

PARENTS 2 Study: consensus report for parental engagement in the perinatal mortality review process

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ABSTRACT

Objectives

Following a perinatal death, a standardised multidisciplinary review should take place. Learning from these deaths and engaging parents in this process could help prevent future perinatal deaths in line with United Kingdom (UK) national and international targets to reduce the number of such deaths by 2020. Moreover, it would support parents in understanding events around the death of their baby. An earlier study (Parents' Active Role and ENGagement in The review of their Stillbirth/perinatal death - PARENTS 1 study) found that parents would endorse the opportunity to give feedback into the perinatal mortality review process (PNMR). In subsequent focus groups, healthcare professionals were positive about parental engagement, although they considered there may be significant challenges. The objective of this study was to develop core principles and recommendations for parental engagement in PNMR in the UK.

Methods

We followed a two-round Delphi technique to reach a consensus on core principles; including a national consensus workshop and an online questionnaire.

The consensus meeting was attended by a national panel of stakeholders (clinical and academic experts, parent support groups, managers and commissioners) in stillbirth, neonatal and bereavement care (n=22).

To develop recommendations for parental engagement, participants discussed four key areas including: receiving feedback from parents; format of the PNMR meeting; the parental pathway; and challenging aspects of engaging with parents in reviews.

Content analysis was conducted to generate recommendations from the meeting for a subsequent, anonymous web-based survey. Attendees of the consensus workshop and members of the PARENTS 2 Project Advisory Board were asked to rank recommendations using a 9-point Likert scale from 1 (not important) to 9 (critical). It had been agreed a priori, in compliance with established Grading of Recommendations Assessment, Development and Evaluation (GRADE) criteria, that 'Consensus' would be achieved if over 70% scored the principle as 'critical' (score 7 to 9) and less than 15% scored the principle as 'not important' (score 1 to 3). Principles where Consensus was achieved would be included in the core recommendations.

Results

Twenty-five of the 29 invited stakeholders participated in the consensus meeting and the subsequent online questionnaire in June 2017 (86.2% response rate). Consensus was agreed on 12 core principles. Ninety-six percent agreed that it was of critical importance that there should be a face-to-face explanation of the PNMR process; 72% considered parents should be offered the opportunity to nominate a suitable advocate; 92% believed responses to parents' comments should be formally documented; 96% indicated that it was vital for action plans to be translated into lessons learnt and that this process is monitored; and 100% of stakeholders voted that a plain English summary should be produced for the parents following the meeting. There was good agreement on a further seven principles.

Conclusions

Key national stakeholders were unanimously supportive of parental engagement and agreed on core principles to make it feasible, meaningful and robust process. A six-month pilot of parental engagement in the perinatal mortality review process (PARENTS 2 Study) in two UK units took place after the consensus on core principles. In collaboration with the National Perinatal Epidemiology Unit, findings will inform the national standardised perinatal mortality review tool (PMRT).

INTRODUCTION

Following a stillbirth or neonatal death, a systematic, multidisciplinary review of the circumstances and care leading up to and surrounding that death should take place within the hospital¹. Learning from these deaths in the perinatal mortality review (PNMR), alongside better information and communication to parents, could help improve transparency and the quality of care provided to bereaved parents and their families. Importantly, learning from previous deaths would help identify where more could be done to improve patient safety in the future². Improving lessons learnt from PNMRs and the quality of such reviews aligns with national and international targets to reduce the number of stillbirths by 50% by 2020³.

The MBRRACE-UK Confidential Enquiry, and the Royal College of Obstetricians and Gynaecologists 'Each Baby Counts' report, showed in 2015 that the quality of the perinatal mortality review process (PNMR) was inconsistent across the United Kingdom and rarely included any formal input into the review from bereaved parents^{4,5}. Similar to the Kirkup report¹, MBRRACE-UK and Each Baby Counts both recommended that all Trusts and Health Boards should inform parents of any local review, offering them the opportunity to engage in the process, and to receive feedback from the review⁴. However, there was a lack of evidence on how to engage parents meaningfully in the PNMR process. This was previously addressed by the PARENTS portfolio of studies (The Parents' Active Role & ENgagement in The review of their stillbirth/perinatal death)^{6,7} which investigated the best pathway to enable parental engagement in the PNMR process. In the PARENTS 1 Study, eleven bereaved parents who experienced the death of a baby at various gestations were interviewed, and the majority were in favour of an opportunity to contribute to PNMR⁶. Subsequently, focus groups took place with a range of maternity healthcare professionals⁸. The participants agreed parental engagement in PNMRs would be beneficial and could improve the quality of the review⁸. Despite having reservations about the financial and emotional support that might be required to enable such a process⁸, healthcare professionals perceived involving parents could help families in the future, improve patient safety and potentially prevent future perinatal deaths⁷.

Prior to piloting parental engagement in PNMRs, we sought to reach expert consensus on how best to engage parents. Here we report findings from the PARENTS 2 consensus study which generated recommendations on parental engagement.

