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Patient and public involvement (PPI) reporting in maternal and neonatal clinical trials: an exploratory review

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Title: Patient and Public Involvement (PPI) reporting in maternal and neonatal clinical trials: an exploratory review

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Abstract

Background: Patient and public involvement (PPI) is increasingly a research priority encouraged by health research funders. It is difficult to know, however, how prevalent PPI is within research. The aim of this review was to gain a contemporary understanding of the frequency and types of PPI being reported in maternal and neonatal clinical trial reports, and if an increase in PPI reporting was evident over time.

Methods: An exploratory review of maternal and neonatal trial reports published in nine healthcare journals between 2017-2022 was undertaken. A search was conducted for eligible trial reports in each journal using SCOPUS, in addition to a manual search of each journal's archive. Once an eligible trial report was identified, a search was conducted for the trial's associated protocol. Both trial documents were reviewed for any information on PPI activity. Descriptive statistics of the included trials' characteristics were produced.

Results: Three-hundred and fifty-two trial reports and 162 associated trial protocols were identified and included in the analysis. Of these, 48 (14%) reported PPI, either within the main trial record (n=47) or solely in the trial protocol (n=1). Twenty (42%) of these trials were conducted in the UK. Thirty-four trials reported PPI contributors in trial design and planning, 31 trials reported PPI during the running of the trial and 20 trials involved contributors in trial analysis and dissemination. There was no sustained increase in PPI reporting over the included timeframe.

Conclusions: There is minimal reporting of PPI in maternal and neonatal clinical trials, with wide variations in the depth of information provided. PPI reporting guidelines in academic journals may be beneficial in prompting researchers to provide PPI information and to raise awareness of the profile of PPI in maternal and neonatal trial research.

Registration number: The review was not registered.

Keywords: Patient and public involvement; neonatal trials; maternal trials; GRIPP2 checklist; clinical trials methodology

Background

There has been a growing emphasis on incorporating Patient and public involvement (PPI) into health research over the past decade, with health research funders in Ireland and the United Kingdom (UK) requesting researchers to incorporate PPI into their research proposals (1(2-3), 2). A considerable amount of the current literature on PPI has emerged from the UK (3), where PPI has been incorporated into their national research policies and governance since the early 2000s (4, 5). PPI is generally understood as involving patient and other members of the public, known as PPI contributors or PPI partners, *in* designing and conducting research as opposed to conducting research *on* these individuals or groups (1). In trials, PPI contributors are typically involved as members of the trial's steering committee (6) or asked to review trial documents, such as Participant Information Leaflets (PILs) (7). While PPI is regarded as particularly important to implement within the conduct of clinical trials (8, 9), there is limited evidence-based guidance available on how best to conduct PPI within a trial (7)**.** Several barriers to implementing PPI have been identified, such as difficulties recruiting PPI contributors, lack of funding to reimburse PPI contributors, a lack of time to conduct PPI activities, and PPI contributors not feeling listened to or valued within the research process (7, 10).

Issues concerning inconsistency or a lack of reporting in research about when, how, and why PPI is conducted have been raised previously (11, 12). Poor reporting of PPI limits the available information on how PPI is being implemented in research and makes it difficult to assess the extent and impact of PPI (13). There have been efforts to improve the extent and quality of PPI

reporting; for instance, the GRIPP2 checklist (Guidance for Reporting Involvement of Patients and the Public) was developed to provide guidance to researchers when reporting PPI (14).

As in many areas of healthcare, PPI is regarded as a means to improve the health and health outcomes of pregnant and postpartum women and their babies, by helping to share research that is relevant and acceptable to the needs of the target population (15-18). For instance, there is evidence of maternity health researchers using innovative and creative approaches in order to involve women from under-represented groups in research (19, 20), which has been viewed as having the potential to reduce health inequalities (20). PPI has become a priority in maternal and neonatal research (16, 20), with PPI strategy or advisory groups now established as part of researchers' agendas, for example, the National Perinatal Epidemiology Centre in Ireland (21). It remains unknown, however, if developments in involving members of the public are translating to PPI reporting in maternal and neonatal trial reports.

To gain a contemporary understanding of the frequency of PPI reporting in published maternal and neonatal clinical trial reports, the types of PPI activities being conducted and who is being involved as PPI contributors, we undertook an exploratory review of PPI reporting in maternal and neonatal trials published over a six-year period, between 2017 and 2022. In undertaking the review, we were interested in determining if PPI reporting had increased over time and, for journals that had PPI reporting guidelines, whether authors provided reasons for not conducting PPI (if this was the case). These explanations may provide some insight into the reasons why PPI was not implemented, and potential barriers to conducting PPI.

Materials and methods

Inclusion criteria

Reports of clinical trials, either academic or industry-led, in maternal and neonatal health, published in nine selected journals from 2017 to 2022, and the trial's protocol, were eligible for inclusion. The six-year time frame was chosen to offer contemporary insight as well as providing a duration that would facilitate a sufficiently comprehensive review. In addition, as the GRIPP2 checklist was published in 2017 (14), we wished to see if the checklist was being adhered to when authors of trial reports were reporting PPI. Protocols that were publicly available via trial registries, as supplementary material of a published trial report or published as a stand-alone journal publication, were eligible for inclusion. Trials that did not provide an assigned trial registry number, or if evidence of registration could not be found elsewhere, were excluded. Systematic reviews of trial data, short reports, secondary analyses papers, and reports of trials that were actively recruiting or currently in progress were also excluded.

For this review, we considered PPI to be any information provided in the manuscript that indicated that lay individuals – which could include, for example, charity representatives, parents, and other members of the public – were involved at any stage of a trial. This could include information that was described by the trial manuscript authors explicitly as PPI, such as information provided under a '*patient and public involvement statement*' within a trial manuscript. This also included trial manuscripts where PPI was indirectly referenced, such as a listed co-author whose affiliation information identified them as a 'non-professional researcher' (22, p. 2-3).

