How useful is qualitative research and experiential accounts of breastfeeding when discussing and informing outcomes for systematic reviews of breastfeeding interventions, and other reviews in pregnancy and childbirth?

Report of a meeting held on the 20th January 2015
Prepared by Sally Crowe and Ann Daly, Crowe Associates Ltd, Cochrane Pregnancy and Childbirth Group and meeting participants

1. Background to the meeting

The OMIPPP project (Outcomes Most Important to Patients, Public and Practitioners) is an exploration in methods – grounded in the James Lind Alliance experience of collecting and prioritising treatment uncertainties from patients, carers and health professionals - for highlighting therapeutic outcomes for Cochrane systematic reviews that are important for patients, public and practitioners. This will be achieved via feasibility work with three Cochrane Review Groups (CRGs), using three different methods, all will involve patient, public and clinician perspectives. This meeting is the concluding part of the work with the Cochrane Pregnancy and Childbirth Group (PCG). With this pilot we were interested in whether important outcomes can be inferred from existing collections of literature about the experiences of women breastfeeding. Two potential sources of outcomes were explored; a collection of narratives of women talking about their breastfeeding experiences in health talk (http://www.healthtalk.org/) and published literature of qualitative research describing women's experiences of breastfeeding. Once assembled the implied outcome themes were mapped to the current topic areas of breastfeeding reviews in the PCG collection and the outcomes currently used in these reviews assembled alongside to allow comparison. This meeting was convened to discuss this material and consider the implications of it in the context of systematic reviews in general and in particular breastfeeding reviews.

2. Participants

The following people took part in the meeting:

- Members of the PCG; Zarko Alfirevic (Co-coordinating Editor), Frances Kellie (Managing Editor), Leanne Jones (Associate Editor for updated reviews), Therese Dowswell (Research Associate) and Helen West (Research Associate)
- Gill Gyte, Consumer Editor of the PCG but also a member of the National Childbirth Trust (NCT), Sarah McMullen Head of Policy Development, NCT
- Sharon Dixon and Susan Kirkpatrick, researchers with the Health Experiences Research Group, Oxford University
- Phyll Buchanan representing the Breastfeeding Network (BfN)
- Prof Pat Hoddinott Primary Care, Nursing, Midwifery and Allied Health Professional Research Unit, University of Stirling and researcher in breastfeeding interventions and policy development took part via Skype
- Ann Daly and Sally Crowe representing the OMIPPP Project

Apologies were received from Jim Neilson (Co-coordinating Editor) and Lynn Hampson (Trials Search Co-ordinator) from the PCG.

3. Meeting objectives

1. To consider and discuss the outputs of work that has elicited implied outcomes associated with breastfeeding from existing literature and a Health Talk module
2. To contrast these with the outcomes reported in Cochrane Systematic Reviews of interventions for breastfeeding
3. To consider the importance of the outcomes in relation to each other, for a breastfeeding review, and a non breastfeeding review (where there were breastfeeding outcomes)

A summary of the data collected thus far was sent to meeting participants ahead of the workshop.

4. Meeting outline - morning

The full programme of the meeting is available in Appendix 1

Following introductions it became quickly apparent that not only did we have a wealth of expertise in the room but also quite a bit of lived experience of breastfeeding.

Frances Kellie, Managing Editor of the PCG gave an overview of the work of the review group and some of the challenges it faces. The Cochrane Pregnancy and Childbirth Group (PCG) was the first Cochrane Review Group to be established (in 1992) and it has been the most productive of the 53 Cochrane Review Groups, worldwide, every year since then. They prepare and maintain Cochrane systematic reviews of interventions that relate to pregnancy and childbirth, and up to 30 days following childbirth, as well as breastfeeding. The editorial base is located within the University of Liverpool's Department of Women's and Children's Health at the Centre for Women's Health Research at the Liverpool Women's Hospital. Currently the editorial team manage a portfolio of around 600 Cochrane systematic reviews, supporting the work of over 1200 review authors from 54 countries, these reviews are based solely on evidence from RCTs. The PCG has a consumer referee panel that provides input and perspectives from women on all aspects of the review process. Of the top five accessed reviews in the portfolio, two concern breastfeeding; one on optimal duration of exclusive breastfeeding the other support for breastfeeding mothers with healthy term babies.

