and resolved (Rihoux & Ragin 2009).

Boolean minimisation

The set was analysed using fsQCA software (Ragin 2006a). The primary metric for these analyses was a measure of *raw consistency*. Consistency is the proportion of all intervention studies with conditions of interest and the outcome of interest (Ragin 2006b). We considered studies with a consistency value of >0.75 to be a valid combination, for two reasons: this was the suggested cut-off value (Ragin 2006a); and our set of studies was sufficiently heterogeneous in terms of outcomes to allow a consistency value toward the lower end of the scale. We also examined *coverage* as a metric. Coverage is ... the proportion of studies in the set of interest that have the condition of interest (Ragin 2006b).

Interpretation

Combinations of conditions, or solutions, were interpreted in light of the studies they are based on, the aims of this study and the original systematic review's

research questions, including the conceptual frameworks which guided the review.

Validity and reliability/rigour

Two authors (GB & AOE) agreed relevant conditions after discussing all options and underlying assumptions, with issues taken to a third author (JT) for discussion and resolution. Further methodological details are available in a related publication (Thomas et al. in preparation). To ensure that the effect sizes were robust and not related to methodological quality (i.e. risk of bias ratings), we undertook two quality checks: (1) random effects multiple regression conducted using macros specific to meta-analysis in SPSS version 20 examining the relationship between risk of bias and calibrated outcomes; and (2) an additional fsQCA examining the relationship between risk of bias ratings and effective intervention set membership.

FINDINGS

The 24 included studies which provided maternity and early years care by utilising community engagement were undertaken most often in the USA (n=21), followed by two in the UK and one in the Republic of Ireland. Four studies each focused on antenatal and immunisation outcomes, fifteen assessed breastfeeding outcomes, and one study measured early intervention as an outcome. Studies focused on populations who were most often disadvantaged by socioeconomic circumstances (n=14). Other disadvantaged groups included those of an ethnic minority (n=6) or those experiencing multiple disadvantages (n=4). Interventions in this set of studies took place most often in a combination of settings, most frequently at home (n=19), through media (n=16), or in clinics (n=11). Interventions were provided most often by peers (n=15), although they were also provided by a combination of other (non-peer) community members (n=8), health professionals (n=5), community workers (n=1) or researchers (n=1). Advice and/or social support were the intervention types most often provided (n=20 and n=14 respectively). Note that most of the descriptive characteristics above were not mutually exclusive (e.g., interventions could be

collaboratively delivered by both a peer and a nurse), so the numbers above often sum to greater than the total number of studies.

The conditions of community engagement, i.e. the ways in which people were engaged, varied to some extent across these intervention studies. Community members were most often engaged through intervention delivery across this set of studies: in 15 studies they led on intervention delivery, and in nine studies they collaborated on delivery with other professionals. The extent of community engagement in intervention design/planning varied across the studies: members led, collaborated or were consulted on intervention design/planning in nine studies; the remaining fifteen studies showed no involvement in intervention design or planning. The number of community-initiated interventions was low in this dataset: only four of the studies described community involvement in identifying the health needs to be addressed. It should be noted that studies could have utilised more than one condition of community engagement (e.g. design consultation and collaboration on intervention delivery).

	Conditions			Outcome			
	Empower	Design	Deliver	Deliver		Effect	Effective
Study	ment	Any	Lead	Collab	Topic	size	fuzzy set
Anderson (2005)	0	0	1	0	Breastfeeding	1.167	1
Arlotti (1998)	0	0	1	0	Breastfeeding	0.676	1
Barnes (1999)	1	1	1	0	Immunisation	0.228	0.333
Caulfield (1998)	0	0	1	0	Breastfeeding	0.727	1
Chapman (2004)	1	1	0	1	Breastfeeding	0.306	0.666
Conway (2004)	0	0	1	0	Breastfeeding	0.045	0.333
Grummer-Strawn (1997)	0	0	0	1	Breastfeeding	0.358	0.666
Johnson (1993)	0	0	0	1	Immunisation	0.617	1
Julnes (1994)	0	0	1	0	Antenatal care	0.464	0.666
Karanja (2010)	0	1	0	1	Breastfeeding	-0.420	0
Kistin (1994)	0	0	1	0	Breastfeeding	0.921	1
Long (1995)	0	0	1	0	Breastfeeding	0.299	0.333
McInnes (1998)	1	1	1	0	Breastfeeding	0.261	0.333
Parsons (1992)	1	1	1	0	Antenatal care	-0.179	0
Poland (1992)	0	0	1	0	Antenatal care	0.590	1
Pugh (2001)	0	0	0	1	Breastfeeding	0.979	1
Pugh (2002)	0	0	0	1	Breastfeeding	0.447	0.666
Rodewald (1999)	0	0	1	0	Immunisation	1.047	1
Schafer (1998)	0	1	1	0	Breastfeeding	1.167	1

