

Innovating for Improvement

The **P**arents' **A**ctive **R**ole and
ENgagement in **T**heir **S**tillbirth/perinatal
death review (**P**ARENTS) Study

PARENTS



Parents' active role and engagement
in their stillbirth & neonatal death review

North Bristol NHS Trust

About the project

Project title:

The **P**arents' **A**ctive **R**ole and **E**ngagement in **T**heir **S**tillbirth/perinatal death review
(PARENTS) Study

Lead organisation:

North Bristol NHS Trust

Partner organisation(s):

Manchester University NHS Foundation Trust

Project lead(s):

Christy Burden

Danya Bakhbakhi

Dimitrios Siassakos

Contents

About the project	2
Part 1: Abstract.....	3
Part 2: Progress and outcomes	4
Part 3: Cost impact.....	11
Part 4: Learning from your project	12
Part 5: Sustainability and spread	14
Appendix 1: Resources and appendices.....	15

Part 1: Abstract

There are approximately 4,500 stillbirths and neonatal deaths at age under seven days (perinatal mortality) in the UK each year. This equates to around 7 in every 1,000 births. The perinatal mortality review meeting (PNMR) that takes place post -death can provide answers to parents and enable healthcare professionals to learn vital lessons to improve care for women and their families. Unfortunately, evidence suggests that parents are unaware that this formal review takes place, and many would welcome the opportunity to participate meaningfully.

We hypothesised that parental involvement in the PNMR (the novel intervention) would have potential to improve patient satisfaction, drive improvements in patient safety, and promote an open culture within healthcare. Challenges included 'buy-in' from professionals due to initial fears about the number of complaints we might generate. Concerns were mitigated through extensive co-development of the intervention; obtaining good input from bereaved parents, stakeholders, charities and healthcare professionals. .

The PARENTS Study has developed and tested a PNMR process, which has already made an impact locally and nationally. We have been approached by the local patient safety officer and assistant medical director to apply our findings to all Serious Untoward Incidents (SUIs) and patient safety incidents at our NHS Trust. Nationally our findings have informed the National Perinatal Mortality Review Tool which is going to be adopted and rolled out across the UK in 2018, the Department of Health Bereavement Care Pathway and the revised international Royal College of Obstetricians and Gynaecologists (RCOG) management of stillbirth guidelines.

Max words: 250

Part 2: Progress and outcomes

This section is intended for you to summarise your outcomes and evidence for how these were achieved.

Our intervention was involving parents in the formal review of their perinatal death. For further information, please see our published protocol paper in Appendix I. This was genuinely innovative as, although patients have previously been involved in healthcare improvement, the involvement of parents in such a sensitive area has not been implemented or formally evaluated. We hypothesised that parental involvement in the PNMR could have the potential to improve patient satisfaction, drive improvements in patient safety, and promote an open culture within healthcare.

This innovation is high on the NHS and political agenda. The Safer Maternity Care campaign has pledged to make the NHS maternity services some of the safest in the world and to reduce the number of perinatal deaths by half by 2025, by improving reviews and lessons learned after a baby has died.

We undertook extensive development of the intervention prior to implementation. We obtained input from bereaved parents, stakeholders, charities and healthcare professionals using modified Delphi methodology to gain a national consensus on how best to implement parental involvement in the PNMR.

Healthcare professional focus groups

As part of the Health Foundation Innovating for Improvement project, we conducted five focus groups with healthcare professionals to obtain their views on parental involvement at two geographically distinct hospital trusts – North Bristol NHS Trust (NBT) and Manchester University Hospital Foundation Trust (MFT). Across the two hospital sites, we interviewed midwives, obstetric consultants, junior doctors - obstetric and neonatal consultants, nursing staff, the Director of Midwifery, the Clinical Director and chaplaincy services.

Five focus groups took place between May and June 2017 (two focus groups were held at NBT and three at MFT). Twenty-seven participants were recruited into the focus group discussions.