Outcomes used in systematic reviews can be defined in terms of five elements: a **domain** e.g. quality of life; a **specific measurement** e.g. SF26 (a Patient Reported Outcome Measure PROM); a **specific metric** e.g. change from baseline; **a method of aggregation** e.g. mean, Standard Deviation; **a time-point when measured** e.g. 2 weeks post-partum.

Ann Daly described how the OMIPPP team conducted literature searches for experiential accounts of breastfeeding in the health research literature including:

- Reports of mothers' experiences of breastfeeding / lactation AND an *outcome* (direct or implied)
- Reports of breastfeeding mothers with diabetes (core is within 28 days postpartum)
- Weaning (included but *not core*)

Fertility and breastfeeding, contraception and breastfeeding and HIV and breastfeeding / weaning were excluded as advised by PCG. The abstracts of 31 papers were examined to identify outcomes relating to breastfeeding and 80 unique implied outcomes were identified.

In addition, Ann watched the breastfeeding module in *healthtalk.org* / *Pregnancy and Children / Breastfeeding* to identify outcomes relating to breastfeeding, 48 unique *implied* outcomes identified.

Primary and secondary outcomes were extracted from an agreed list of 35 Cochrane Systematic Reviews, so that the material from experiential sources could be compared with the outcomes currently used in Cochrane reviews, 30 unique outcomes were identified.

A full search strategy is available on request.

The research team from Health Talk presented their more in-depth work on the breastfeeding module. Compared to Ann's exercise, the researchers accessed the original transcripts of the interviews, looking for discussion points in interviews that could be interpreted as outcomes. They presented their methods and showed clips from highlighted discussions that they thought illustrated their work. This more in depth work superseded Ann's assessment of the health talk material and was used for the purposes of the workshop. However, the health talk and OMIPPP teams are keen to compare and contrast these two exercises to see if there is a need to always go to the original transcripts for clues about outcomes. This will be reported later in 2015.

Finally, Gill Gyte Cochrane Consumer Editor for PCG gave a more personal view about outcomes used in reviews. Gill described how consumer involvement in Cochrane Reviews often focussed on outcomes, especially including outcomes that are important to women/parents and she felt that important information is gathered from asking women. She made the point that outcomes need to be important, particularly to women and babies, but are often what researchers and clinicians want to measure, are easy to measure and mean something to them. Gill then highlighted the particular expectations of Cochrane authors of systematic reviews:

- Compare an intervention against no intervention, or two interventions against each other, to see if outcomes for women and babies can be improved
- Outcomes are listed as primary and secondary, and need to cover potential benefit and potential harms, for both mother and baby
- There is a need to limit the number of outcomes

Gill described the tensions in finding outcomes that are important to both women and health professionals caring for them, and that can be measured in a reliable and meaningful way. She illustrated this using an outcome discussed within the context of a clinical trial that she is currently involved in:

When considering using haemoglobin (Hb) measurement for postpartum bleeding:

- Having an Hb below 9 g/dl means nothing to women – but may be helpful to clinicians deciding on care
- What women might want to know is:

  a) How will I feel?

  b) Will I be too tired to care for my baby?

  c) Will I be too tired to breastfeed?

Gill introduced to the discussion a Patient Reported Outcome Measure (PROM) called the Mother Generated Index (**Appendix 2**), which is unusual in that it asks the mother to generate her own outcomes (conceptualised as 'important areas of your life since having a baby'), before putting them in priority order. This generated much discussion and introduced the group to more information about breastfeeding related patient reported outcome tools. Pat Hoddinott who has done extensive work in this area highlighted that both researcher identified outcome measures and some PROMs tend to be quite long and complex and often challenging for some women to complete. This is particularly problematic for women (of lower socioeconomic status and/or lower educational attainment level) who are often the women who are less likely to breast feed.

