Outcomes Most Important to Patients, Public and Practitioners (OMIPPP)

Final project report

Sally Crowe, Sandra Regan and Ann Daly, Crowe Associates Ltd - June 2015

Contents

| | | Page |
|----|---|------|
| 1. | Executive summary | 2 |
| | | 2 |
| 2. | Introduction | 3 |
| 3. | Literature Review | 4 |
| | | |
| 4. | Overview of three methods | 5 |
| | 4.1 Face to face workshop | 5 |
| | 4.2 Online survey | 6 |
| | 4.3 Using online experiential data | 7 |
| | | |
| 5. | Results from three methods | 8 |
| | 5.1 Face to face workshop | 8 |
| | 5.2 Online survey | 10 |
| | 5.3 Using online experiential data | 11 |
| 6. | Costs of each approach | 14 |
| 7. | Comparison of three methods | 14 |
| 8. | Acknowledgements | 16 |
| 9. | Appendices | |
| | 9.1 Search strategy - Literature review | 18 |
| | 9.2 Airways Review Group - tips for running workshops | 19 |
| | 9.3 Asthma workshop report | * |
| | 9.4 Search strategy for Breastfeeding Project | 20 |
| | 9.5 Comparison of outcomes for breastfeeding | * |
| | 9.6 Report of breastfeeding meeting | * |
| | 9.7 Unline survey report | * |
| | | * |

1. Executive summary

The project explored methods for engaging patients, the public and health practitioners in the development of outcomes for systematic reviews. The project team worked with three Cochrane Review Groups (CRGs): Airways; Ear Nose and Throat and Pregnancy and Childbirth focussing on outcomes in Asthma, Rhinosinusitis and Breastfeeding.

A different method of engagement was used to explore outcomes:

- Asthma: in partnership with Asthma UK perspectives of asthma were gathered from a Face book survey and review of existing core outcome sets. This was followed by a workshop of people with asthma, carers and health practitioners who generated and prioritized their own important outcomes and discussed the results.
- Ear Nose and Throat: working in partnership with evidENT perspectives of rhinosinusitis were gathered using an online survey distributed through social media, and email lists. This was followed by a comparative review of survey responses with existing outcomes in systematic reviews of chronic rhinosinusitis.
- **Breastfeeding:** women's direct experiences of outcomes in breastfeeding were identified through reviewing the transcripts from the Breastfeeding module of Healthtalk.org. The literature was also searched for qualitative research of women's experiences. Once all the data was assembled including outcomes used in systematic reviews of breastfeeding interventions the review group met breastfeeding advocates, and healthtalk researchers to discuss findings.

All three methods resulted in lists of outcomes that had relevance for outcomes used in systematic reviews. Two sets of outcomes were prioritized (asthma and rhinosinusitis). The most effective method for producing a ranked list of important outcomes from patients, the public and health practitioners was the online survey. This work will now contribute to a larger exercise to determine a core outcome set for trials of interventions for chronic rhinosinusitis. This method was the most cost effective of the three approaches, with most of the resource being allocated to the data analysis.

The most effective method for discussing in detail the nuances, contexts and understanding of outcomes for systematic reviews was the workshop approach. This enabled the review group to interact with both people with asthma and specialist asthma practitioners, sharing understandings of outcomes used in systematic reviews, and outcomes important to participants. An example of developing a shared understanding of an outcome was "asthma control". There were different interpretations of this term between asthma specialists and people with asthma attending the workshop. In terms of cost and resource allocation this option was more expensive than the online survey but cheaper than using online experiential data. The workshop required careful planning and attention to detail and a guide written by the Airways Group is available in the appendices.

Using existing online experiences of breastfeeding via Healthtalk provided insightful context for discussing outcomes in systematic reviews of breastfeeding interventions. It was noted that descriptions of these outcomes differed greatly from those used in systematic reviews. Whilst there was some overlap of outcome themes, there were outcomes indicated by experience that were not being addressed in systematic reviews. This may be because some of these would be challenging to measure in clinical trials, or because outcomes for systematic reviews play more to policy decisions

than individual choice for example length of time to breastfeed is commonly used in reviews, but did not appear in the experiential outcomes, as a distinct outcome.

All three methods provided the review groups with new relationships with people and organizations in their community of interest. For Airways they now have a small group of people they can revisit with ideas and questions, and two of these are working with them more substantively on review production. In ENT two people with CRS helped to design the survey and write the project report, both of these people will continue their relationship with the review group. For Pregnancy and Childbirth they now have access to an additional advocacy group, and a very experienced researcher engaged with breastfeeding issues both in qualitative, trials and review contexts.

Airways and ENT are preparing papers on aspects of the work; Airways has written up the Face book survey and ENT are writing up the survey process for publication in relevant journals. A presentation at the COMET 5 conference (by invitation) in Calgary was well received, the presentation for this is part of the appendices. A workshop in Dublin was also well received, with two of the review groups taking part. Further dissemination will be decided by UKCC.

We are grateful to the review groups for all their efforts and enthusiasm for the project.

'Unexpected' Asthma UK acebook survey 235 people participated, 155 Face to face workshop practitioners, 80 people with 51 interview transcripts, independently assessed x 2 18 people participated sinusitis 'in scope' outco 69 outcomes described erated 15 outcome the Some overlap with outcomes More diverse than outcomes 73% of these concerned used in breastfeeding reviews, some correlation used in Asthma systematic symptoms (sino nasal and general), expressed by <u>both</u> reviews. Important outcomes symptoms, quality of life, flare ups, adherence Unable to ID important patients and professionals outcomes

Summary of key findings from the project.