ETHICS

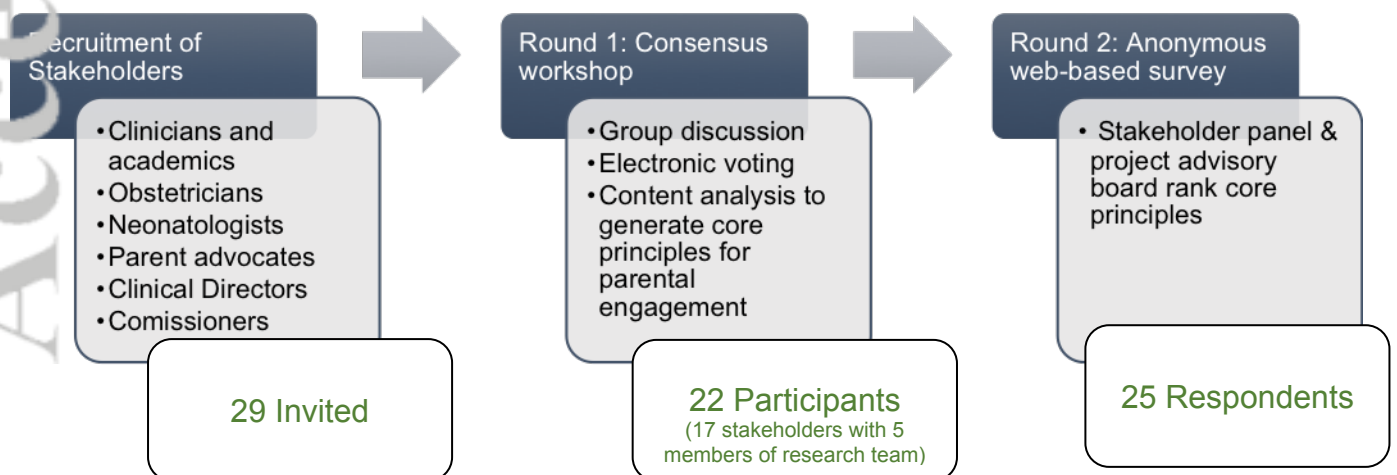
This study has ethical approval from the UK Health Research Authority (Integrated Research Application System (IRAS) 216018. Research Ethics Committee reference 17/WM/0123. Date of IRAS approval: 03/05/2017.

METHODS

The study methods for this consensus have been published in detail in the full PARENTS 2 protocol⁷. We followed a modified Delphi method to achieve consensus on recommendations on parental engagement in PMRs⁹. The Delphi method is an iterative process that uses systematic repeated rounds of anonymous voting to achieve expert group consensus where there is little or no definitive evidence^{9,10}. We used a modified Delphi method to allow expert members of the panel to discuss the principles for parental engagement in a group prior to anonymised voting, which has been perceived as being more cooperative and effective in other research studies^{11,12}. We conducted two sequential Delphi rounds, including a national stakeholder consensus workshop and an anonymous survey.

Figure 1 illustrates the process performed to reach consensus on core principles for parental engagement in the perinatal mortality review process.

Figure 1 Flowchart for consensus process for generating core principles for parental engagement in the perinatal mortality review process



Recruitment of stakeholders

A national stakeholder panel of clinical and academic experts in perinatal loss, neonatal and bereavement care were purposively sampled from key informants through the International Stillbirth Alliance, Stillbirth and neonatal death charity (Sands), Child Bereavement Care UK and Bliss UK charity groups. Twenty-nine stakeholders were identified and invited to attend the consensus workshops. Parent advocates and bereaved parents themselves were also invited to attend. The national stakeholder consensus meeting was attended by 17 participants in addition to five members of the research team. Table 1 shows the distribution of participants according to each stakeholder group for each Round of the consensus process.

Table 1: Distribution of participant according to each stakeholder group for each round

Stakeholder	Number of participants Round 1	Number of participants Round 2
Neonatologist	1	1
Charity representative	2	2
Clinical commissioner	1	1
Clinical psychologist	1	1
Bereavement midwife	3	2
Parent representative	3	3
Clinical academic	4	4
Child death reviewer	1	1
Ultrasonographer	1	1
Research team	5	6
Project advisory board	0	3
Total	22	25

Round 1 – Consensus workshop

A five-hour consensus workshop took place in June 2017. Twenty-four experts and stakeholders were invited. The consensus meeting programme was emailed to participants in advance. Results and themes from the qualitative analysis of the focus group interviews of parents and healthcare professionals were presented to the panel alongside current evidence in this area of practice.

The workshop focused on four key areas including: the format of the PNMR meeting; the parental pathway; and challenging aspects of involving parents in reviews, including the impact of receiving negative feedback from parents about care. The expert panel was divided into four breakout cohorts containing four to five members each with a balanced mix of stakeholders in each group. All groups discussed all four areas. The participants were then asked to generate ideas for solutions specifically addressing the four key areas; with the overall aim to create a set of core principles on how to implement a PNMR process with parental engagement. A facilitator and transcriber who was also a member of the research team (DB, CB, DS, CS and ML) was assigned to each group to facilitate discussion and transcribe by paraphrasing.