Healthcare professionals **unanimously agreed** that parental involvement in the perinatal mortality review process is essential. Following qualitative thematic analysis **nine key themes** emerged including:

- 1) *The recognition of parental involvement as a priority*
- 2) *The multi-faceted role of the review for healthcare professionals*
- 3) *The importance of multidisciplinary attendance;*
- 4) *The structure of perinatal mortality review meeting*

- 5) *Learning from the review*
- 6) *Co-ordination and stream-lining of care*
- 7) *Advocacy for parents and role of the bereavement care lead (midwife/nurse)*
- 8) *The need for formalised follow-up*
- 9) *A requirement for training and support for staff to enable parental involvement.*

For more information please see our Healthcare professional Focus Group paper (Appendix II)

Consensus meeting

A Delphi technique was used to gain a national consensus on parental involvement in the PNMR. We used three sequential rounds including a consensus meeting workshop and a two-stage anonymous questionnaire. A national panel of 25 experts in stillbirth and bereavement, as well as patient advocates, were identified from the International Stillbirth Alliance, The Sands Stillbirth and Neonatal Death Charity, Child Bereavement Care UK and Bliss UK charity. The expert group also included a small sub-sample of clinical directors, clinical commissioners and NHS managers, lead obstetricians and neonatologists, lead midwives and neonatal nurses and the research team.

A five-hour consensus workshop took place in Bristol. The meeting focussed on four key areas including: getting feedback from parents, the format of the perinatal mortality review meeting, the parental pathway and challenging aspects of involving parents. Themes and principles, from focus groups of parents and healthcare professionals, were presented to the panel of experts alongside current evidence in this area of bereavement care. The expert group were asked to generate ideas and solutions specifically addressing the four key areas with the overall aim to create principles of how to implement and pilot a perinatal mortality review process with parental involvement. Each participant was asked to submit their solutions to the moderator of the group (member of the research team) collated information to generate over-arching principles for parental involvement.

The expert panel from the consensus meeting were invited via a personalised email to complete an anonymous web-based survey (Smart Survey). Participants ranked the principles generated from Round 1 using a nine-point Likert scale from 1 (not important) to 9 (critical). This scale was created by the Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group and has been used widely in other consensus research studies. 'Consensus' was reached if over 70% of participants scored the principle as 'critical' (score 7 to 9) and less than 15% of participants scored the principle as 'not important' (score 1 to 3). Principles were excluded if 70% or participants scored the principle as 'not important (score 1 to 3) and less than 15% of participants' scored the principle as 'critical' (score 1 to 3).







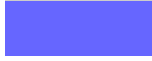
Results

The principles in the second round generated from the Round 1 meeting consisted of the following;

1. There should be a face-to-face explanation of the perinatal mortality review process, supported by a written information leaflet, prior to hospital discharge
2. The form to obtain parental feedback should be completed in a face-to-face consultation at a private location of the parent's choice (If the parent declines offer by telephone, email or post).
3. There should be 4 different feedback forms (for stillbirth, neonatal death, coroner's case, and termination for fetal abnormality).
4. The parents should be offered the opportunity to nominate a suitable advocate or bereavement care midwife; a person who completes the feedback form with parents and attends the perinatal mortality review meeting.
5. The meeting should take place within approximately 12 weeks from the baby's death.
6. All healthcare professionals involved in the case should be notified of the perinatal mortality review meeting in good time and attend when possible.
7. Staff who cannot attend the perinatal mortality review meeting should submit their comments at the very least.
8. Responses to the parental feedback should be formally documented in the perinatal mortality review meeting.
9. Action plans should be made from the parental responses if necessary and monitored.
10. A plain English summary should be produced following the perinatal mortality review meeting for the parents.
11. The feedback from the perinatal mortality review meeting should be discussed at the consultant follow up consultation, supported by the plain English summary.
12. The consultant follow up meeting should take place as soon as possible after the perinatal mortality review meeting (approximately 2-4 weeks).
13. Parents should have the option to nominate a second member of staff (which could be the designated parents' advocate) to attend the follow-up meeting with the consultant.
14. If parents decline attending a consultant follow up meeting, then the written plain English summary should be offered to be sent to the parents instead.

An example of the data obtained for each principle is as follows (for principle 2), the full tables of results can be found in Appendix III.

2. The form to obtain parental feedback should be completed in a face-to-face consultation at a private location of the parent's choice (If the parent declines offer by telephone, email or post).