2. Introduction

The Outcomes Important to Patients Public and Practitioners (OMIPPP) project is an exploration in methods – grounded in the JLA 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.

The role of outcomes and outcome measures in systematic reviews and the Cochrane review process is an important consideration when compiling a review. Editors and authors face challenges of combining primary studies that often address different outcomes and outcome measures, and being forced to select a range of outcomes and measures for their review based on the views and

experiences of the review team, rather than a wider group of people with potentially relevant perspectives.

We worked with three Cochrane Review Groups (CRGs); Airways, ENT and Pregnancy and Childbirth. All UK based review groups were asked to express an interest in the project, we selected our three groups on a range of criteria, including existing outcomes work they were doing. We used a different method with each group; workshop, online survey and using existing online experiential data to identify and inform discussions about outcomes used for systematic reviews.

The project objectives were to:

- To take account of the literature (including relevant COMET resources) in developing the three methods used in the project.
- To undertake three methodological approaches to identify important outcomes and discuss these with review groups.
- Evaluate each approach for useful outcomes generated for the CRG, costs of each method and appropriateness of each method for CRGs and Cochrane more generally

3. Literature review

A literature search was conducted to identify papers relating to Core Outcome Sets. See Appendix 9.1 for the search strategy, including databases and search terms used. This search retrieved 4400 references which were exported to Reference Manager where duplicates were removed leaving a total of 1186 references. Following sifting for relevance, 75 references remained from which data was extracted to triangulate relevance. A second sift was conducted to limit references to Asthma, Ear, nose and throat and Pregnancy and child birth leaving 11 references. References from the Core Outcome Measures for Effectiveness Trials (COMET) database relating to Asthma, ENT and Pregnancy and child birth were added. In total the complete search identified:

- 14 papers relating to Asthma
- 6 papers relating to Ear, nose and throat
- 10 papers relating to Pregnancy and child birth

A recent systematic review was also identified, Gargon E, et al. (2014) *Choosing Important Health Outcomes for Comparative Effectiveness Research* that remained the benchmark document to guide this project as it identified studies seeking to determine which outcomes or domains to measure in all clinical trials in a specific condition and to describe the methodological techniques used in these studies (Gargon, 2014). The literature search supporting this systematic review retrieved 250 reports relating to 198 studies; all of which were listed in the COMET database. To avoid duplication of effort in searching, it was considered that the COMET database was the best resource to search to identify new papers relevant to Asthma, ENT and Pregnancy and childbirth. The protocol for this work is available in Appendix 9.1.

From this review we identified two methods that were previously described (online survey and workshop) and one method that wasn't (using online experiential data) were chosen. With the former two we wanted to explore how much we could simplify the process to one step and conduct it on a minimal budget, thus replicating real conditions for engagement work to inform outcomes.

4. Overview of three methods

4.1 Face to face workshop

The review group had already decided to review and prioritise asthma systematic review questions, in three key areas and had made a decision to conduct a stakeholder event. To extend this work to incorporate a specific focus on outcomes seemed a sensible idea. Over a six month period the OMIPPP team worked with Airways to plan and facilitate the workshop (2nd October, 2014, London) for a small group of people with asthma, parents and carers and asthma specialist health practitioners. The workshop was designed to address three objectives:

- Agree the issues that the Cochrane Airways Group need to consider for their systematic reviews
- Agree which of these issues matter most in terms of developing research questions for reviews of research
- Discuss research outcomes (results) in asthma research reviews, talk about the most important for reviews of asthma research

The team decided to bring the focus of the discussion to three areas that they required more understanding of; what do you do when you have an asthma attack? What are the problems/issues you face in taking your regular inhaler? What helps you (or not) to control your asthma?

A great deal of thought was given to running a workshop with a wide range of people, some with debilitating asthma. A list of tips is available in Appendix 9.2 as this was thought to be potentially useful for other review groups contemplating a workshop approach.

In this report we describe the afternoon workshop but the full account is available in Appendix 9.3. The focus for the afternoon was on outcomes for systematic reviews that participants felt were important to either people with asthma or health professionals. The scene was set by the Airways group and examples and a rank order of outcomes that are routinely used in systematic reviews for asthma interventions.

Participants worked in small groups to discuss outcomes. The asthma specialists worked together in a group, with three small groups of people with asthma, this separation was a deliberate strategy, and offered a contrast to the morning where there were mixed discussion groups.

To help discussion people were asked to address the following trigger questions:

 What are the **five most important** areas of your life at present in relation to your asthma treatments and self-care?

OR

2. What are the **five most important** things you would like your asthma treatment and self-care to achieve?

OR

3. What are the **five most important** research outcomes that would help your clinical/professional asthma practice?

Some participants found naming five outcomes too much, others not enough and had to decide which ones to include in their top five. Once participants had settled on their 5 outcomes they recorded them on separate post its and distributed them on pre labelled 'outcome posters' according to the outcome areas that they felt best fitted their priorities. The outcome posters were

pre labelled as per outcomes currently used by the Cochrane Airways Group, and those suggested via the Face book survey with Asthma UK members. There was also an 'other' category for those outcomes that didn't have an obvious home.



Once all the outcomes were displayed, participants reviewed them (over tea and cake) and a discussion followed. Post workshop the team analysed the data generated at the workshop and did some slight re-allocation to themes (agreed between the team and the Airways group), these were checked with participants. The team then compared these results to the outcomes used in systematic reviews.