Search strategy:

Our decision-making on which journals to include was pragmatically drive. Two journals were initially chosen as they had implemented PPI reporting guidelines at the time of the review, had a high impact factor, and regularly published trial reports of relevance to maternal and neonatal health; the *British Medical Journal (BMJ)* implemented their guidelines in 2014 (23), and the *British Journal of Obstetrics and Gynaecology* (*BJOG*)'s PPI reporting guidelines were introduced in 2018 (24). We wished to compare these journals to other journals with similar fields of interest.

i) **General health journals:** *The Lancet* and the *New England Journal of Medicine (NEJM)*), in addition to the already included *BMJ* were previously identified by trials methodology researchers involved in a similar study to this current review as "key journals for publishing trials."(25 p. 3).

ii) **Maternal Health research journals:** A search was conducted of high-impact journals listed on Clarivate. *BJOG* and *Obstetrics & Gynecology* were listed in the top seven journals, as was the *American Journal of Obstetrics and Gynecology (AJOG)* which was used to conduct a pilot search as part of planning this review. *BJOG* and *Obstetrics & Gynecology* were chosen based on our familiarity with these journals in comparison to the other listed journals. We then decided to include *BMC Pregnancy and Childbirth* as it is an open-access journal, and we had prior knowledge that it regularly published relevant trial reports.

iii) **Neonatal health journals:** *Archives in Disease-Fetal & Neonatal Edition* and *Pediatrics* were listed in the top eight high-impact journals in the field of paediatric journals listed on Clarivate. Some of the other high-impact journals were not considered for inclusion as they were too specific or were not focused on the cohort of interest (e.g., *Child and Adolescent Psychiatry and Mental Health* and *Journal of*

Adolescent Health). Finally, *Neonatology* was chosen as it was one of the top journals that focused specifically on neonates.

NEJM request that authors provide the trial protocol as supplementary material when submitting a trial report (26), which would likely increase the probability of protocol availability for trials included in this review that were published in that journal.

Search of journals

A search strategy was developed to search the *SCOPUS* database for each included journal (Supplementary file 1). The SCOPUS search results were downloaded as Excel spreadsheets for each journal and all publications screened by title and abstract. Potentially eligible reports were accessed, and the full texts were screened.

All nine of the journals' websites were also searched manually. This entailed accessing the online archive of each journal and searching through each issue published between January 2017 and December 2022 inclusive. The Table of Contents for each published issue was screened for potentially relevant trial reports. Potentially relevant trial reports were accessed, and the title and abstract were screened to determine if the report was eligible for inclusion. If a trial report met the inclusion criteria, the reference for the trial report was recorded in an Excel database for full text screening and data extraction.

The results from the SCOPUS and manual searches were compared to ensure all potentially relevant reports were included. All included trial reports were searched for a reference to a published trial protocol. If it was not located in the trial report, the trial registration number was located on the relevant trial registry to check for a published trial protocol. Both the report and published trial protocol, if available, were reviewed in full for any information relating to PPI. All

data that appeared related to PPI were extracted verbatim onto a purposively pre-designed data extraction form (Supplementary file 2).

Data extracted from each report and/or protocol included author information and affiliations, country of origin, health condition or condition of interest, the type and purpose of the intervention under evaluation, and details related to funding. Any information relating to PPI was extracted, such as the type of contributor involved, the number of PPI contributors reported, the trial stage at which PPI occurred, and if any reference to training or reimbursement for PPI contributors' input was provided. No assessment of methodological quality was conducted on included reports as this was not the focus of the current review. All trial reports that were identified as eligible, irrespective of quality, were included.

The lead author reviewed and extracted the data from the identified trials. In the event of trial reports where it was unclear if PPI had occurred or not, this was discussed among the reviewers until a decision was reached.

Patient and Public involvement in this review

Although PPI contributors were not involved directly in the design or conduct of this review, the review was conducted as part of a wider study on PPI in maternal and neonatal trials, and which involves PPI contributors at different stages, including as members of the overall study Advisory Group.

Results

Screening

A total of 21,311 records were identified using SCOPUS (Figure 1). Following removal of duplicates (n=92), 21,219 records were screened by title and abstract and 20,553 were excluded.

A total of 666 were screened at full text and 205 records were excluded, leaving 461 eligible reports. Of these, 143 (31%) were published in *BMC Pregnancy and Childbirth.* For balance and volume management, a decision was taken to only include 30 trial reports from this journal, consisting of the first five trial reports published in each included year. Forty-one of these trial records were excluded because 24 were economic analyses or follow up studies of already included trial reports, and the trial registry numbers could not be located for 17 records. The manual search results identified four additional trials that had not been captured by the SCOPUS search. Thus, 352 trial reports were included for purposes of analyses, with 162 associated trial protocols; published trial protocols were not found for the remaining 190 trial reports. Of the 162 associated trial protocols, 31 protocols were published as supplementary files of the main trial report. Supplementary file 3 provides a list of all included trial reports and associated trial protocols.