We asked if these measurement properties are too restricted when considering the experiential data? For example the number of visits by health professional or breastfeeding support worker may not translate to effective support - how do we capture the nature of the relationship between the health professional or support worker – trust for example? How would we capture the issue of conflicting advice in breastfeeding which is a prevailing issue in qualitative research of breastfeeding experiences? There was an interesting cultural issue of the language that we use for breastfeeding research generally, the word lactation is not one used by women or families, and 'failure' to breastfeed is an interesting word to use when it could be linked to a variety of cultural, mechanical, familial, structural issues, which can be very negative for families.

There are particular challenges in using the qualitative and experiential material for outcome development in Cochrane systematic reviews – these reviews are for use by international audiences and need to reflect where possible international perspectives of treatment and care, and outcomes. The group wondered about the limitations of using qualitative material for Cochrane review outcomes, or is this a state of mind rather than an actual problem? How much does it matter if the quality of the collection of experiences is not reflective of the possible whole range of experiences of breastfeeding internationally?

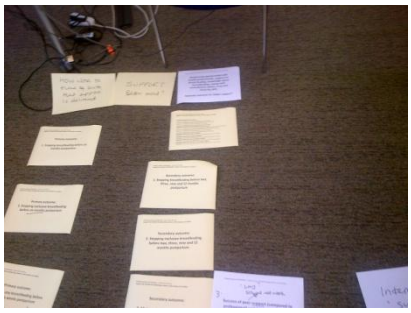
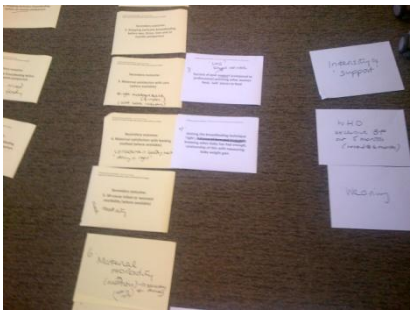
Finally the group wondered if the restriction of seven primary outcomes per review for the Summary of Findings table was for a particular reason? There are statistical reasons why it is important to pre-specify and restrict the number of outcomes. When reporting the findings of the review in summaries and abstracts it ensures that all important outcomes are mentioned. The authors of the review do report additional outcomes in the main body of the review. There was a general feeling though that the choice of outcomes should consider the views and experiences of users of these reviews, both clinical and public.

5. Meeting outline - afternoon

In order to give the afternoon discussion some focus it was decided by the planning group to focus on specific review questions. A general review was chosen i.e. not breastfeeding specific but with breastfeeding outcomes, a breastfeeding specific review and a new but similar breastfeeding review title was introduced at the workshop by a member of the CRG team for opportunistic discussion!

The general idea was to reflect on the morning's discussion when appraising the list of outcomes for the reviews. Cochrane primary and secondary outcomes had been printed onto A4 paper and laid out on the floor. Summaries of the outcomes from experiential literature (different colour) were available on the walls in the meeting room to help the facilitator make connections during the discussion. Where an experiential outcome was discussed this was placed alongside the relevant

Cochrane outcome under review. Where potential new outcomes were considered these were introduced to the map of outcomes.

First systematic review; Caesarean section versus vaginal delivery for preterm birth in singletons (Review), *Alfirevic Z, Milan SJ, Livio S*, Cochrane Library 2013

There were a lot of primary and secondary outcomes used in this review – too many to put on the floor of the meeting room, so we focussed on the ones that we thought either had a breastfeeding focus, or were potentially relevant to breast feeding. New outcomes for consideration are in red. The table below summarises the discussion that we had about these.