4.2 Online survey

The choice of rhinosinusitis was made by the Cochrane ENT Disorders Group. There are a suite of systematic reviews of interventions for this currently incurable and prevalent condition. Following a review of the literature, and informed by the team's experience with developing similar surveys for James Lind Alliance prioritisation projects, the survey was developed using Survey Monkey software. It was designed to achieve two main goals; to gather outcomes of interest in rhinosinusitis to both health practitioners and people with the condition; and get a sense of the most important of these. Survey participants were asked to suggest or describe their three most important outcomes of interest for rhinosinusitis.

For people with rhinosinusitis: What results from treatments are most important to you?

For health professionals: What are the most important outcomes that you want from treatments for people with rhinosinusitis?

Other prioritization processes often use two - four steps in refining responses and developing consensus (Delphi and James Lind Alliance prioritization processes) and we were interested in getting results from one 'hit'. The choice of offering only three options for suggestions ensured that people focussed on the most important issues for them, and very few survey responders tried to fit in more than three outcomes.

The survey was piloted and then was open from 19th December 2014 until 10th February 2015. There was an incentive for people to complete the survey (£25 vouchers) and this may have encouraged some spamming of the survey. We developed a 'route to survey' which outlined all potential people and groups that might be interested in participating. This was updated regularly and suggestions made for additions. Where organisations declined to participate, a reason was sought and recorded. A flyer was developed and circulated to interested parties. Smaller card versions of the flyer were offered for distribution via clinics and other healthcare settings. The Cochrane ENT Disorders Group has excellent links with relevant professional organisations and was confident that their views could be sought on this question. The team were less confident about accessing the views of the general public and recipients of rhinosinusitis treatment and care. There are no patient advocacy groups; Fifth Sense (a group concerned with loss of smell) did assist in the survey however. We developed a social media strategy and used this route to communicate with the public. We asked survey respondents to tell us where they heard about the survey to assess the success of these different routes.

All free text data was downloaded from Survey Monkey in an excel spreadsheet. A unique ID was allocated for each responder and outcome, in accordance with the data analysis protocol developed earlier with the ENT team. We kept the responses within their professional and individual categories to allow for comparison between the two data sets.

Two people analysed the data in two stages, applying an emergent approach to thematic analysis. This was checked and amended following consultation with the ENT team. A meeting was held on 20th March to consider the results of the survey and compare them with outcomes currently used in systematic reviews for CRS.



Themes emerging from the online survey data.

3.3 Using online experiential data

Breastfeeding features in two of the top five downloaded systematic reviews for the Pregnancy and Childbirth Review Group, and is considered a small but important part of their portfolio. Women's experiences of outcomes were collated through two researchers from Health Experiences Research Group (HERG) reviewing the transcripts of the Pregnancy and Children/Breastfeeding module within <u>healthtalk.org</u>. The OMIPPP team also conducted a literature search. The scope of the exercise was agreed with the review group, e.g. excluding weaning as this is outside of the scope of breastfeeding reviews. Details of the two sources explored for breastfeeding outcomes:

- Healthtalk.org (http://www.healthtalk.org/). A collection of narratives of women talking about their breastfeeding experiences available as videos and excerpts of transcripts and themes of the overall dataset
- Published literature of qualitative research describing women's experiences of breastfeeding following sifting of more than 300 references; 30 were found to be relevant. (However, due to time/cost constraints we decided not to pursue this further).

Neither of these sources focussed on reporting outcomes for research but provided more general accounts of breastfeeding experiences, therefore outcomes identified were implied. HERG were

keen to explore the idea as they thought it important for women's experiences of breastfeeding to inform research, including systematic reviews.

The HERG team reviewed the transcripts independently, compared their findings and developed a mind map, from which they developed their outcome themes, see below.



A literature search was conducted to identify qualitative research relating to breastfeeding; see Appendix 9.4 for the search strategy. Once outcomes from healthtalk.org and qualitative research were identified, they were assembled in a table to allow comparison with outcomes reported in Cochrane systematic reviews of breastfeeding, Appendix 9.5.

A meeting was convened to discuss findings and consider implications in the context of specific systematic reviews. Representatives from several stakeholder groups were invited to participate in this meeting: National Childbirth Trust; Breastfeeding Network and Ann Hoddinot, a researcher with experience in systematic reviews, clinical trials and qualitative research. The morning was spent sharing data and discussing the opportunities and challenges of using qualitative sources for outcomes for systematic reviews, and the afternoon comparing outcomes in the context of specific reviews. The full description of this meeting is available in Appendix 9.6

Finally a project team member spent eight hours viewing the online Health talk material, noting potential outcomes. This will form a further evaluation strand and is not included in this report as it is not yet complete. This was not a planned objective but the team and HERG were interested in comparing these two different appraisals of the data.

5. Results from three methods

5.1 Face to face workshop

Engagement and face to face working

Eighteen people participated in the workshop (5 had to pull out at the last minute due mainly to ill health). Participants ranged from health practitioners (GP with interest in respiratory medicine, practice nurse, asthma clinic nurse, respiratory physiologist, and children's respiratory specialist), adults and teenagers with asthma (severe asthma, longstanding asthma) and two parents of teenagers with asthma. The team felt that people with mild asthma were not well represented at the workshop.

Reflecting on the workshop a few weeks later the CRG team members involved identified several advantages to the workshop approach. These included working outside the medical model of thinking about asthma, and appreciating the different language used between people with asthma, health practitioners and researchers. The 'in person' experience was refreshing for review group staff that spend a lot of their day working on screens. Certain phrases and experiences have stood out and they felt that the experience helped achieve a personalised feel to measuring treatment

effects. Another advantage of a face to face setting was that non verbal cues for how people felt about outcomes could be followed up by the facilitators and the discussion taken to new areas. The whole team felt that the tone set of sharing perspectives about outcomes, rather than establishing was right or wrong, good or bad, enabled participants to have some control of the agenda.