Shaw (1999)	0	0	1	0	Breastfeeding	0.459	0.666
St James (1999)	0	0	1	0	Antenatal care	1.430	1
Vogler (2002)	0	1	0	1	Early intervention	0.373	0.666
Wright (1997)	0	1	0	1	Breastfeeding	0.420	0.666
Zhou (2003)	0	1	0	1	Immunisation	-0.573	0

The final dataset of included studies, their conditions and outcomes are illustrated in Table 3. A total of three studies had non-membership in the 'effective' set; four studies had weak membership; seven studies had partial membership; and ten studies had full membership in the 'effective' set.

Table 3. Dataset, conditions and outcomes

Fuzzy set qualitative comparative analysis of all possible combinations for 'effective' and 'not effective' cases, and the assignment of the studies in our dataset to those combinations, is illustrated in Tables 4 and 5. For the 'effective intervention' set, three combinations of conditions, which were present in a total of sixteen studies, had raw consistency values above 0.75. 'Raw' consistency refers to the consistency rating that is explained by all possible combinations of conditions (Ragin 2006b). These three combinations of conditions are therefore associated with effective interventions (Table 4).

For the 'not effective intervention' set, one combination of conditions, which was present in three studies, had a raw consistency value above 0.75. This combination of conditions was associated with ineffective interventions (Table 5).

Table 4. Truth table of combinations and 'effective intervention' set membership

Number of studies	Empower ment	Design: any	Deliver: lead	Deliver: collab	Membership in the 'effective intervention' set	Raw consistency
1	0	1	1	0	1	1.000
4	0	0	0	1	1	0.833
11	0	0	1	0	1	0.818
1	1	1	0	1	0	0.666
4	0	1	0	1	0	0.333
3	1	1	1	0	0	0.222

0	0	0	0	0
0	0	0	1	1
0	0	1	0	0
0	0	1	1	1
0	1	0	0	0
0	1	0	0	1
0	1	0	1	0
0	1	0	1	1
0	1	1	0	0
0	1	1	1	1

Table 5. Truth table of combinations and 'not effective' intervention set membership

Number	Empower	Dociona	Deliver:	Deliver:	Membership in the 'not effective	
of studies	Empower ment	Design: any	lead	collab	intervention' set	Raw consistency
3	1	1	1	0	1	0.778
4	0	1	0	1	0	0.667
1	1	1	0	1	0	0.334
11	0	0	1	0	0	0.182
4	0	0	0	1	0	0.167
1	0	1	1	0	0	0
0	0	0	0	0		
0	0	0	1	1		
0	0	1	0	0		
0	0	1	1	1		
0	1	0	0	0		
0	1	0	0	1		
0	1	0	1	0		
0	1	0	1	1		
0	1	1	0	0		
0	1	1	1	1		

Re-examination of the initial studies in this set did not identify any contradictory configurations of conditions, and both positive and negative configurations went forward into the Boolean minimisation to determine solution sets. Two of the combinations of conditions that were associated with the effective set could be combined in the Boolean minimisation. These were the studies that did not have an empowerment component, did have a leading on delivery component, and did not have a collaborating on delivery component – regardless of whether they had involvement in the design of the intervention. In other words, Rows 1 and 3 of Table 4 could be combined to a new solution set:

~empowerment*deliverlead*~delivercollab

Thus, we were left with two solution sets for the 'effective interventions' and one solution set for 'not effective interventions'. These solution sets are shown below in Table 6.