Outcomes in review **P= Primary** **S= Secondary**	**Suggestions, considerations for change**	**Comments from group**
S. Mother; Maternal satisfaction	Inc breastfeeding for as long as wanted by mother?	
S. Infant: Breastfeeding at discharge		Group thought this appropriate
S Infant: Breastfeeding at three months		Group thought that this was appropriate but questioned the nature of duration of breastfeeding time spans – a discussion that was revived in the next review outcomes appraisal
S: Mother: Breastfeeding not attempted	Group felt that there was something important about recognising the challenge in C-section about not attempting breast feeding and that current outcomes may not capture this?	New outcome proposed
S. Mother: Success in expressing milk	Possible to measure if mother is supported in expressing milk for premature baby to have via tube if indicated?	New outcome proposed

Second systematic review: Support for healthy breastfeeding mothers with healthy term babies, *Renfrew MJ, McCormick FM, Wade A, Quinn B, Dowswell T*, Cochrane Library 2012

There was an initial discussion about this review that initially focussed on the title of this review and also a more precise description of the intervention was also debated. What do we mean by 'support'? It is a potentially complex term, and will differ across support providers (for some usual care is supportive) and will mean different things to different women and families.

Do we want to refer to the intensity of support as well as its nature? Do we want to consider how close to the time of birth the support is delivered and if this has any effect on outcomes? In the qualitative literature support is typified by several elements such as; the quality of the relationship with the support provider (especially trust), their knowledge about giving appropriate support for the breastfeeding mother, their listening skills in understanding the context and particular needs of the mother and baby, and how mothers and parents deal with contradictory advice from support givers.

We also debated (and lamented) the issues around agreed measurement time points for the duration of breastfeeding and the lack of consensus internationally what we should be aiming for. In broad terms it is about getting started (often in hospital) and sustaining breastfeeding once home. Currently different timescales are used internationally, often to fit in with developmental child assessment time points, resulting in different policy makers and institutions using different parameters and timelines. This presents a clear challenge for Cochrane Reviews of breastfeeding where 'duration' is a primary outcome.
From a woman's perspective situation and contextual changes might be more important than number of weeks e.g. going home from hospital; end of paternity leave; return to work; first social outing/event etc.
From the reviewers perspectives reasons for duration time points are described and discussed in the review protocol (plan for the review), for this review the primary outcomes for duration were four to six weeks and six months. The use of other breastfeeding cessation time points may reflect the need to use all data in the included trials; however international consensus about breastfeeding duration categories would be desirable.

On a related note we discussed the role of outcomes capturing exclusive and non exclusive breastfeeding. Again there seems to be discrepancies internationally about this with WHO recommending exclusive breastfeeding for up to 6 months, but this is not universally adopted. Mixed feeding is a more accessible term than non exclusive feeding for systematic review users, and may also include supplementary feeding. Although weaning (introduction of solids to feeding) was not in the scope of this meeting we touched on this; in fact weaning seems not to have a 'home' in the Cochrane Collaboration. It was recognised that concepts of exclusive breastfeeding are linked to parents' decisions about weaning, again where there appears to be much disagreement about the best time to introduce solids.

It was generally felt that breastfeeding trials rarely collect quality of life information for reviewers to use, and that people involved in quality of life work find that the measures used or adapted for breastfeeding are more geared to illness and disease, and breastfeeding is neither.
Due to the burden of completing Patient Reported Outcomes Measures (PROMs) that may disadvantage women from lower socio economic groups, and education achievements there is a need to focus on simpler PRO tools that can capture a wider group of women's quality of life experiences.

Finally, we returned to the concept of 'support' once more and wanted to recognise and discuss the role of peer support in breastfeeding, and how this sits with the concept of self efficacy in breastfeeding. There was disagreement within the group about the role of self efficacy models in breastfeeding. We started by discussing the terminology surrounding 'peer support' and the merits of other descriptors such as lay support or social support, and even changing the word to 'help'. An effective review must attempt to describe these other types of support in a language that makes sense to women reading it – currently peer support is a term used by researchers and health professionals.