The review group valued the neutral and skilled facilitation of the process which freed them up to listen, and contribute to the debate. At times the discussion felt somewhat abstract, challenging and slightly overwhelming to think about <u>all</u> outcomes for asthma reviews. The team agreed that next time we would structure outcomes discussion in the context of specific reviews. Sometimes it wasn't easy to envisage measuring some of the outcomes that were expressed in the workshop, however these discussions provided useful backdrop and were considered useful by the review group.

Important outcomes

The workshop participants produced 69 separate post its, each with an outcome described. Once these had been allocated to their relevant theme posters around the room, the group had a general discussion about the results. We focussed on where there were clusters of post its (quality of life, asthma control, relationships with asthma specialists and health care professionals), but also where there were gaps e.g. death. Discussion ranged from measuring quality of life using different scales, difficulties in creating valid questionnaires to assess quality of life, and practical difficulties with usage of these tools. Some participants described the extreme variability of their life with asthma for example, and how could tools capture accurate pictures of outcome measures. A very interesting discussion about asthma control was initiated; people with asthma wanted a more 'positive spin' in how asthma control is perceived as an outcome for asthma research. Too often outcomes (in reviews and clinical trials) do not reflect the aspirations of people with asthma to choose and enhance their life. Another interesting discussion point was patients aspirations for being 'drug free' (or reducing drugs), and the health practitioners focus on compliance/adherence to treatments. The review group found the debate around measuring 'good' and 'bad' outcomes insightful sharing how they use it to frame plain language summaries of reviews.



Figure 1 Workshop results compared to CRG outcomes in Asthma systematic reviews

"It validated our current strategy to have primary and secondary outcomes that are a mix of clinical and objective and more subjective outcome measures"

"Interesting debate around measuring 'good' and 'bad' outcomes, and altered the way that we look at this - could be used in how we frame and position plain language summary for example"

5.2 Online survey

Engagement via an online survey

217 survey respondents told us how they found the survey, giving the team an indication which communication strategies had been most effective and for whom. We estimate that twitter activity was most effective in helping patients with rhinosinusitis and non ENT specialists such as alternative therapy practitioners find the survey. This accounted for 44 people completing the survey. We had 7 people register for the survey via the INVOLVE People in Research website (which matches the public interest in research to projects) and also the Cochrane Consumer Network and Face book page (7 people).

The team used the INVOLVE SoMe (Social Media) guidance <u>http://www.invo.org.uk/wp-</u> <u>content/uploads/2014/11/9982-Social-Media-Guide-WEB.pdf</u> as a starting point. The learning from this approach is described in the overall report of the survey Appendix 9.7

The most effective route to encourage ENT specialists to contribute was peer to peer contact and personal endorsement from the clinicians in the working group (24), and ENT professional society email lists (74). Fifty two people described their route to the survey via 'email' and it is likely that some of these will fit in the peer to peer, and mailing list categories. Specially designed survey postcards offered to healthcare professionals to use in clinics, were underused, yielding 1 patient respondent.

Respondents to the survey

There were over 900 responses to the survey (approx 600 of these were spam). We extracted 235 usable responses, from 155 healthcare professionals and 80 people with CRS. More male healthcare practitioners responded to the survey than female (109 and 18 respectively). In people with rhinosinusitis more women than men responded (59 and 39 respectively). The gender of respondents across both groups was as the evidENT team would expect - whilst there are more men with the condition, in their experience women are more likely to participate in surveys. There was a good spread of ages responding in both groups, with a few more people under 30 with the condition responding than we had imagined might.

Important outcomes

From the 235 usable responses there were 653 suggestions of important outcomes. Of these 549 (169 from people with rhinosinusitis, and 380 from healthcare practitioners) fitted our description of an outcome. 104 outcome suggestions were removed from the data as they didn't fit the description e.g. suggestions for treatments, comments on the properties of outcome measurement tools, and items that we were unable to understand, these were shared across patients and professionals. We contacted one respondent to clarify their responses.



Figure 2 Survey results compared to CRG outcomes in CRS systematic reviews

Figure 2 shows the degree of alignment between the survey results and current use of outcome measures for systematic reviews. The dominance of symptoms outcomes being important for both patients and ENT practitioners is interesting, and suggests that other non symptom related outcomes used in CRS reviews should be considered carefully in relation to the review question. What is not reflected in the graph is the specific symptoms that people described in the survey. For example whilst the review group identify smell specifically, items such as headache and pain (mostly facial) are not highlighted specifically for systematic review outcomes. They may be represented in patient reported outcome measures though. There are a number of instruments that capture the impact of CRS across a number of symptoms and domains, and some were specifically named by ENT Specialists, highlighting awareness of these tools.

These results suggest some investment in patient reported outcome measure (PROM) tools that are able to capture these specific symptoms accurately and reliably would be important. A starting point for this could be to compare these findings with SNOT22 a current Patient Reported Outcome Measure for CRS research.

The working group were pleased with these results which support an earlier editorial decision within the Cochrane ENT Disorders Group to use symptom improvement and management outcomes in all CRS reviews. This is also reflected in plans this summer (2015) to develop set of core outcomes for clinical trials that assess treatments for CRS. It will be interesting to see how much convergence there is in these results and that of core outcomes development for CRS.