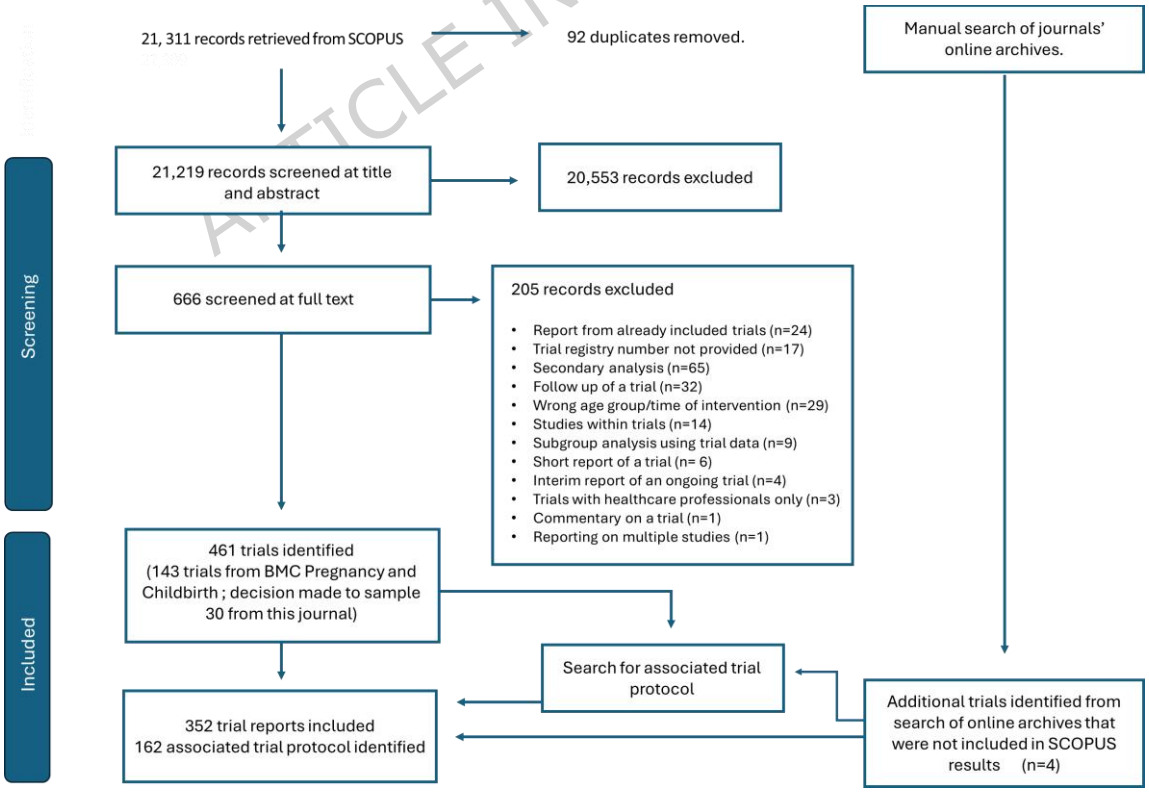

Figure 1: Screening process to identify trial reports and associated trial protocols

A summary of the characteristics of the included trials is presented in Table 1 (see supplementary file 4 for more information). Of the 352 trials identified, the majority were reports of randomised trials (n=330) with the remainder of reports being quasi-experimental trials or non-randomised controlled or open label trials. Forty-six were multinational trials, and 306 were single-country trials, conducted in 42 locations. A total of 119 were reports of neonatal trials and 233 were reports of pregnancy or early postpartum trials. A total of 109 trials (31%) were investigating drug interventions while 49% (n=174) trials were for the purpose of treatment of a condition or illness.

Table 1: Characteristics of all included trials (n=354)

PPI status			**Total (n=352) n (%)**
Reported PPI			48 (14%)
Stated PPI did **not** occur			28 (8%)
No information on PPI activity provided			271 (77%)
Unclear on PPI status			4 (1%)
Trial population			
Neonatal trial			119 (34%)
Maternal trial			233 (66%)
- *Antepartum intervention*			*141 (40%)*
- *Intrapartum intervention*			*63 (18%)*
- *Postpartum intervention*			*29 (8%)*
Trial design			
Randomised trials			330 (94%)
Non-randomised trials			19 (5%)
Quasi-experimental trials			3 (<1%)
Type of intervention tested	**Maternal trials (n=233)**	**Neonatal trials (n=119)**	**Total trials (n=352)**
Drug	81 (35%)	28 (24%)	109 (31%)
Other	43 (18%)	35 (29%)	78 (22%)
Device	29 (12%)	27 (23%)	56 (16%)
Behavioural	36 (15%)	5 (4%)	41 (12%)
Procedure	23 (10%)	17 (14%)	40 (11%)
Testing two or more interventions *(e.g., comparing a device to a drug intervention)*	12 (5%)	4 (3%)	16 (5%)
Dietary supplement	4 (2%)	2 (2%)	6 (2%)
Diagnostic test	4 (2%)	-	4 (1%)
Vaccine	1 (<1%)	1 (<1%)	2 (1%)
Purpose of the trial	**Maternal trials (n=233)**	**Neonatal trials (n=119)**	**Total trials (n=352)**
Treatment	103 (44%)	71 (60%)	174 (49%)
Prevention	87 (37%)	25 (21%)	112 (32%)
Diagnostic/ Screening	13 (6%)	5 (4%)	18 (5%)
Supportive Care	7 (3%)	6 (5%)	13 (4%)
Health Services Research	6 (3%)	1 (<1%)	7 (2%)
Other*	17 (7%)	11 (9%)	28 (8%)

*__Maternal trials:__ 'Other' category includes 13 described as 'other' intervention on the trial's registry, 2 QoL interventions, 1 educational intervention, and 1 basic science intervention

*__Neonatal trials:__ 'Other' category includes 1 basic science intervention, 1 device feasibility study, 1 QoL, and 8 described as 'Other' on the trial's registry.

PPI reporting in included trials

Of the 352 trials, 48 (14%) mentioned PPI activity in either the main trial record (n=47), including reports of PPI within the trial record's supplementary material, or in the trial's associated protocol (n=1). A total of 23 trials reported PPI in both the main trial report *and* the trial's associated protocol. In the 47 main trial reports that reported PPI, seven trials reported PPI only in the supplementary material. Twenty-eight trials (8%) explicitly stated that they did not conduct PPI at any stage of the trial, with the majority of trials (77%, n=271) providing no details as to whether PPI had occurred. PPI reporting in four trial reports was categorised as 'unclear reporting' because the information was insufficient to determine if it constituted PPI. For example, one of these trials mentioned the involvement of community representatives in a Trial Advisory Group (27). However, in the list of Advisory Committee members provided, only healthcare professionals appear to be listed (28).

One trial reporting PPI in the main trial report provided conflicting information about the extent of involvement in the trial protocol. The trial protocol stated that while PPI contributors were not involved in trial design or conduct, the results would be disseminated through established patient groups (29). However, the main trial report stated that maternal service users *were* involved in the trial's development, with particular input into the PIL and trial questionnaire development (30). The authors also acknowledged the involvement of a panel of service users in developing the trial protocol (30), however this was not referenced in the published protocol itself (29).

Trials reporting 'no involvement' of patients or the public

Eight of the 28 trials that stated that no PPI had occurred provided reasons for non-involvement and 21 did not. Explanations included that PPI was not common practice or required at the time the trial began (n=4, 14%), or that the trial outcome (an economic evaluation) did not require public involvement (n=1). Other trialists reported that formal research with participants and/or healthcare professionals was conducted in preparation for the trial (n=3).

PPI reporting in main trial reports over time period and by journal (n=354)

During 2017 to 2022, the *BMJ* (50%) and *The Lancet* (38%) had the highest reporting of PPI in maternal and neonatal trial reports, followed by *BJOG* (28%). *Obstetrics & Gynecology* did not appear to report PPI in any of the 83 trial reports from this journal (Table 2).