						Response Percent	Response Total	
1	1	Not important				8.00%	2	
2	2					4.00%	1	
3	3					0.00%	0	
4	4					4.00%	1	
5	5					12.00%	3	
6	6					0.00%	0	
7	7					24.00%	6	
8	8					12.00%	3	
9	9	Critical importance				36.00%	9	
Analysis	Mean:	6.8	Std. Deviation:	2.5	Satisfaction Rate:	72.5	answered	25
	Variance:	6.24	Std. Error:	0.5			skipped	0

Pilot of intervention (August 2017 – January 2018)

Women and their partners were invited to participate in the study, if they experienced a perinatal death within the six-month pilot period. This included all stillbirths (birth of a baby with no signs of life after 24 weeks completed gestation) and neonatal deaths (death of a baby within 4 weeks of birth). With an estimated perinatal death rate of about 1:200 and conservative estimates of recruitment rate of about 60% we estimated that we would recruit a pragmatic sample of about 10-12 parent sets at each site. We are positively encouraged that only one parent that was approached declined to participate. We have, so far, recruited 8 sets of parents at NBT. Due to a change in research midwife personnel at MFT, the need for a revision to ethics, and geographical logistics, there has been a recruitment delay at MFT. We still feel confident that we will be able to achieve our recruitment targets by our revised study end date at MFT as well.

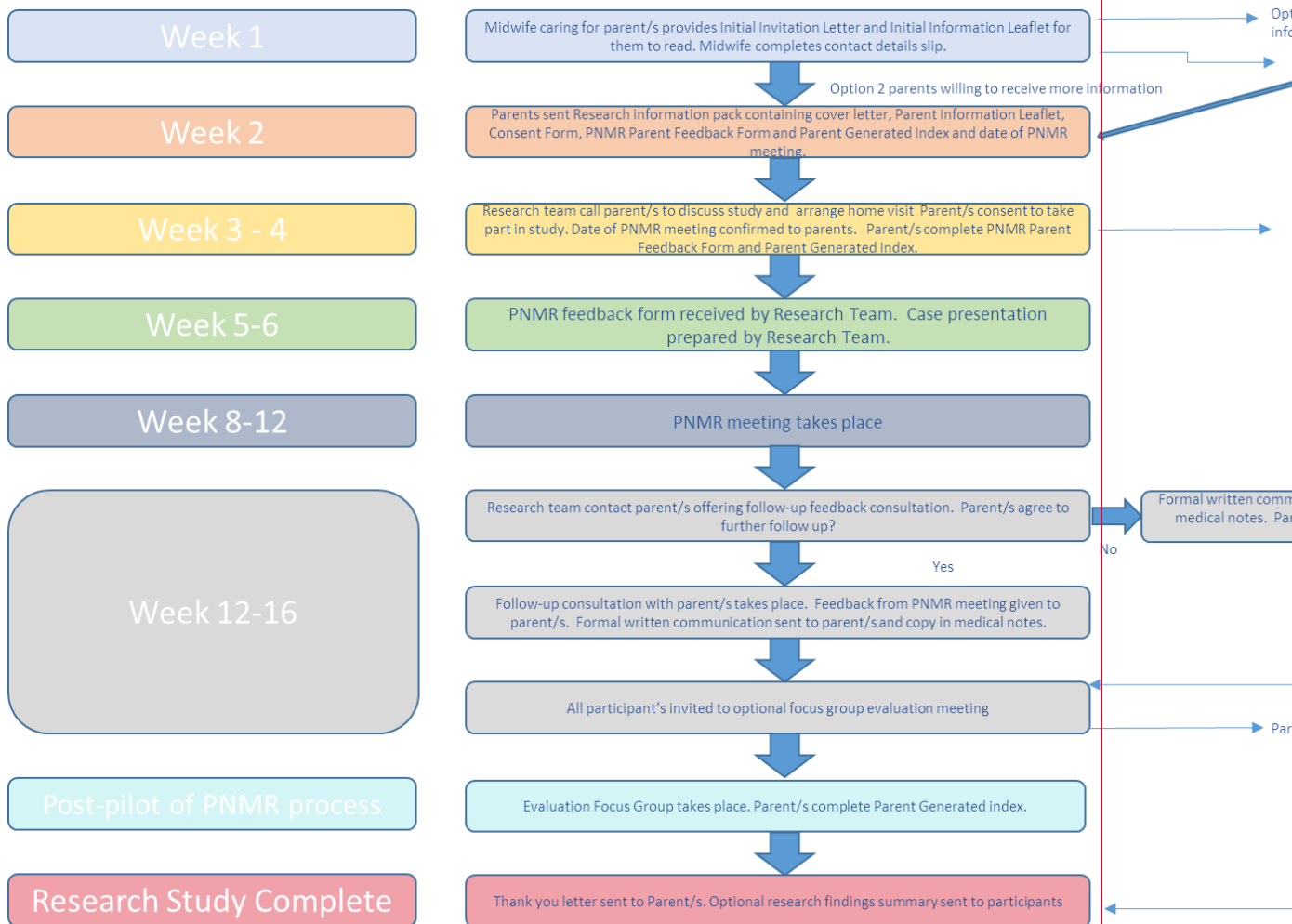
Parents who were recruited into the pilot were asked to complete a PNMR Parent Feedback Form, which was developed from the consensus meeting. This form was completed with facilitation from the research midwife during a home visit to ensure the data from parents was comprehensive. The form allows parents to submit questions, comments or views which can then be discussed in the PNMR. Furthermore, parents were asked to complete a Parent Generated Index (PGI) questionnaire. The PGI is a validated antenatal and postnatal quality of life instrument in which the variables and scores are completely respondent-driven. It allows participants to include quality of life issues that are important to them which are not captured by existing tools. Parents will be invited to complete the PGI before and after their involvement in the pilot PNMR process at NBT and MFT for comparison. Both the Feedback Form and PGI templates can be found in Appendix IV – the former is a direct output from this project. We found some parents reluctant to complete the forms and therefore we intend to collate the reasons why and analyses this at the end of the study.