One limitation of the survey was asking people to pick 3 outcomes, making respondents prioritise which was our intention, but didn't allow us to see all the outcomes respondents may suggest. Some professionals used one of their three options as an overall symptom management choice, and ditto for QoL. Whereas patients were much more likely to describe specific symptoms and none used the term QoL. This may have resulted in some imbalance in the data. Overall the CRG felt it was a useful exercise, that a comparison and evaluation between this online approach and face to face work being undertaken later this year, will be useful.

5.3 Using online experiential data

Engagement

49 women and 2 men were interviewed for breastfeeding Healthtalk module, providing outcome perspectives for the group to work with. The 'in person' engagement was with the advocacy groups that we shared the results with, and who were invited to the final meeting. One of these groups was known to the CRG but the other wasn't. In addition we were able to introduce a breastfeeding expert (unusually in qualitative, clinical trials and systematic reviews) to the review group.

The process of sharing online experiential data in the first half of the meeting proved interesting and informative to all participating. The Healthtalk team showed video clips during the meeting to illustrate the themes they had found in the transcripts and this proved powerful source of discussion. *"It felt like the women were in the room"*. Sharing understandings of what outcomes mean in practice also proved insightful and the challenge of finding ways of measuring some of the Healthtalk themes became evident early on. The HERG researchers also acknowledged that there are some misunderstandings about using qualitative literature - a discussion around representativeness and data saturation helped clarify things.

All of the advocate group representatives were keen to stay involved with review group developments, especially in developing core outcomes for breastfeeding reviews and trials, and reviews. One of the participants is also exploring the feasibility of registering her Masters systematic review with the group.

"I would be particularly interested in helping to develop a core outcome set for breastfeeding trials"

"Thanks to everyone participating in the day; my thinking moved on."

"I started the day feeling defensive - I ended feeling as though I had learned a great deal and feeling more positive about building on the qualitative work - thanks very much".

Important outcomes

The Healthtalk team identified 15 themes from the interview transcripts, some of these mapped across to the outcomes used in systematic reviews of breastfeeding interventions, but many didn't have any direct correlation. A summary of outcome themes below illustrates this:

- Respect
- Decision making
- Developing role as motherSupport (overarching principles, early,
- peer, community)
- Benefits (mum, baby, bonding)
- Routine, sleep
- Practical techniquesMonitoring weight
- Management in challenging
- circumstances
- Managing difficulties in feeding
- Impact on relationship
 Managing return to work, sharing childcare
- Cultural and emotional impacts
 Antenatal propagation (considering)
- Antenatal preparation (considering feeding, practical and managing at home)

Healthtalk outcome themes

- Measures of breastfeeding, e.g. incidence, duration, proportion, prevalence, rates
- Objective outcomes for baby e.g. growth, development, morbidity, mortality
- Objective outcomes for mother e.g. weight loss, amenorrhea and chronic diseases
- Benefits to baby e.g. prevention of conditions in child and subsequent adult chronic conditions

Systematic review outcome themes

Outcomes used in systematic reviews that were not referenced in the experiential data included; use of Vitamin A and other supplements, use of pacifiers (dummies), breastfeeding for neo natal pain, breastfeeding for oral health, more clinical (rather than developmental) measures of benefits for baby e.g. development of asthma, eczema, type 1 diabetes etc.

In contrast areas in the Healthtalk data that weren't reflected in CRG outcomes included; barriers to initiating breastfeeding, impact on breastfeeding by delivery method (instrumental), mother's attitude to breastfeeding, support for breastfeeding especially in the community, impact of breastfeeding on mother, perceived breast milk inadequacy, monitoring growth and longer term breast feeding (systematic review outcomes generally stop at 12months).

We realised that it was inappropriate identify and rank the most important outcomes from the healthtalk data. Instead we attempted to focus on a small number of reviews to debate the relative merits of outcomes from the Healthtalk themes, and those used by the review group. 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.



Where changes were suggested to the systematic review outcome selection these were captured and are described in the final meeting report (Appendix 9.6).

With hindsight and reflection we could have approach this meeting differently. Interviews with the HERG participants and two of the CRG have suggested the following:

- The afternoon lacked some direction in purpose and outcome, no one was sure what we could achieve with the discussion
- The room was not well laid out for this sort of discussion (cards on the floor etc) and pitting the qualitative information against the Cochrane outcomes in the review under discussion had been rather difficult to process and discuss.
- The review topics were being approached from two very different perspectives and may lend themselves to two stage process, with time for reflection on the material in between
- A shorter and more concise overview of the similarities and differences of the outcomes may have helped the discussion
- A better way forward could have been to explore the idea of a PROM for breastfeeding
- Another idea was to create a mind map of the outcomes under discussion, rather than treat the outcomes in a linear fashion.

6. Costs of each approach

| Method used | Costs (people time) | Costs (other) | Total |
|-------------------|---------------------|-----------------|--------|
| | | | |
| Workshop | 2,325 (OMIPPP) | 127 (OMIPPP) | £6,026 |
| | 650 (Airways) | 2,924 (Airways) | |
| | | | |
| Online survey | 5,378 (OMIPPP) | 594 | £5,972 |
| | | | |
| Using online | 5,209 (OMIPPP) | 132 | £8,341 |
| experiential data | 3,000 (HERG) | | |
| | | | |

7. Comparison of three methods

The use of any of the three methods described in this report will to a certain extent be determined by what a review group want to achieve in outcomes development, and how much resource they have to allocate. A review group could be interested in the following;

- developing a greater understanding of living with or treating the health status/condition that the review group focuses on, to further understand outcomes of interest, especially if their editorial group is light on particular perspectives
- exploring with research users (patients, carers, public, health professionals, policy makers) outcomes that help them make judgements and decisions when using systematic reviews
- getting a sense of relative importance of outcome measures to research users (patients, carers, public, health professionals, policy makers)
- checking existing systematic review outcome measures used, for relevance to research users
- looking for and unearthing important outcomes that are not currently reflected in systematic reviews
- by consensus, setting aside outcome areas that are interesting, relevant and important but as yet don't have appropriate measurement tools or approaches developed

Regardless of the method used the review groups summarised and appraised the current outcomes used in their systematic reviews for the health area we were working in. This enabled the OMIPPP team to compare our findings with what is currently used, but also raised awareness within reviews groups of what they were using most frequently, and initiated conversations about these choices and decisions.