Exploring PPI reporting over time found that PPI reporting, overall, increased from a low of 3% (n=2) of trials in 2017 to 21% (n=13) of all trials analysed in this review that were published in 2019. After 2019, however, there was a slight decrease in PPI reporting to 16% (n=10) in 2020, 15% (n=8) in 2021, and 14% (n=7) in 2022. When examining each individual journal's reporting by year of publication, there was no indication that the proportion of PPI reporting had steadily increased over time, other than in *BJOG* (supplementary file 5).

Table 2: Frequency and source of PPI reporting in maternal and neonatal trials (2017-2022)

Journal	No. of trials published	Reported PPI in trial record n (%)	Reported in trial protocol only n (%)	Unclear Reporting n (%)	Reported no involvement n (%)	Did not report any information on PPI n (%)
The BMJ	14	7 (50%)		1 (7%)	6 (43%)	-
The Lancet	32	12 (38%)*	1 (3%)	1 (3%)	-	18 (56%)

NEJM	42	8 (19%)**		1 (2%)	-	33 (79%)
BJOG	52	15 (29%)		-	21 (40%)	16 (31%)
Obstetrics & Gynecology	83	-	-	-	-	83 (100%)
BMC Pregnancy & Childbirth	30***	1 (3%)	-	-	1 (3%)	28 (93%)
Pediatrics	26	1 (4%)	-	-	-	25 (96%)
Archives in Disease-Fetal & Neonatal Edition	48	2 (4%)	-	-	-	46 (96%)
Neonatology	25	1 (4%)		-	-	24 (96%)
Total trials	352	47 (13%)	1 (<1%)	-	-	-
Total trials reporting PPI		**48 (14%)**				

*The Lancet – One trial reported PPI solely within the supplementary material of the main trial

** NEJM – Six trials reported PPI solely within the supplementary material of the main trial

*** A total of 143 potentially eligible trial reports were published in *BMC Pregnancy and Childbirth* from 2017-2022 – a sample of 30 reports were included in this review.

Reporting of PPI contributors and activities

Tables 3 and 4 presents the characteristics of the 48 trials that reported PPI. A range of conditions were investigated in the 36 maternal trials (22 discrete conditions) and 12 neonatal trials (11 discrete conditions) (supplementary file 6). Miscarriage management and prevention (n=4), and preeclampsia (n=4) were the most frequently investigated maternal health conditions that reported PPI, and neonatal respiratory conditions were the most frequently investigated neonatal health condition (n=2). Twenty trials (42%) reporting PPI were conducted in the UK, followed by 11 multi-national trials (23%). Of these 11 multi-national trials, six included the UK as one of their locations. The remaining 17 trials reporting PPI were conducted

in nine different countries. Sixteen trials (33%) were funded by the UK's National Institute for Health and Care Research (NIHR), who require funding recipients to include PPI.

In 12 trials, only one PPI contributor was reported to be involved. In 11 trials, the number of PPI contributors reported ranged from two to five individuals. In the remaining 25 trials, it was unclear how many PPI contributors were involved, with two trials indicating that at least two PPI contributors were involved at some stage of the trial.

A range of terms was used in the trial reports to describe PPI contributors. For this review, we categorised PPI contributors into seven main categories.

- *'Consumer organisations/charities'*: representatives from charities or other similar organisations focused on maternal and neonatal health.
- *'Maternal service users and families'*: PPI contributors who were described as parents, service users, or as pregnant women and women with personal experience of the condition or illness under investigation.
- *'PPI contributors':* individuals who were described solely based on their role in relation to PPI, for example, being described as a lay member or as a member of the public.
- '*Former trial/research participants or their guardians'*: PPI contributors who had been a *participant* of a previous research study or trial. This category also included parents of neonates previously enrolled in a pilot trial.
- The three remaining categories were 'patient representatives', 'community representatives/ community leaders', and 'lay member of ethics committee/safety committee.'

[Tables 3 and 4 are located on Pages 26- 37, adhering to formatting guidelines]

Overall, PPI contributors associated with consumer or charity organisations constituted the largest group of contributors (n=24 trial reports, 50%) followed by '*maternal service users and families*' (n=13 trial reports, 27%). A total of 21 consumer organisations and charities were reported as PPI contributors. Three UK organisations were the most commonly reported organisations; the National Childbirth Trust, BLISS, and the Miscarriage Association. Supplementary file 7 provides an overview of the organisations that were involved in PPI. Two trials did not provide the name of the organisations involved in PPI (31, 32).

PPI activities were reported at all stages of a trial, from trial conceptualisation to disseminating the findings, with 23 trials reporting that PPI contributors were involved at multiple stages of the trial (Figure 2). For example, PPI contributors were involved in trial design and planning in 34 trials, including providing input into trial or protocol development (71%), producing or reviewing study materials (19%), or completing grant applications (8%). Thirty-one trials reported PPI during the running of the trial (65%), including contributor involvement on trial steering committees (n=19 trials, 40%), and 42% of trials reported PPI during trial analysis and dissemination of findings, which included PPI contributors reviewing or analysing the findings (10%) or co-writing and reviewing trial reports (70%). Some trials reported PPI at multiple stages of a trial, because of the role of a PPI contributor within that trial. For example, a PPI contributor who was a trial co-investigator was involved from grant application, developing trial documents, attending trial meetings, to the co-writing of trial reports (33).

Only two trials described training opportunities for PPI contributors during involvement in the trial (34, 35). None of the included trials provided information on financial reimbursements made to PPI contributors.