All questions and comments received from parents via the feedback form were discussed in a standardised format at the PNMR meeting. The research team members ensured that each feedback comment on the Parent Feedback Form was addressed with any salient learning points clearly documented on a PNMR Outcome Form.

Furthermore, the PNMR meetings themselves were observed with ethnography, and key challenges and successes of implementation of parental input into the meeting were captured. We used a 'Rapid Cycle Evaluation' system, and 'single loop learning' to continuously refine the PNMR process using our learning points of the meeting. Initial challenges were ensuring high staff attendance because of changing the time of the meeting and increasing the number and length of the meetings to ensure all parental feedback could be discussed. However, the consensus meeting with attendance of stakeholders was critical in ensuring the successful management of these challenges. For example, at NBT there was agreement to increase the frequency of the meeting to one per month (as opposed to one every two months) and the duration from one to two hours, just one day after the Consensus meeting.

Following the PNMR parents were offered a face-to-face consultation, verbal telephone or postal feedback on the outcome of the PNMR meeting. A formal lay summary was also created to describe the outcome of the meeting in Plain English.

Flow Chart of pilot of intervention



Evaluation of parent and healthcare professionals experience of intervention

We hypothesised that parental involvement in the PNMR could have the potential to improve patient satisfaction, drive improvements in patient safety, and promote an open culture within healthcare. Results to date are encouraging but we have not completed the full suite of follow up measures from the pilot yet.

Following the six-month pilot of parental involvement in the PNMR, parents will be invited to take part in an evaluation focus group. There will be one focus group comprising of

five to ten parents at NBT and one focus group comprising of five to ten parents at MFT. The focus groups will discuss parents' perceptions of their inclusion in the PNMR process and will aim to ascertain what went well and what might be improved, and how. Parents' experience of care will again be evaluated with the PGI and this will be compared to the results from the pre-intervention questionnaire.

We will also undertake one focus group of five to ten healthcare professionals at NBT and one focus group of five to ten healthcare professionals at MFT. We will assess healthcare professionals' perceptions on the inclusion of parents in the PNMR process and ascertain what went well and what could facilitate future, wide-spread implementation and any implications for future safety improvements.

A qualitative analysis of the focus groups of parents and healthcare professionals will take place.

Demonstrable Impact of the Study:

Our study, to pilot the involvement of parents in the review process after a baby dies, is a completely novel approach that has already improved patient experience and driven improvements in hospital processes and patient safety. Our results have informed, and will continue to inform, a national care pathway and a standardized tool (PMRT), that will both be rolled out across the UK in 2018, to standardise and improve bereavement care nationally.

Example of bereaved parents quotes:

'Being involved in the process has been an invaluable experience for people in our devastating position' (AP05 38/40 SB diagnosed in labour)

'It has been really good to talk to you about the experience of losing M as I had no one else. Hospital was such a shock and a complete blur, I didn't take anything in' (AP01 32/40 SB at home).'