By comparing the three methods we can make some observations about which approaches may be useful and why.

A **workshop** is resource intensive in the planning and running phases and less so in the analysis of the material gained. There are significant upfront costs and preparation is key to ensure that participants know why they are there, what they are doing, and what subsequent impact their input will have on outcomes. The Airways group suggest that to pursue this approach one lead person needs to set aside 3 - 4 weeks in total to plan, organise and write up a workshop. Regular meetings or conference calls with collaborators will also be needed. Whilst this will mean a lot of direct

contact and communications with people there are advantages in that these relationships can encourage further work with the review group.

The workshop can provide access to how people conceptualise and live with a condition and provide nuance and context to outcomes discussions. With a relatively small number of participants (15 - 20 per workshop) these ideas may need to be tested with a wider group of people to establish validity. Another outcome of the workshop process was a deeper understanding by the review group of how and what to communicate about systematic reviews, and developing accessible pre workshop documents.

An **online one step survey** can potentially reach a much wider audience, and gather the views and priorities of large group of research users. A survey is much more of a 'blunt instrument' than face to face approaches and what may be lost is the nuance and detail of people's views about outcomes.

This approach offers a less onerous and more cost effective process. The emphasis is less on developing and marketing the survey, (especially if existing examples are adapted), with more effort and resources invested in the data analysis. Developing and piloting the survey with people that the review group wants to reach is vital to ensure that people can complete the survey, and relevant and usable data is provided by survey participants. Demographic details are important to match clinical aspects of the survey responders and the outcomes for the condition in focus. Thought needs to be given to who analyses the data, one advantage of having the OMIPPP team undertaking this part of the process was our relative 'distance' from rhinosinusitis and taking an emergent approach to the findings.

The ENT group wouldn't do anything different if they were to replicate this survey except to explore ethics approval, and recruit more people with rhinosinusitis via the NHS and specific clinicians. The presence of a specific patient group or charity representing the interests people the review group is interested in engaging with is important - they should be invited to participate in the endeavour and play a full part in proceedings.

Using **existing online experiential data or published qualitative synthesis** to inform outcomes had a much less clear outcome in this project, which makes it more complex to comment on. Firstly this was an unexpectedly expensive option, in addition to the reasonable fee paid to the Health Research Experiences Group to reanalyse the data, we felt compelled to look at published literature on women's experiences in breastfeeding, however we quickly realised that this would take us outside our funding allocation, so we curtailed this activity and focussed exclusively on the online material. Additionally a meeting to discuss the accrued data seemed very important, and this added cost to the exercise.

Feedback from those involved in this meeting was that the discussion was rich and touched on areas in outcomes for systematic reviews that have been rarely tread in Cochrane settings. The distinct difference between the implied outcomes gathered from the interview transcripts, and those used in breastfeeding systematic reviews were marked, and presented challenges for the discussion. For example the review group were interested in the representativeness of the sample of women interviewed, however the qualitative researchers were more interested in whether saturation of outcomes had been reached in the data set.

Perhaps one of the participants summed it up best;

"It is always going to be a challenge to get experiential implied outcomes shoe-horned into a systematic review based solely on RCTs but I thought the day went really well and was very useful". Review Group Member

At the very least the Healthtalk modules offer insights to a condition, and health state or particular population that can be accessed easily, are reliable in their sourcing and presentation and offer review groups a no cost (apart from the time spent watching) way of immersing yourself in an area from a patients, or public perspective. It is why we are interested in comparing the experiences of watching the video clips and reading the narratives with that of the two researchers reanalyzing the transcripts. As a group we were not sure what the difference would be between these two approaches. We will report on this later in 2015.

We don't have any specific recommendations for review groups to use one method in preference to another, but we do feel that it is important for groups to reflect on how they make their decisions about outcomes and if there are opportunities to widen this dialogue out. This project has plenty of material to suggest how this might be done.

8. Acknowledgements

We would like to thank UKCC for funding this project, and the three Cochrane Review Groups that partnered with us, especially Emma Welsh, Chris Cates, Frances Kellie, Leanne Jones, Gill Gyte, Anne Schilder, Aneeka Degun, Kim Airey, Iliatha Papachristou, Claire Hopkins, and Carl Philpott. From Health Experiences Research Group Susan Kirkpatrick and Sharon Dixon. From National Childbirth Trust, Sarah McMullen. From Breastfeeding Network Phyll Buchanan and breastfeeding researcher Pat Hoddinot. Jim Boardman from Fifth Sense. Asthma UK. Lay reviewer From COMET (Core Outcome Measures for Effectiveness Trials) Paula Williamson and Heather Bagley.

9. Bibliography

References

Brown A, Jordan SJ, (2013). Impact of birth complications on breastfeeding duration: an internet survey. Advanced Nursing 69 (4) 828-39.