Table 6. Solution sets

	Unique	
Aligned with 'effective intervention' cases	coverage	Consistency
~empowerment*deliverlead*~delivercollab	0.625	0.833
~empwerment*~designany*~deliverlead*delivercollab	0.208	0.833
	Unique	
Aligned with 'not effective intervention' cases	coverage	Consistency
empowerment*designany*deliverlead*~delivercollab	0.291	0.78

^{~ =} not

The first solution set for the effective interventions was one in which mothers led on providing interventions to other mothers (i.e. peer-delivered interventions) without collaborating with professionals and without being involved in identifying the need. Within all studies which had this combination, a consistency of 0.833 related to an effective outcome was noted; and this combination had a unique coverage of 0.625 relative to all 'effective interventions' in the dataset. 'Unique' coverage explains the coverage attributed to a specific condition (Ragin 2006b). The second combination aligned with 'effective interventions' was one in which mothers collaborated with professionals, but did not identify the initial health need, did not provide input into the design of the intervention, and did not lead on the intervention. This combination aligned with 'effective interventions' produced a consistency value of 0.833 and had a unique coverage of 0.208 relative to all 'effective interventions' in the dataset.

Only one combination of conditions was consistently aligned with 'not effective intervention' set membership (Table 6). Studies in which communities identified the health need, were involved in the intervention design, and led on – but did not collaborate in – delivery, had a consistency value of 0.778 across the 'not effective intervention' studies. This combination of conditions had a unique coverage of 0.291.

^{* =} and

Meta-regression to determine whether methodologically biased studies were more likely to over- or under-estimate effect sizes did not show a statistically significant relationship (R^2 = .0003, p=.8645). This result means that only 0.03% of the variation in effect sizes was explained by the variation in risk of bias. The parallel fsQCA of risk of bias conditions on effectiveness revealed a raw consistency value of 0.666, which is below the cut-off level for consistency. In other words, both meta-regression and the fsQCA analysis indicate that there is no cause for concern about a risk of methodological bias influencing the results of the main analysis.

DISCUSSION

The findings from this study suggest that, when utilising community engagement to provide health interventions to disadvantaged new and expectant mothers and their children, two solutions are reasonably consistent in producing an effective outcome. The first of these occurs through an intervention which is layor peer-delivered; the second, when the intervention delivery is undertaken in collaboration between community members and service providers.

This suggests that there are two possible ways forward for people wanting to commission such interventions: either to recruit lay people or peers to deliver the intervention, or to involve members of the community in its development. With the knowledge that these types of community engagement are supported by the literature, decision makers can then build upon either of these types, taking other factors into consideration (e.g. resources, staff skills, etc.). Nurses and midwives working with populations of disadvantaged new and expectant mothers are well-placed to help develop and implement such interventions, although their public health role must be supported to do so (RCM 2001 p.975; RCM 2012, RCN 2012). This finding supports the emphasis by government and professional bodies on the need for tailored care developed specifically for and in conjunction with women (NICE 2010, RCM 2011).

Even though the community engagement literature asserts that community empowerment is the most appropriate and effective means of helping people improve their health, only four studies in this dataset had an empowerment condition. Intriguingly, the condition of empowerment was not present in any of the solution sets in the 'effective intervention' set. While the theoretical case for empowerment is persuasive, we can only conclude that it is yet to be supported by research evidence (Davidson 1998, Popay 2006, Popay et al. 2007, Swainston & Summerbell 2008, World Health Organisation 2002).

The lack of empirical evaluations of empowerment strategies in this area may have been due to the challenges in evaluating this type of engagement. Empowerment strategies are difficult to compare with other intervention strategies, as they might be expected to impact on more outcomes across a wider population (South et al. 2012). The studies included in this analysis measured short term outcomes such as breastfeeding or immunisation rates, leading us to suggest that other models of change, including empowerment, may be more useful for medium-term (e.g. infant development) and long-term (e.g. family wellbeing outcomes) (McNeill et al. 2012). This is an area that requires future development and evaluation, and the use of such models demand the development of appropriate metrics for comparison.