Max words: 1,000

Part 3: Cost impact

At present, parental involvement in the PNMR is not commissioned and no additional payment is received for the hospital Trusts to deliver this service. Once the pilot of the intervention is complete we will complete a financial evaluation with input from a health economist to aid our business case for wider adoption. It is anticipated that there are excess treatment costs to delivering parental involvement in perinatal death reviews. It is predicted that there will be costs associated with the increased frequency and length of meetings; staff members taking time away from clinical activity; co-ordination of obtaining parental feedback and running the PNMR meetings and a potential requirement for a bereavement midwife to support parents through the process. The latter is funded at some NHS Trusts, but not all and so will need to be funded by local commissioning bodies. However, we are developing a business case to implement parental involvement locally at North Bristol NHS Trust that will complement the National Bereavement Care Pathway and drive a “top-down” push for perinatal bereavement care funding at a national level.

Our study is high on the NHS and political agenda. The Safer Maternity Care campaign has pledged to make the NHS maternity services some of the safest in the world and to reduce the number of perinatal deaths by half by 2025, by improving reviews and lessons learned after a baby has died. Reducing the number of perinatal deaths may result in cost savings for the NHS and society. Data from our systematic review in the Lancet Stillbirth Series (Appendix V) showed that the psychosocial impact of perinatal death is significant, including depression, problems with subsequent pregnancies and impact on employment. Data for direct costs of stillbirth are sparse but suggest that stillbirth costs are greater than a livebirth, both in the perinatal period and in additional surveillance during subsequent pregnancies. Indirect and intangible costs of stillbirth are extensive and are usually met by families alone. For example the experience of stillbirth on parents’ employment, with 10% of bereaved parents remaining off work for 6 months, and 38% of mothers and 21% of partners reducing their working hours. Although the exact extent of the costs and difficult to ascertain data indicate the cost of still birth is ten to seventy times that of a live birth.

With greater parental involvement in review and improved parental satisfaction with the process there is a hypothesis of potential savings from reduced litigation payouts and transaction costs of protracted litigation or complaint procedures.

Max words: 500

Part 4: Learning from your project

Our aim was to develop, pilot and evaluate parental involvement in the PNMR. We believe we are on track to achieve our objectives determined at the start of the project, once recruitment of our target number of parents has been completed and we have analysed and evaluated our results.

Enablers that facilitated this project included involving parents from the outset of the PARENTS portfolio (The PARENTS 1 study- Appendix IV) and securing 'buy-in' from healthcare professionals prior to implementation by conducting in-depth focus groups. We also included key stakeholders in a national consensus meeting and had good representation from charity representatives and parent advocates. Our intervention, therefore, was relevant and meaningful to those it would impact from the start.

Implementing parental involvement has become increasingly higher on the national agenda for improving the safety of maternity care since the commencement of this project. *'National Guidance on Learning from Deaths'* was published in March 2017 by the NHS National Quality Board. It referenced the Report of the Morecambe Bay Investigation, which highlighted poor care and tragic deaths of mothers and babies. The report recommended that an investigation of these incidents should be subject to a standardised process, which includes input from and feedback to families. In *'Learning not Blaming'* the government accepted these investigations. Locally, both hospital units in this study support an open non-blame culture, which helped discuss feedback from parents within the PNMRs.

As part of the grant we appointed a Project Manager who we felt made a significant contribution to co-ordinating the delivery of the project. Their appointment was particularly useful as project leads were full-time clinicians. In addition we received financial support for two Research Midwives. These roles were crucial for the identification of parents who might be eligible for the study, recruitment, follow-up and support for parents.

During our study a midwife was employed to co-ordinate the patient pathway of a bereaved couple which has been invaluable to the smooth running of the project and will be a key part of our business case to commissioners to fund a dedicated bereavement midwife PNMR coordinator in every Trust

We also set up a Project Advisory Board who included parent representation and input from experts in perinatal loss around the world. This was beneficial as we were able to obtain impartial expert advice and guidance throughout the study.

As this was a novel process in a sensitive area, there was a relatively long lead-in time before we were able to start recruitment of parents. There was an underestimation of the time required to gain HRA and ethical approval, as in spite of being an experienced research team, there was a new application system, which was introduced at the time of our submission.