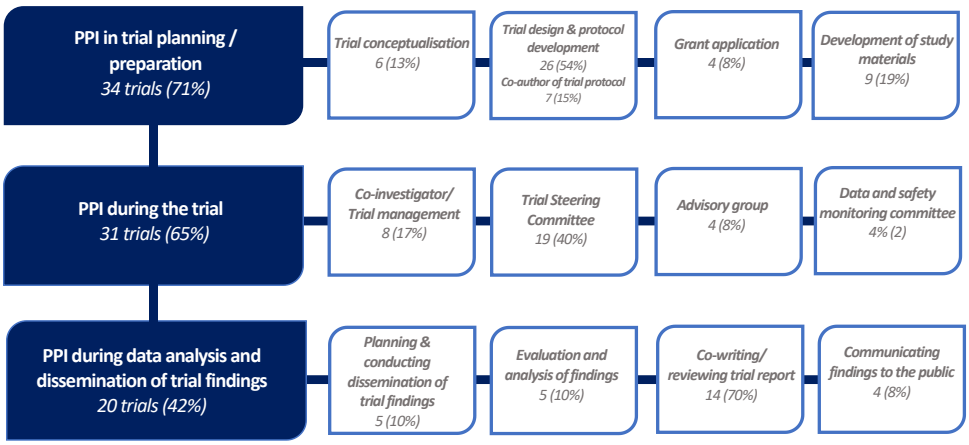

Figure 2: Type and stage of PPI reported in trial reports (n=47) and protocols (n=1)

Discussion

The results of this exploratory review demonstrate that, during the years 2017 to 2022, PPI reporting is lacking and, where reported, inconsistencies in reporting across trial reports exists. Previous reviews in other health research areas have found similarly low frequencies of PPI reporting (13, 23, 36, 37).

A review exploring PPI reporting in published orthopaedic trials (n=475) found that only two trials reported PPI (36), whereas Gray *et al. (37)* found no evidence of Patient and Public Involvement and Engagement (PPIE) in 89 nursing trials reports. These frequencies of reporting are similar to those found in five of the six maternal and neonatal specific journals included in this review. Poor reporting limits our ability to understand how PPI is being conducted, which impacts the ability to reproduce methods of implementing PPI into research (11). There is a reoccurring discussion on whether researchers can adequately assess or evaluate PPI's impact on research (38, 39), with the suggestion that improved PPI reporting will allow for greater clarity on the impact of PPI within individual studies (13, 40). Introducing reporting guidelines into maternal and neonatal specific journals could help to

provide a clearer understanding of the extent that PPI is currently being implemented, in addition to raising the profile of PPI within the clinical research areas of maternal and neonatal health.

Only one trial report included in this review referred to the GRIPP2 checklist. The lack of consistency across the included journals on where PPI information was located within the trial report, in addition to the varying levels of details provided in terms of PPI aims and methods, would suggest that the GRIPP2 reporting guideline is not being consulted when reporting PPI. A review of PPI reporting in patient safety research found that 6% of 82 articles adhered to the GRIPP2 checklist (40). The authors suggested that a published guide, providing detailed explanation on how GRIPP2 should be completed, could be beneficial in improving the use of the checklist and therefore enhance the consistency of reporting (40).

This review also found some discrepancies on what activity was considered 'PPI'. For instance, in response to the journals' PPI reporting prompt, two trials cited lay representation on an institutional Ethics Committee which, arguably, does not constitute researchers' intentionally incorporating PPI into the trial. Another trial which did report some form of PPI additionally stated that a member of the trial team experienced the condition being investigated by the trial in response to the PPI reporting prompt. This would suggest that alongside the implementation of PPI reporting guidelines, it would be beneficial for journals requesting PPI reporting to provide information and examples of PPI in order to foster a common and shared understanding of constitutes 'PPI'.

Price *et al.* (23) compared PPI reporting within *The BMJ* before and after the journal implemented PPI reporting guidelines and found that, while PPI reporting increased from 0.5% (2013-2014) to 11% (2015-2016), the overall quality and quantity of reporting remained low. Lang *et al.*'s (22) review of PPI reporting in articles published in *BMJ Open* in 2020 revealed that 21% reported PPI, with 44.5% of PPI reported occurring in the UK. Both Price *et al.* (23) and Lang *et al*. (22) noted that the lack of reporting cannot be entirely interpreted as simply an issue of under-reporting PPI that *was* conducted. Price *et*

al. suggests that the overall lack of reporting in the *BMJ* during the selected years was due to a lack of PPI being conducted in general or researchers not wishing to share details of PPI that did not work well or that did not achieve its objectives (23). While a substantial number of trials that reported PPI included this review were conducted in the UK, future work could be done to compare the implementation of PPI in research on a national and organisational level by country, as well as exploring trends of PPI reporting based on geographic location.

This review included two journals which have existing PPI reporting guidelines, both of which had higher levels of reporting in comparison to the majority of the seven other included journals. However, as previously highlighted**,** this may be due to authors intentionally submitting PPI informed research to journals with PPI guidelines (22). Despite their levels of reporting, *BJOG* and the *BMJ* still had considerable numbers of trials stating that no PPI took place (42% and 43%, respectively). Most authors who reported that no PPI had occurred in response to the PPI guidelines did not provide reasons for this decision. As evidenced in two reviews on the impact of PPI reporting guidelines in journals (22, 23), reporting remained low in quality despite the implementation of a reporting guideline. The updated CONSORT 2025 checklist (41) and the SPIRIT 2025 (Standard Protocol Items: Recommendations for Interventional Trials) checklist (42), now request that authors provide information of PPI when reporting randomised trials and randomised trial protocols, respectively. As both checklists are requested of prospective authors by a substantial number of academic journals, including those included in this review, we would anticipate that this should increase the frequency of PPI reporting. However, trial journals can still implement PPI reporting guidelines to raise awareness of and frequency of PPI reporting across all research reports.

The numerous existing organizations who advocate for specific maternal and neonatal health and health needs, such as preeclampsia or miscarriage, enables trial research teams to have access to

individuals with experiential knowledge to take part in PPI. This was evidenced by more than half of the included trials that reported PPI involving an individual linked to a maternal or neonatal charity or consumer organization. However, several of the trials that reported PPI did not include information that would provide insight on how they were able to recruit PPI contributors. For example, in eight trials, PPI contributors were discussed only as 'contributors'; no other information was provided to explain how and why they, as individuals, were involved in a particular trial. Involving individuals with lived experience who are most likely to benefit from the research is an integral aspect of why PPI has the potential to improve the relevance of research (39, 43, 44). As such, it would be helpful to have more information provided on who was involved in PPI.

Strengths and limitations

The review provides an overview of PPI reporting in maternal and neonatal trials published between 2017 and 2022, which to our knowledge has not been addressed previously, and which provides a 'state of the art' landscape from which to build on. The strengths of this study include the range of journals and years included, with the latter providing contemporary insight. The review, however, has some limitations. As only a sample of trials published in *BMC Pregnancy & Childbirth* were included in this review, it is possible that PPI was reported in other eligible trials reports published in this journal. However, based on the low levels of PPI reported in the included journals overall, particularly the neonatal and maternal health specific journals, it is unlikely that the frequency of reporting would have changed substantially. It is also possible that had we chosen different journals for inclusion in this review, our results may have been different.