Brown A, Lee M, (2013). An exploration of experiences of mothers following a baby-led weaning style: developmental readiness for complementary foods. Matern Child Nutr. Apr 9 (2) 233-43. Brown A, Lee M (2011). An exploration of the attitudes and experiences of mothers in the United Kingdom who chose to breastfeed exclusively for 6 months postpartum. Breastfeed Med. Aug 6 (4) 197-204.

Brown A, Rance J, Warren L, (2014). Body image concerns during pregnancy are associated with a shorter breast feeding duration. Midwifery Jul 2.

Cantrill RM, Creedy DK, Cooke M, Dykes F, (2014). Effective suckling in relation to naked maternalinfant body contact in the first hour of life: an observation study. BMC Pregnancy Childbirth Jan 14 14 (20).

Chambers JA, McInnes RJ, Hoddinott P, Alder EM, (2007). A systematic review of measures assessing mothers' knowledge, attitudes, confidence and satisfaction towards breastfeeding. Breastfeed Rev. Nov 15 (3) 17-25.

Cloherty M, (2004). Supplementing breast-fed babies in the UK to protect their mothers from tiredness or distress. Midwifery Jun 20 (2) 194-204.

Cohen RJ, (1995). Maternal activity budgets: feasibility of exclusive breastfeeding for six months among urban women in Honduras. Social Science Medicine 41 (4) 527-536.

COMET Initiative [available at http://www.comet-initiative.org/]

Dowling S, Brown A, (2013). An exploration of the experiences of mothers who breastfeed long-term: what are the issues and why does it matter? Breastfeed Med. Feb 8 (1) 45-52.

Dykes F, (1999). Falling by the wayside: a phenomenological exploration of perceived breast-milk inadequacy in lactating women. Midwifery Dec 15 (4) 232-46.

Dykes F, Moran VH, Burt S, Edwards J, (2003). Adolescent mothers and breastfeeding: experiences and support needs: an exploratory study. J Hum Lact Nov 19 (4) 391-401.

Dykes F, Williams C, (1999). Falling by the wayside: a phenomenological exploration of perceived breast-milk inadequacy in lactating women. Midwifery Dec 15 (4) 232-46.

Flacking R, Dykes F, Ewald U, (2010). The influence of fathers' socioeconomic status paternity leave on breastfeeding duration: a population-based cohort study. Scand J Public Health Jun 38 (4) 337-43.

Gargon E, Gurung B, Medley N, Altman DG, Blazeby JM, et al. (2014) Choosing Important Health Outcomes for Comparative Effectiveness Research: A Systematic Review. PLoS ONE 9(6): e99111. Healthtalk.org available at [<u>http://www.healthtalk.org/</u>]

Hinsliff-Smith (2014). Realities, difficulties, and outcomes for mothers choosing to breastfeed: primigravid mothers experiences in the early postpartum period (6-8 weeks). Midwifery Jan 30 (1) e14-9.

Hoddinott P, Britten J, Pill R, (2010). Why do interventions work in some places and not other? A breastfeeding support group trial. Soc Sci Med. Mar 70 (5) 769-78.

Hoddinott P, Craig LC, Britten J, McInnes RM, (2012). A serial qualitative interview study of infant feeding experiences: idealism meets realism. BMJ Open Mar 14 2 (2) e000504.

Hoddinott P, Kroll T, Raja A, Lee AJ, (2010). Seeing other women breastfeed: how vicarious experience relates to breastfeeding intention and behaviour. Matern Child Nutr. Apr 6 (2) 134-46. Hoddinott P, Pill R, (1999). Qualitative study of decisions about infant feeding among women in east end of London. BMJ Jan 2 318 (7175) 30-4.

Hoddinott P, Tappin D, Wright C, (2008). Breast feeding. BMJ Apr 19 336 (7649) 881-7. Kouba J, (2007). Some women found breast feeding physically and emotionally demanding. Evidence Based Nurs. Apr 10 (2) 62.

Kvist LJ, Larsson BW, Hall-Lord ML, (2006). A grounded theory study of Swedish women's experiences of inflammatory symptoms of the breast during breast feeding. Midwifery Jun 22 (2) 137-46.

Manhire KM, Hagan AE, Floyd SA (2007). A descriptive account of New Zealand mothers' responses to open-ended questions on their breast feeding experiences. Midwifery Dec 23 (4) 372-81.

McFadden A, Toole G, (2006). Exploring women's views of breastfeeding: a focus group study within an area with high levels of socio-economic deprivation. Matern Child Nutr. Jul 2 (3) 156-68.

McGuinness D, (2014). An exploration of the experiences of mothers as they suppress lactation following late miscarriage, stillbirth or neonatal death. Evidenced Based Midwifery 12 (2) 65-71. McInnes, RJ, Chambers JA, (2008). Supporting breastfeeding mothers: qualitative synthesis J Adv Nurs. May 62 (4) 407-27.

McInnes RJ, Hoddinott P, Britten J, Darwent K, Craig LC, (2013). Significant others, situations and infant feeding behaviour change processes: a serial qualitative interview study. BMC Pregnancy Childbirth May 16 13 114.

Montrone AVG, (2006). Nipple trauma and breast-feeding: a study of women in the early stages of lactation. Revista de Atencao Primaria a Saude (portugese journal).

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.

Schmied V, Beake S, Sheehan A, McCourt C, Dykes F, (2011). Women's perceptions and experiences of breastfeeding support: a metasynthesis. Birth Mar 38 (1) 49-60.

Tully KP, (2014). Maternal accounts of their breast-feeding intent and early challenges after caesarean childbirth. Midwifery Jun 30 (6) 712-9.