Further challenges included obtaining 'buy-in' from healthcare professionals as there were initial concerns and fears about the number of complaints we might receive. However, the development of the intervention was extensive and by obtaining input from the outset from bereaved parents, stakeholders, charities and healthcare professionals we felt we were able

to mitigate these fears. Staffing changes also caused delays.

Secondly the recruitment for participants into the pilot phase from Manchester has only just commenced. Although we still hope to achieve our planned target recruitment in Manchester, it has been challenging to drive commencement of the project in this Unit. This can be difficult with sites at separate geographical locations and without face-to-face meetings.

Lastly we had initially planned to recruit 5 to 10 stakeholders at each site into the focus group interviews yet due to participant availability we only recruited two stakeholders. We were able to overcome this set-back by having a diverse representation from 25 stakeholders at the national consensus meeting on parental involvement which was held in June 2017. Involving stakeholders from NBT ensured improvement of the PNMR and 'buy in' at our local Trust.

We were pleased at the higher than expected recruitment rate of parents into the study. Parents were keen to be involved and to have their views included in the review and only one parent has declined to date. Again we learnt that involvement of staff and parents from the outset was important to achieve to enable the process to be feasible. This has particular importance when introducing and sustaining innovations in the NHS. As a team we feel that parental involvement in the PNMR is feasible and crucial in order to learn from perinatal deaths and improve patient safety.

Max words: 1,000

Part 5: Sustainability and spread

We plan to sustain parental involvement in the PNMR at North Bristol NHS Trust by presenting our business case (including a consideration for the excess treatment costs) to Trust management and local commissioners. We are also developing a Policy Brief (Appendix VII) to circulate to relevant politicians, commissioners and other stakeholders, so national funding provisions can be driven “top down” and accessible across the UK.

So far our work has had external interest from the RCOG ‘Each Baby Counts’ Report and has informed the development of the National Perinatal Mortality Review Tool (<https://www.npeu.ox.ac.uk/pmrt>). Our abstract for the findings of the healthcare professional focus groups was accepted and presented as an oral presentation at the International Stillbirth Alliance Conference in Cork in September 2017. We also presented our work at The University of Bristol Academic Showcase and received local interest from academics within the region. Furthermore, we received additional media interest during Stillbirth Awareness Week (Appendix VIII) for press releases and social media post). Our protocol has been accepted and published in BMJ Open (See appendix i). We have drafted the paper for the results of the healthcare professionals focus groups for submission in BMJ Quality and Safety. The Consensus meeting paper has been invited for submission to a prestigious specialty journal (Ultrasound in Obstetrics and Gynaecology) with high impact factor.

We plan to disseminate our findings via a University of Bristol Policy Brief, which is currently being finalised via our University Comms Team. We have produced an infographic (Appendix IX) and are also in the process of creating at least one videographic of our findings to share with members of the public. We also plan to publish the findings from the Consensus Meeting and from the Pilot of the intervention in a peer-reviewed journal. We will submit an abstract of our complete findings to the World RCOG Congress in 2019.

We endeavour to work with the Health Service Investigation Branch (HSIB) to spread the findings from the PARENTS study, i.e. start involving parents in hospital reviews, to other critical intrapartum incidents including hypoxic ischaemic encephalopathy (brain damage) and other birth traumas in the first instance. In the future, we also plan to start involving families in maternal mortality and morbidity reviews.

Max words: 800

Appendix 1: Resources and appendices

Appendix I - PARENTS 2 study protocol: pilot of Parents' Active Role and Engagement in the review of Their Stillbirth/perinatal death



PARENTS BMJ
Protocol.pdf

Appendix II – Health Care Professionals Perceptions of Parental Involvement in the Review Process after Perinatal Loss (draft paper)



HCP FG paper
draft.doc

Appendix III – Results of National Consensus Meeting



National Consensus
Meeting Results.doc

Appendix IV – Parental Feedback Form and Parent Generated Index



Parent Generated
Index+V.2 (TRACKED).do

Appendix V – Lancet Series Systematic Review



Lancet Stillbirth
Series.pdf

Appendix VI – PARENTS1 Study



PARENTS 1
STUDY.pdf

Appendix VII – Policy Brief (draft)



PARENTS study
Policy brief draft.pdf

Appendix VIII – Stillbirth awareness week social media post/press release



Stillbirth Awareness
week.jpg

Appendix IV – PARENTS Study Infographic



PARENTS
Infographic.png