There is also the potential that trial researchers did conduct PPI but did not explicitly report this in the trial report, particularly in journals without PPI guidelines. For instance, information provided in two included trials were only identifiable as related to PPI due to further information provided in their

associated trial protocols. This suggests that other trials that conducted PPI, and acknowledged an individual's involvement but did not explicitly cite their role as a PPI contributor, may have gone undetected in this review. Emailing authors to request PPI information was considered for this current review, however a similar review that used this method reported a low response rate which had little impact on the review's findings (13).

Conclusion

The reporting of PPI in maternal and neonatal clinical trials is lacking, and there is a wide variation in the depths of information provided, including those involved as PPI contributors and how they contributed to the trial. Implementing PPI reporting guidelines in academic journals may be beneficial in prompting researchers to provide information on whether PPI was conducted. Implementing structured reporting frameworks, such as the GRIPP2 or the GRIPP2 short form, alongside journal reporting guidelines could help to standardise PPI reporting (11).

Declarations

Ethics approval and consent to participate: Not applicable, ethical approval was not required to conduct this review.

Consent for publication: Not applicable.

Availability of data and materials: The dataset created and analysed for the purpose of this review is available from the authors, upon reasonable request.

Competing interests: The authors declare that they have no competing interests.

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Table 3: Characteristics of trials reporting PPI (n=48)

			Total (n=48) n (%)
Type of trial			
Maternal trial			36 (75%)
Neonatal trial			12 (25%)
Type of intervention	**Maternal trials (n=36) n (%)**	**Neonatal trials (n=12) n (%)**	**Total (n=48) n (%)**
Drug	11 (31%)	3 (25%)	14 (29%)
Other*	9 (25%)	5 (42%)	14 (29%)
Procedure	7 (19%)	1 (8%)	8 (17%)
Behavioural	4 (11%)	2 (17%)	6 (13%)
Device	3 (8%)	1 (8%)	4 (8%)
Testing two or more interventions	1 (3%)	-	1 (2%)
Dietary supplement	1 (3%)	-	1 (2%)
Vaccine	-	-	
Diagnostic test	-	-	
Purpose	**Maternal trials (n=36) n (%)**	**Neonatal trials (n=12) n (%)**	**Total (n=48) % (n)**
Treatment	14 (39%)	8 (67%)	22 (46%)
Prevention	16 (44%)	4 (33%)	20 (42%)
Diagnostic/ Screening	4 (11%)	-	4 (8%)
Supportive Care	-	-	-
Health Services Research	1 (3%)	-	1 (2%)
Other	1 (3%)	-	1 (2%)
Location			**Total (n=48) n (%)**

UK	20 (42%)
Multi-national trials	11 (23%)
Australia	4 (8%)
Netherlands	4 (8%)
Ireland	3 (6%)
France	1 (2%)
India	1 (2%)
Sweden	1 (2%)
Denmark	1 (2%)
South Africa	1 (2%)
Hong Kong, China	1 (2%)
PPI reporting by year of publication – main trial report only	**n (%)**
2017 (n=70)	2 (3%)
2018 (54)	7 (13%)
2019 (63)	13 (21%)
2020 (61)	10 (16%)
2021 (53)	8 (15%)
2022 (51)	7 (14%)
Location of PPI reporting	**Total (n=48) n (%)**
Reported PPI in protocol	30 (63%)
Reported PPI in protocol *only*	1 (2%)
PPI in main trial report	47 (98%)
- *Co-authors/ authors' information*	10 (21%)
- *Methods section*	24 (52%)
- *Discussion section*	2 (7%)
- *Acknowledgements*	11 (24%)
- *Funding information*	4 (9%)
- *Supplementary material (e.g. protocol)*	12 (26%)
Description of involved PPI contributors	**Total (n=48) n (%)**

Charities, advocacy, or other non-profit organisations	24 (50%)
Maternity service users and families	29% (14)
PPI contributor	9 (19%)
Patient representatives	7 (15%)
Former trial/research participants or their guardians	4 (8%)
Community representatives/ community leaders	3 (6%)
Lay member of ethics/safety committee	2 (4%)
	Total (n=48) n (%)
Reported training provided to PPI contributors	2 (4%))
Reported reimbursement	0% (0)

***Maternal trials:** 'Other' category includes 13 described as 'other' intervention on the trial's registry, 2 QoL interventions, 1 educational intervention, and 1 basic science intervention

***Neonatal trials:** 'Other' category includes 1 basic science intervention, 1 device feasibility study, 1 QoL, and 8 described as 'Other' on the trial's registry.

Table 4: Details of trials that reported PPI (n=48)

Journal Author	Country	Funder	Maternal trial/ Neonatal trial	Health condition/ Area under evaluation	Location of PPI reporting	PPI activity	PPI contributors
BMJ							
Tappin *et al.* (45)	UK	- Cancer Research UK - Chief Scientist Office (Scotland) - HSC Public Health Agency, Northern Ireland (NI); - Health and Social Care R&D Division (NI); - Northern Ireland Chest Heart and Stroke; - Scottish Cot Death Trust; - Lullaby Trust.	Maternal	Smoking Cessation in Pregnancy	Methods	- Trial planning	- Two previous smokers who participated in a feasibility trial
						- Trial Steering committee (TSC)	- Patient representative
Cluver et al. (46)	South Africa	- Mercy Health Foundation - Peter Joseph Pappas Preeclampsia Foundation - South African Medical Research Council	Maternal	Preeclampsia	Methods	- Reviewed trial manuscript	- Member of the public
						- Developed dissemination plan	- Knowledge users
Hayes-Ryan *et al.* (47)	Ireland	Health Research Board Mother and Baby Clinical Trial Network Collaborative Ireland	Maternal	Preeclampsia	Methods	- Reviewed trial protocol	- Lay representatives on research ethics committees