Summary of discussion in relation to specific primary and secondary outcomes;

Outcomes in review **P= Primary** **S= Secondary**	**Suggestions, considerations for change**	**Comments from group**
P 1. Stopping breastfeeding before 6 months post partum		For all primary outcomes suggest a more simple time span of 4 - 6 weeks, or consider it in a setting format as well hospital or home feeding
P 2. Stopping exclusive breastfeeding before 6 months post partum	Exclusive within the last 7 days	
P 3. Stopping any breastfeeding before 4 – 6 weeks postpartum		
P 4. Stopping exclusive breastfeeding before 4 – 6 weeks postpartum	Exclusive within the last 7 days	
S 1. Stopping breastfeeding before 2, 3, 9 and 12 months postpartum	As there is no consensus on when the agreed target for optimum breastfeeding is – are these over complicating the outcome? From a mothers perspective it is more about breastfeeding in hospital and breastfeeding at home	These secondary outcomes are to enable the review to capture data from trials with different measurement and end-points. Targets have changed over time and many trials pre-date WHO 6 months recommendation.
S 2. Stopping exclusive breastfeeding before 2, 3, 9 and 12 months postpartum	As above in terms of no agreement about optimum exclusive breastfeeding targets	
S 3. Maternal satisfaction with care (where available)		Single analogue scale would be helpful, for least health inequity e.g. http://bmjopen.bmj.com/content/2/2/e000652.full And http://bmjopen.bmj.com/content/2/2/e001039.full

S 4. Maternal Satisfaction with feeding method (where available)	Satisfaction....and confidence in their feeding method "getting it right"	
S 5. All cause infant or neonatal morbidity (where available)		What about infant mortality? Comment about most trials being too small for this to be meaningful however
S 6. Maternal morbidity	Suggest mastitis	New outcome suggestion
S 7. General wellbeing of mother	Could be impact of breastfeeding on daily life, quality of life, impact of breastfeeding on personal life e.g. sex	New outcome suggestion
S 7. General wellbeing of mother		New outcome suggestion
S.8 Expressing breast milk		Potential confounder to some important outcomes e.g. infant attachment, later behavioural problems in childhood? There is uncertainty about the extent to which it is the breast milk itself is the mediator of effects (proposed for infant infections) and the attachment relationship of the mother and baby during feeding at the breast. The evidence suggests that breast milk expression is increasing in both prevalence and duration of expressing milk.

Finally we discussed a proposed new title in supporting breastfeeding mothers of twins. The key points from this discussion are below:

- There are statistical methods to take account of non-independence of twin outcomes, which means it is possible to use data for both babies
- It would be good to integrate more qualitative information into outcomes
- Twin support needs to be very practical and particular to a twins context and this needs to be reflected in the review
- Much of the existing discussion on single babies, has relevance for this review, and so the suggested outcomes apply

6. What will happen to this information? Next steps

1. Forward the OMIPPP report on breastfeeding outcomes to the PCG Editor for breastfeeding reviews for her to consider when preparing a generic protocol for breastfeeding reviews (currently under development). We will suggest that she also get in touch with breastfeeding specialists involved in the OMIPPP meeting to see if they will contribute to the generic protocol.

2. A generic protocol on breastfeeding reviews will be developed, incorporating the outcomes from OMIPPP and disseminated to all relevant review authors for consultation. The development of the generic protocol will ensure consistency between Cochrane reviews on breastfeeding.

7. Ideas

Several ideas were suggested during the meeting and merit a mention in this report, we did not attempt to achieve consensus on them but they were:

- In the background of a **published Cochrane Review what about a short video** of a mother talking about her experience of breastfeeding?
- At the end of a Cochrane Review a short video of a woman (or family) talking about the overall result of the review? This is another way to communicate the results (it could be translated into other languages)
- **Using Health Talk excerpts as trigger videos** for discussions about outcomes in meetings and workshops (it certainly worked in this meeting)
- Do we need to **rethink the language** that the CRG use? Lactation (breastfeeding) or refer to 'infant feeding' either by breast or bottle or both
- Is it time to agree and set of **set of core outcomes for breastfeeding reviews?** Prof Christine East in Australia has started this work and it would be potentially very useful if the specialist participants from this meeting were involved or consulted in some way?