Some further research gaps emerged from this study. First, breastfeeding interventions were the most common health issue evaluated within this set of studies. There were relatively fewer studies focused on antenatal care, immunisation, or child illness interventions, and none located on intrapartum and immediate postnatal care interventions. This suggests a potential area for future community engagement and intervention development and testing.

Second, peer involvement was the most often-used community engagement strategy, though non-peer involvement, outreach, volunteers, community action and community partnerships were also used. If more evidence had been available on alternative community engagement strategies, we would have been able to test those as conditions in the fsQCA analysis.

This method of understanding 'what works' in interventions for disadvantaged expectant and new mothers examines community engagement without simplifying its complexity. The methods used overcame limitations in regression-based synthesis methods by allowing multiple 'routes' through to an effective outcome, treating the studies as 'cases' rather than observations in a survey (Thomas et al. in preparation). However, we identified some limitations which should be considered.

Limitations

There are three key aspects to this review that might limit the conclusions that can be drawn from the results. These are the extent of searching for maternity and early years research; the problem of limited diversity; and concerns about the methodological soundness of the intervention evaluations.

Firstly, there are many more areas of intervention in maternity and early years care than the ones found in this review (e.g. contraceptive counselling, postnatal nutrition counselling etc.). We may have missed some studies of maternity and early years interventions targeted to disadvantaged expectant and new mothers, simply because our systematic review searches were designed to identify community engagement concepts rather than those related to maternity and early years care.

Secondly, there was evidence of limited diversity in the dataset. Limited diversity affects QCA in that there may be too few cases for a given condition to adequately assess its membership in a set. In this dataset, we only had four studies that had the condition of empowerment; we are therefore limited in the conclusions we can draw about empowerment in maternity and early years interventions.

Finally, the quality of research varies: our risk of bias assessment indicated that 13 of the included studies were 'not methodologically sound'. While research suggests that poorer quality studies tend to over or under estimate observed effect sizes (Hempel et al. 2011), our regression analysis and fsQCA examining

the relationship between effect size and risk of bias rating did not identify any statistically significant or consistent relationships. This suggests that on average in this dataset, methodological quality was not likely to have been related to the observed effect sizes.

CONCLUSIONS

Examining the 'active ingredients' in community engagement for disadvantaged expectant and new mothers identified several opportunities for future intervention development and evaluation. Descriptive analysis revealed gaps in the evidence in terms of other areas of intervention in maternity and early years care, the potential effectiveness of other community members providing care, and interventions targeted to specifically disadvantaged groups (e.g. ethnic minorities, geographic disparities, teenage mothers).

Policy- and decision-makers should consider using either peer delivery or collaborative delivery models when planning similar interventions for disadvantaged women and children across maternity and early years care. More 'pragmatic' intervention evaluations with disadvantaged pregnant women and new mothers could be developed, particularly testing the circumstances in which peer-delivered models and models of collaborative delivery with nurses and midwives work. Understanding expectant women's and new mothers' perspectives of involvement in identifying their health needs, appropriate intervention design and most effective ways of collaborating with their communities could help develop community engagement in maternity and early years care.

Finally, understanding why empowerment models have not been utilised more often in trials of maternity and early years care is an important next step. Increasing our understanding of the ways in which empowerment models could be appropriate, and designing trials that evaluate those models, might go some way toward building woman-centred care in an area of health services delivery that has been criticised for not being woman-centred (Leap 2009).

REFERENCES

Arlotti JP, Cottrell BH, Lee SH, Curtin J (1998) Breastfeeding among low-income women with and without peer support. *Journal of Community Health Nursing* 15(3), 163 – 78.

Barnes K, Friedman SM; Brickner Namerow P, Honig J (1999) Impact of community volunteers on immunization rates of children younger than 2 years. *Archives of Pediatrics & Adolescent Medicine* 153(5), 518 – 24.

Brenner B, Manice M (2011) Community engagement in children's environmental health research. *Mount Sinai Journal of Medicine* 78(1), 85 – 97.

Cohen J, Onunaku N, Clothier S, Poppe J (2005) *Helping young children succeed: strategies to promote early childhood social and emotional development.* National Conference of State Legislatures Research and Policy Report, Washington DC.