						- TSC	- Public representatives
Henrichs *et al.* (31)	Netherlands	- Netherlands Organisation for Health Research and Development (ZonMw)	Maternal	Perinatal morbidity and mortality	Methods	- Contributed to developing the grant proposal and gave feedback on trial design, partook in discussions concerning trial findings.	- Patient representative
						- Communicating trial findings to the public	- Client organisations [unnamed]
Keulen *et al.* (48)	Netherlands	- ZonMw	Maternal	Post-term birth, Prolonged pregnancy	Methods	- Plan to conduct future PPI: Developing public facing material and documents	- Patient representatives
Adnan *et al.* (49)	Ireland	- Trinity College Dublin - Coombe Women and Infants University Hospital.	Maternal	Postpartum haemorrhage	Methods	- Feedback on design	- Women in pilot trial
						- Feedback on Patient Information Leaflet (PIL)	- Lay members of the institutional research ethics committee
Bick *et al.* (33)	UK	- National Institute for Health Research (NIHR)	Maternal	Spontaneous vaginal birth	Methods	- Trial planning and trial meetings	- PPI co-investigator
						- Grant application	
						- Trial protocol development	

						- Trial report/paper manuscript - Developing PILs - Disseminating findings, including producing a summary report	
The Lancet							
The INFANT Collaborative Group (50)	Multinational	NIHR	Maternal	Foetal monitoring	Author of trial report (not identified as PPI contributor); Supplementary material	- Protocol development - Trial running and trial management - Co-writing trial report	-Two PPI contributors - National Childbirth Trust (NCT) (one listed as co-investigator)
Norman *et al.* (51)	Multinational	- Chief Scientist Office, Scottish Government - Tommy's - Sands	Maternal	Stillbirth	Acknowledgements	- TSC	- Lay member
Wilson *et al.* (52)	UK	- NIHR	Maternal	Pain management	Discussion; Role of the funding source	- TSC	- Two PRIME members (Public and Researchers Involvement in Maternal and Early pregnancy group)

						- Reviewing information resources for participants	- PRIME group members
						- Trial design	
Hartley *et al.* (53)	UK	- NIHR - Wellcome Trust	Neonatal	Pain management	Acknowledgements	- Trial design - Trial protocol co-authors	- SSNAP (Supporting Sick Newborn and their Parents) charity representative PPI contributor
						- Trial promotion - Development of trial material - participant information resources - Trial conduct	
						- TSC	- PPI contributor
Griffiths *et al.* (54)	UK	- NIHR	Neonatal	Infection	Authorship; Acknowledgements	- Trial co-investigators	- BLISS Representative
						- Trial development and delivery	- Infant and family representatives mainly recruited through BLISS
Knight, Chiocchia (55)	UK	- NIHR	Maternal	Surgical/ Operative birth infection	Supplementary material (protocol)	- TSC	- PPI representative from NCT
						- Trial Collaborative Group	- Lay member – PRIME group

						- Protocol co-author	
Chappell *et al.* (56)	UK	- NIHR	Maternal	Intrahepatic cholestasis of pregnancy	Authorship; Acknowledgements (indirect); only identifiable as PPI from protocol	- Co-author of trial manuscript and protocol	- ICP Support representative
						- Co-Investigator Group	
						- TSC	- PPI Representative
Chappell, Brocklehurst *et al.* (57) **Protocol:** Chappell, Chambers et al. (58)	UK	- NIHR	Maternal	Preeclampsia	Protocol	- TSC	- Action On Pre-Eclampsia (APEC) Representative
						- Co-Investigators Group - Co-author of trial manuscript	- APEC Representative
Chu *et al.* (59)	UK	- NIHR	Maternal	Miscarriage	Authorship; Discussion	- Consulted about the trial's primary outcome	- Women diagnosed with miscarriage
						- TSC	- Two PPI contributors: Miscarriage Association representative and one PPI representative
						- Co-author trial report	- Tommy's charity representative

Caeymaex, *et al.* (60) **Protocol:** Caeymaex, Lebeaux *et al*. (61)	France	- Solidarity and Health Ministry (France)	Neonatal	NICU adverse events	Authorship (indirect); only identifiable as PPI from protocol	- Co-author of main trial report - Dissemination of findings	- Association SOS Prema representative
Edqvist *et al.* (62)	Sweden	- Swedish Research Council for Health, Working Life and Welfare - Jan Hains Research Foundation - Skane County Council's Research and Development Foundation.	Maternal	Birth injury prevention	Acknowledgements	- Trial design and acceptability, - Review of trial questionnaires	- User representative - Focus groups with women
Hodgetts Morton, Toozs-Hobson *et al.* (63) **Protocol:** Israfil-Bayli, Morton *et al.* (64)	UK	NIHR	Maternal	Miscarriage prevention	Protocol	- TSC	- PPI representative
Chalmers *et al.* (65)	UK	NIHR	Neonatal	Eczema	Acknowledgements; Supplementary material (protocol)	- Trial design - Trial design and "associated documentation"	- Patients involved in pilot trial - Panel of parents (previously involved in pilot trial)
NEJM							
Lissauer *et al.* (66)	Multinational	- Medical Research Council (UK), and	Maternal	Miscarriage	Supplementary material	- Developing trial documents – PILs	- Two patient champions and

		others			(protocol)	and consent forms	other patients
						- TSC	- Miscarriage Association representative
Curley *et al.* (67)	Multinational	- NHS Blood and Transplant (NHSBT); others	Neonatal	Severe thrombocytopenia	Supplementary material (protocol)	- TSC	- Parent Representative (s)
Manley *et al*. (68)	Australia	- Australian National Health and Medical Research Council (NHMRC) - Monash University	Neonatal	Neonatal respiratory conditions	Methods; Supplementary material (protocol)	- Trial co-investigator - Provided input into trial design	- Life's Little Treasures Foundation representative
Coomarasamy *et al.* (69)	UK	NIHR	Maternal	Miscarriage prevention	Supplementary material (protocol)	- TSC	- Two PPI contributors: Patient representative and Tommy's representative
Dorling *et al.* (70) **Protocol:** Abbott *et al.* (71)	UK	NIHR	Neonatal	Feeding	Authorship; supplementary material (protocol)	- TSC	- Representatives from PPI groups
						- Protocol co-author	- Bliss representative
						- Consulted on trial design/acceptability	- TAMBA (Twins And Multiple Births Association) - BLISS - SSNAP
Deprest, Nicolaides *et al.* (72)	Multinational	- European Commission - KU Leuven	Maternal	Congenital Diaphragmatic Hernia	Supplementary material	- Data Monitoring and Safety	- CDH representative