8. Acknowledgements

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The Cochrane Pregnancy and Childbirth Group (PCG) is part of the international Cochrane Collaboration, an independent not-for-profit consortium dedicated to providing up-to-date, accurate information about the effects of health care. The PCG receives infrastructure funding from the National Institute for Health Research (NIHR). Some aspects of this meeting were supported by the PCG. Other aspects of this meeting have been supported by the UK Cochrane Centre (which is funded by NIHR) as part of a project called Outcomes Important for Public, Patients and Practitioners (OMIPPP).

Appendix 1 - meeting agenda

10.00	**Refreshments available**	
10.30	Introductions, meeting objectives and overview of OMIPPP Project	All Sally Crowe
10.50	Overview of Pregnancy and Childbirth Group and systematic reviews	Frances Kellie
11.00	Published literature on experiences of breastfeeding from mothers and professional perspectives	Ann Daly
11.20	Experiences of breastfeeding, as part of the Health Talk Module	Susan Kirkpatrick and Sharon Dixon
11.40	Outcomes from a Systematic Review Perspective	Gill Gyte
12.00	Discussion arising from presentations	Sally Crowe
12.30	**Lunch break**	
13.15	Recap of progress so far and key themes from discussion	Sally Crowe
13.30	Can we interpret the findings from Health Talk and experiential literature into meaningful outcomes for systematic reviews? This discussion will be in the context of two Systematic Review questions; "Support for healthy breastfeeding mothers with healthy term babies" *Renfrew MJ, McCormick FM, Wade A, Quinn B, Dowswell T* Cochrane Library 2012 Caesarean section versus vaginal delivery for preterm birth in singletons (Review) *Alfirevic Z, Milan SJ, Livio S* Cochrane Library 2013	All
14.45	Reflections by CRG on the outcomes identified as potentially important for reviews	All and especially CRG members
15.15	Summary of discussion, next steps and writing up today's meeting	Sally Crowe
15.30	**Meeting concludes**	

Appendix 2 - Mother Generated Index - Quality of Life Assessment

THE TAYSIDE MOTHER-GENERATED INDEX © *A QUALITY OF LIFE ASSESSMENT*

Step 1: Identifying areas		Step 2: Scoring each area	Step 3: Allocating points
We would like you to think of the most important areas of your life that have been affected by having a baby. These can be POSITIVE or NEGATIVE. Please write up to eight areas in the boxes below, and indicate if you think the area is positive, negative, or neither of these.		Now please score the areas you mentioned in Step 1. This score should reflect how you have been affected by this area over the past MONTH. Please place a cross along the line in each case: 0 is the worst - you couldn't feel any worse than this 10 is the best - you couldn't feel any better than this Worst … Best 0 1 2 3 4 5 6 7 8 9 10	Please think how important these areas are to your quality of life. You have **20 points** to allocate. You don't have to allocate points to an item if you don't want to. **Give more points to the areas you think are most important.** Write the points in the boxes below.
Examples other mothers have given are: • How they feel about themselves • How they feel about their baby • How their feel about their relationship with their partner or other family members • Physical or emotional issues (good or bad) • How they feel about going back to work • How they feel about their social life These are only examples. We want you to say what you feel.	Please circle whether you think this point is Positive, Negative, or Neither		
	Positive Negative Neither	0 1 2 3 4 5 6 7 8 9 10	
	Positive Negative Neither	0 1 2 3 4 5 6 7 8 9 10	
	Positive Negative Neither	0 1 2 3 4 5 6 7 8 9 10	
	Positive Negative Neither	0 1 2 3 4 5 6 7 8 9 10	
	Positive Negative Neither	0 1 2 3 4 5 6 7 8 9 10	
	Positive Negative Neither	0 1 2 3 4 5 6 7 8 9 10	
	Positive Negative Neither	0 1 2 3 4 5 6 7 8 9 10	
	Positive Negative Neither	0 1 2 3 4 5 6 7 8 9 10	

Remember: points in Step 3 must add up to 20