Craig P, Dieppe P, MacIntyre S et al. (2008) *Developing and evaluating complex interventions: new guidance*. Medical Research Council, London UK.

Crombie IK, Irvine L, Elliott L, Wallace L (2005) *Closing the health inequalities gap: an international perspective.* WHO Regional Office for Europe, Copenhagen.

Dale J, Caramlau IO, Lindenmeyer A, Williams SM (2008) Peer support telephone calls for improving health. *Cochrane Database of Systematic Reviews* 2008, Issue 4. Art. No.: CD006903. DOI: 10.1002/14651858.CD006903.pub2.

Davidson LL, Durkin MS, Kuhn L, O'Connor P, Barlow B, Heagarty MC (1994) The impact of the Safe Kids/Healthy Neighborhoods Injury Prevention Program in Harlem, 1988 through 1991. *American Journal of Public Health* 84(4), 580 – 586.

Davidson S (1998) Spinning the wheel of empowerment. *Planning* 1262, 14 – 15.

Department of Health (2002) *Shifting the Balance of Power: The Next Steps.* Department of Health, London UK.

Department of Health (2004) *National Service Framework for Children, Young People and Maternity Services.* Department of Health, London UK.

Department of Health. (2005) *Commissioning a Patient-led National Health Service.* Department of Health, London UK.

Department of Health. (2006b) *Our Health, Our Care, Our Say: A New Direction for Community Services (White Paper)*. The Stationery Office, Norwich UK.

Department of Health. (2006a) A Stronger Local Voice: A framework for creating a stronger local voice in the development of health and social care services. Department of Health, London UK.

Department of Health. (2006) *Health reform in England: update and commissioning framework.* Department of Health, London UK.

Department of Health. (2010) *Maternity and early years: making a good start to family life.* Department of Health, London UK.

Department of Health. (2011) *Health Inequalities National Support Team.* URL: http://www.dh.gov.uk/en/Publichealth/NationalSupportTeams/HealthInequalities/index.htm. Accessed: 16 May 2011.

Hempel S, Suttorp MJ, Miles JNV, Wang Z, Maglione M, Morton S, Johnsen B, Valentine D, Shekelle PG. (2011) *Empirical Evidence of Associations Between Trial Quality and Effect Sizes. Methods Research Report*. AHRQ Publication No. 11-EHC045-EF. Agency for Healthcare Research and Quality, Rockville MD. June 2011. Available at: http://effectivehealthcare.ahrq.gov.

Higgins J, Green S (editors) (2009) *Cochrane Handbook for Systematic Reviews of Interventions Version 5.0.2* [updated September 2009] The Cochrane Collaboration, Oxford UK.

Kavanagh J, Oliver S, Lorenc T, Caird J, Tucker H, Harden A, et al. (2009) School-based cognitive-behavioural interventions: a systematic review of effects and inequalities. *Health Sociology Review*, 61 – 78.

Leap N (2009) Woman-centred care or women-centred care: does it matter? British Journal of Midwifery 17(1), 12 - 16.

Lewin S, Munabi-Babigumira S, Glenton C, Daniels K, Bosch-Capblanch X, van Wyk BE, Odgaard-Jensen J, Johansen M, Aja GN, Zwarenstein M, Scheel IB (2010) Lay health workers in primary and community health care for maternal and child health and the management of infectious diseases. *Cochrane Database of Systematic Reviews* 2010, Issue 3. Art. No.: CD004015. DOI: 10.1002/14651858.CD004015.pub3.

Manley K et al. (2011) Person-centred care: Principle of Nursing Practice D. *Nursing Standard* 25(31), 35 – 37.

Marmot M et al. (2010) *Fair society, healthy lives: the Marmot Review. Strategic review of health inequalities in England post-2010.* London: The Marmot Review.

McNeill F, Lynn F, Alderdice F (2012) Public health interventions in midwifery: a systematic review of systematic reviews. *BMC Public Health* 12, 955 – 978.

Milton B, Attree P, French B, Povall S, Whitehead M, Popay J (2012) The impact of community engagement on health and social outcomes: a systematic review. *Community Development Journal* 47(3), 316 – 334.