		- Wellcome Trust - Engineering and Physical Sciences Research Council (UK); others			(protocol)	Committee (DMSC)	
Deprest, Benachi *et al.* (73)	Multinational	- European Commission - KU Leuven - Wellcome Trust - Engineering and Physical Sciences Research Council (UK); others	Maternal	Congenital Diaphragmatic Hernia	Supplementary material (protocol)	- DMSC	- CDH representative
Hodgson *et al.* (74)	Australia	NHMRC	Neonatal	Neonatal respiratory distress	Supplementary material (protocol published in BMJ)	- Consulted on trial design/ acceptability	- Parents of infants who participated in pilot trial
BJOG							
Smith *et al*. (75)	Ireland	Health Research Board (HRB) Ireland	Maternal	Caesarean section	Methods	- TSC	- Maternal service user
Bellad *et al.* (76)	India	Thrasher Research Foundation (US)	Maternal	Preterm birth	Methods	- Protocol development	- Pregnancy women, community leaders, potential participants
Hyldig *et al.* (77)	Denmark	- University of Southern Denmark - Odense University Hospital - Lundbeckfonden - Smith & Nephew	Maternal	Surgical/ Operative birth infection	Methods	- Feedback on information material, questionnaire and patient follow-up.	- Women giving birth at the main trial site.

Goldenberg *et al.* (78)	Multinational	- Bill & Melinda Gates Foundation - Eunice Kennedy Shriver National Institute of Child Health	Maternal	Maternal and neonatal mortality	Methods	- Sought input on trial design	- Community meetings: women, families and community leaders
Ahmed *et al.* (79)	UK	Medical Research Council	Maternal	Preeclampsia	Study funding information; supplementary material	- TSC	- Action on Pre-eclampsia patient–parent representative
Bick *et al.* (80)	UK	NIHR	Maternal	Postnatal weight management	Methods	- Trial design - Trial conduct	- Four local women with experience of pregnancy at BMI over 25kg/m2
						- TSC	- Lay member
Beckmann *et al.* (81)	Australia	The Mater Foundation	Maternal	Induction of labour	Methods	- Trial design - Reviewed protocol	- Maternal Choices Australia
Ngai *et al.* (82)	Hong Kong, China	General Research Fund (Hong Kong government)	Maternal	Postpartum depression	Methods	- Trial design	- Expectant parents
Slade *et al.* (83)	UK	NIHR	Maternal	Traumatic childbirth - PTSD	Methods	- Trial management group - Co-investigators - Reported involvement across trial lifespan (from	- Two PPI contributors: Birth Trauma Association representative (co author on main trial manuscript),

						development through to evaluating results) - Co authored trial paper	Expert by Experience
Husain *et al*. (84)	UK	Barts Charity	Maternal	Vaginal health	Methods	- Trial design and conduct - Protocol development	- Patient representatives
						- Future trial dissemination in a PPI session	- Patient network
Stegwee *et al.* (85)	Netherlands	ZonMw	Maternal	Caesarean section complications	Methods, Funding information.	- Trial design - grant proposal for funding	- Dutch gynaecological patients' association (patient involvement panel)
Gurol-Urganci *et al.* (34)	UK	The Health Foundation	Maternal	Birth injury prevention	Methods	- Independent Advisory Group	- Lay representatives
						- Development of intervention component (information sheet).	- PPI groups
Acosta-Manzano *et al.* (86)	Multinational	- European Union FP7 programme - ZonMw - Polish Ministry of Science	Maternal	Gestational diabetes mellitus	Methods	- Involved in development of trial's interventions	- Women

		- Odense University (Denmark) - CAIBER 1527-B-226 (Spain); others. Supported by NIHR Clinical Research Network					
Flenady *et al.* (87)	Multinational	- NHMRC - Stillbirth Foundation Australia	Maternal	Stillbirth	Methods; Acknowledgements	- Consulted on trial design/ acceptability	- Aboriginal women and community representatives
						- Developed study material - brochure	- Perinatal Society of Australia and New Zealand (PSANZ) Consumer Advisory Group - Stillbirth Foundation Australia
van der Nelson et al. (30)	UK	- Ferring Pharmaceuticals - North Bristol NHS Trust	Maternal	Postpartum haemorrhage	Methods, Strengths and limitations, Acknowledgements	- Consulted on trial design - Reviewed PILs and questionnaire - Developed study protocol	- Maternal Service User Panel

Neonatology							
Schindler *et al.* (88)	Australia	Running for Premature Babies	Neonatal	Patient ductus arteriosus	Funding sources	- Study conception - Research question and trial proposal - Trial progress - Dissemination of trial results	- Running for Premature Babies founder
						- Trial design and acceptability	- The Royal Hospital for Women's Quality and Patient Safety Committee
						- Plans to disseminate trial findings	- Running for Premature Babies & Royal Hospital
Archives of Disease in Childhood – Fetal and Neonatal Edition							
De Kort *et al.* (89)	Netherlands	- Fonds NutsOhra - ZonMw	Neonatal	Anaesthesia Intubation	Acknowledgements	- Trial design - Trial evaluation	- Parents' organisation (VOC)
Duley *et al.* (35)	UK	NIHR	Neonatal	Cord clamping	Methods; Collaborators information section	- Research question - Trial funding application - Trial design and conduct - Consulted on recruitment - Analysis and	- Three parent representatives - Two Bliss representatives - NCT representative

						interpretation of results - Writing report of results	
						- Protocol co-author	- NCT representative
						- TSC	- Two parent representatives
Pediatrics							
Gaden *et al.* (90)	Multinational	Research Council of Norway	Neonatal	Mother-infant bonding, parental anxiety, and maternal depression	Methods; Acknowledgements	- Protocol development - Research question - Acceptability of intervention	- Parents of premature infant for protocol feedback.
						- Dissemination strategies - Consulted during trial progress - Recruitment	- User Advisory Group (3 named) - Parents of premature infants
BMC Pregnancy and Childbirth							
Clarke *et al.* (91)	Multinational	European Union FP7 programme	Maternal	Vaginal Birth After Caesarean	Authorship	- Trial report co-author	- AIMS UK representative