Wambach KA, Cohen SM, (2009). Breastfeeding experiences of urban adolescent mothers. J Pediatr Nursing Aug 24 (4) 244-54.

Williamson PR, Altman DG, Blazeby JM, Clarke Mike, Devane D, Gargon E, Tugwell P, (2012). Developing core outcome sets for clinical trials: issues to consider. Trials 13 132.

9. Appendices

9.1 Search strategy - Literature Review

Collation and assessment of published material on important therapeutic outcomes from patient and practitioner perspectives (rapid, pragmatic review) generic and in relation to the specific areas of the selected CRGs

• Search Strategy

Search terms (free text)

- 1. "Core outcome*"
- 2. "Core outcome* set*"
- 3. "Core outcome measure"
- 4. "Outcome* set"
- 5. "Patient reported outcome*"
- 6. "Patient-reported outcome*"
- 7. "Patient reported outcome measure*"
- 8. "Patient-reported outcome measure*"
- 9. "Outcome reporting bias"

Databases to search

PubMed Embase CINAHL PsycINFO AMED NICE Evidence Search The Cochrane Database of Systematic Reviews

Other *subject specific* databases to consider searching when we know which CRGs we'll be working with)

Pedro (physiotherapy) MIDIRS (maternity)

Additional databases if we want to take a systematic review type search (e.g. everything!)

Web of Science BIOSIS Citation Index LILACS Dissertation Abstracts Online SCOPUS Reference lists of relevant papers Google Scholar for conference proceedings Grey literature Personal contacts and electronic mailing lists

Selection criteria

Patient and / or carer and / or clinician involvement in developing a core outcome set Therapy (safety, effectiveness, etc.)

Main inclusion criteria

Relevance

- Does the study set out to assess or gather research outcomes that are important to patients, public and practitioners?
- Does the study review the literature on research outcomes that are important to patients, public and practitioners?

Quality and methods

- Does the study involve patients, public and practitioners in the process?
- Does the study describe the way in which they were involved?
- Does the study describe the methods used to elicit their preferences?
- Does the study relate any of the above to Systematic Review production or updates

9.2 Airways Review Group - tips for running workshops

Running a face-to-face workshop is enlightening and enjoyable – but not without its headaches! Here are some points to think about before you start!

Costs

- Venue
- Refreshments for facilitators and participants
- Pay for facilitators
- Travel for participants and facilitators
- Pay for participants?
- Travel and other incidentals for participants
- Stamped addressed envelopes for participants to send claim forms and receipts
- Our total cost was £3500, but we estimate we would have paid an additional £3100 for facilitation, but this was covered by another project fund

Venue

- Easy for people to get to?
- Toilet on the same floor as meeting room?
- Breakout rooms nearby to main room and accessible?
- Suggest someone go and check out the venue before the workshop, if not before booking
- Arrive an hour early to set up the room or ask for any changes from the venue staff

Refreshments

- Have at least tea/coffee on arrival, tea/coffee with lunch and then afternoon tea/coffee for a full day
- Make sure the venue will clear up dirty plates after lunch before the afternoon session

Other

- Have plenty of bluetack and flipchart paper
- Work with a partner organisation Asthma UK helped us enormously. They have research and policy volunteer group and promoted the workshop on Face book and twitter for us.
- People are most active on Face book and twitter on Sunday evenings (though your partner organisation may vary) make sure you are on twitter then to promote the workshop and ask your partner organisation to promote it at the key times for them!
- Ask your partner organisation to help out with the wording they knew their volunteers the best!
- Consider doing a survey for people to fill out of they are not going to the workshop. This was suggested by Asthma UK and we got some very rich information which we triangulated with what was discussed in the workshop.

What we would do next time

- Have someone there to liaise with the venue who is not presenting or delivering the workshop to deal with practical issues like getting more tea and coffee and asking for plates and rubbish to be cleared
- We did a whole day workshop, but it was quite long. I think next time we would have 3 hours instead. 45 mins introduction, 1.5 hours small group and 30 mins voting and wrap up. Maybe tea and coffee to start the voting.
- Use this as an opportunity to link with other partner organisations

9.3 Asthma Workshop Report

This is attached separately.

9.4 Search strategy for Breastfeeding Project

Healthcare databases searched MIDIRS Medline CINAHL

Search terms (Medline)

Patient*.ti,ab
 mother*.ti,ab
 1 OR 2
 exp LACTATION/
 exp LATCHING, BREASTFEEDING/
 lactation.ti,ab
 latching.ti,ab
 "breast feeding".ti,ab
 4 OR 5 OR 6 OR 7 OR 8
 exp QUALITATIVE STUDIES/
 "qualitative research".ti,ab
 10 OR 11
 3 AND 9 AND 12

Date of search

Database conception to 3/8/14 (weekly Alert created to identify relevant references from 3/8/14 onwards)

Inclusion criteria

Qualitative research

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*, CRG to advise when data is complete)

Exclusion criteria

Fertility and breastfeeding (as advised by LH CRG) Contraception and breastfeeding (as advised by LH CRG) HIV and breastfeeding / weaning (as advised by LH CRG)

Limits

MeSH term for qualitative studies applied as a limit

Results of search

MIDIRS 86 Medline 119 CINAHL 117 Total number of references 322 Duplicate references removed 32 Total 290 Not relevant 279 **Relevant 11** (see Appendix 4)

Others databases / references recommended

References from PB (19) COMET (no references located) Royal College of Midwives (No references located)

9.5 Comparison of outcomes for breastfeeding

This is attached separately.

9.6 Report of breastfeeding meeting

This is attached separately.

9.7 Online survey report

This is attached separately.

9.8 COMET presentation