National Institute of Clinical Excellence (NICE) (2010) *Pregnancy and complex social factors: a model for service provision for pregnant women with complex social factors. NICE clinical guideline 110*National Institute for Health and Clinical Excellence, London UK.

O'Mara-Eves A, Brunton G, McDaid D, Oliver S, Kavanagh J, Jamal F, Matosevic T, Harden A, Thomas J (2013 in press) Community engagement to reduce inequalities in health: a systematic review, meta-analysis and economic analysis. *Public Health Research*.

Popay J (2006) Community engagement for health improvement: questions of definition, outcomes and evaluation. A background paper prepared for NICE. London: NICE.

Popay J, Attree P, Hornby D, Milton B, Whitehead M, French B, et al. (2007) *Community Engagement in Initiatives Addressing the Wider Social Determinants of Health: A rapid review of evidence on impact, experience and process.* University of Lancaster, Lancaster UK.

Ragin C et al. (2006a) *Fuzzy-set Qualitative Comparative Analysis 2.0.* Tucson, AZ: Department of Sociology, University of Arizona.

URL: http://www.u.arizona.edu/~crain/fsQCA.software.shtml. Accessed: 10 May 2013.

Ragin C (2006b) 'Set relations in social research: evaluating their consistency and coverage', *Political Analysis* 14(3), 291 – 310.

Renfrew MJ, McCormick FM, Wade A, Quinn B, Dowswell T (2012) Support for healthy breastfeeding mothers with healthy term babies. *Cochrane Database of Systematic Reviews* 2012, Issue 5. Art. No.: CD001141. DOI: 10.1002/14651858.CD001141.pub4.

Research Councils UK (RCUK) (2011) *RCUK response to the Royal Society's study into science as a public enterprise.* RCUK, London UK.

URL: http://www.rcuk.ac.uk/documents/submissions/SAPE_Aug2011.pdf. Accessed: 13 June 2013.

Rihoux B, Ragin C (2009) *Configurational comparative methods: qualitative comparative analysis (QCA) and related techniques.* Sage, London UK.

Royal College of Midwives (RCM) (2001). *The midwife's role in public health: Position paper no. 24.* Royal College of Midwives, London UK.

Royal College of Midwives. (2011) *Woman centred care: position statement.* Royal College of Midwives, London UK.

Royal College of Midwives website (2012) *Midwives' role in the social determinants of health*.

URL: http://community.rcm.org.uk/consultations/midwives-role-social-determinants-health.

Accessed: 9 May 2013.

Royal College of Nurses (2012) *Health inequalities and the social determinants of health*. Royal College of Nurses, London UK.

Sandall J (2012) The politics of evidence and complex interventions: taking a long view through a sociological lens of continuity of midwifery care. *Evidence Based Midwifery* 10(3), 76 – 79.

Schafer E, Vogel MK, Viegas S, Hausafus C (1998) Volunteer peer counselors increase breastfeeding duration among rural low-income women. *Birth* 25(2), 101 – 106.

South J, Kinsella K, Meah A (2012) Lay perspectives on lay health worker roles, boundaries and participation within three UK community-based health promotion projects. *Health Education Research* 27(4), 656 – 70.

Swainston K, Summerbell C. (2008) The effectiveness of community engagement approaches and methods for health promotion interventions. University of Teeside, Teeside UK.

Thomas J, O'Mara-Eves A, Brunton G (2013 in preparation) Configuring causal conditions in systematic reviews of complex interventions: a worked example of Qualitative Comparative Analysis (QCA). Systematic Reviews.

United Nations Safe Motherhood Initiative (2010) *Priorities for safe motherhood. Safe Motherhood initiative.*

URL: http://www.safemotherhood.org/priorities/index.html.

Accessed: 10 June 2013.

University College London Institute of Health Equity (2013) Working for Health Equity: The Role of Health Professionals. *Healthcare system and workforce's role in reducing health inequalities through action on the social determinants of health.* Institute of Health Equity, Department of Epidemiology & Public Health, University College London, London UK.

World Health Organisation (2002) *Community participation in local health and sustainable development: approaches and techniques.* World Health Organisation, Europe.