Each participant was asked to submit their solutions to the facilitator who collated information to inform the initial draft of overarching core principles for parental engagement. Following discussion of each workshop key area, the groups reconvened, and the facilitator presented a synopsis of the main points made by participants to the wider panel. In addition, anonymised voting took place following each workshop to ask participants and the project research team to vote using electronic keypads on specific questions that had emerged from the focus groups with parents and healthcare professionals^{8,6}. Live results for each question were presented to the participants and were followed by additional discussion of residual issues. Content analysis was conducted by the research team on the data collected from these discussions to generate an initial list of principles for engaging parents in the PNMR process. Content analysis is a systematic way of determining inferences or categories within data¹³. Two members of the team read the transcriptions and field notes, independently coded the data, and subsequently developed themes to produce the consensus recommendations. The final principle list was used in the Round 2 web-based survey.

Round 2 - Web-based survey

The national stakeholder panel from the consensus meeting was then invited via a personalised email from the research team to complete an anonymous web-based survey (Smart Survey). The independent members of the Project Advisory Board (PAB) and research team were also invited to complete the survey. The PAB were purposively sampled to include academic and clinical experts in perinatal death and bereavement care. Twenty-nine participants were invited to complete the web-based survey. The principles of the Delphi consensus process and the survey had been piloted first by the PAB to ensure face validity (readability and ease of completion). Participants were asked to rank the principles generated from round one using a 9-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 including Core Outcome Set development¹⁴. To minimise bias, it had been agreed a priori that 'Consensus' would be achieved 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 would be 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 7 to 9). These criteria have been successfully used in other consensus studies¹⁵. Principles outside the range of these criteria were deemed 'borderline'¹⁵. Responses to each round were analysed using descriptive statistics and histograms.

RESULTS

Round 1 – Consensus workshop

In-meeting electronic voting took place during the four workshops. Participants and research team members (22 respondents) were asked their opinion on seven questions in relation to parental engagement in the PNMR process. All questions and responses are illustrated below in **Table 2**.

Table 2: Consensus workshop in-meeting electronic voting results (n=22)

Question 1			
Should we have a free-text box included in the parental feedback form?	Yes % (n)	No % (n)	Unsure % (n)
	77 (17)	9 (2)	14 (3)
Question 2			
Should we have the option	Yes % (n)	No % (n)	Unsure % (n)

of positive feedback in the parental feedback form?	82 (18)	0 (0)	18 (4)				
Question 3							
Should we differentiate between clinical & non-clinical care within the parental feedback form?	Yes % (n)	No % (n)	Unsure % (n)				
	36 (8)	46 (10)	18 (4)				
Question 4							
Should we use the draft parental feedback form developed by the Department of Health and Sands task group?	Yes % (n)	No % (n)	Unsure % (n)				
	41 (9)	0 (0)	59 (13)				
Question 5							
What do you think is a proportionate amount of time to spend of parental feedback?	Up to 5 minutes % (n)	Up to 10 minutes % (n)	Up to 20 minutes % (n)	Up to 30 minutes % (n)	More than 30 minutes % (n)	As long as it takes % (n)	No response % (n)
	9 (2)	9 (2)	18 (4)	4 (1)	0 (0)	50 (11)	9 (2)
Question 6							
How should we offer feedback lessons from the perinatal mortality review meeting to parents?	Face-to-face % (n)	Written % (n)	Email % (n)	All of the above % (n)	None of the above % (n)	Parental choice % (n)	
	0 (0)	0 (0)	0 (0)	5 (1)	0 (0)	96 (21)	
Question 7							
Do you think a formal report should be produced for the parents following the perinatal mortality review meeting?	Yes % (n)	No % (n)	Unsure % (n)				
	86 (19)	0 (0)	14 (3)				

Workshop 1: Communication with parents

Providing information about engagement sensitively

Stakeholders thought it was crucial that parents should be informed about the review process, including the opportunity to share their perspectives of care as part of the review, before they left hospital. This should be supported by giving parents an information leaflet describing the review process prior to discharge. It was suggested that parents be advised they would be also sent a follow up letter in the post with the timeline,

the estimated date of when the review meeting will take place, information about the review, and the offer to engage them in the process. In addition, there was discussion around the feasibility of an earlier interim debriefing appointment with parents within one or two weeks from discharge to be able to obtain feedback from parents about any aspect of their care and mitigate the wait for the consultant postnatal appointment which could be up to 12 weeks later. A bereavement care midwife or nurse was suggested as a potential healthcare professional that could coordinate this appointment and provide a continued point of contact.

Sustaining feedback

Stakeholders were asked their opinions on parental engagement and receiving feedback to input into the PNMR. Parental engagement may include parents being asked for feedback about their care (including praise or criticism), the ability to ask questions to the PNMR panel about the circumstances around the death of their baby, and the sharing of knowledge obtained from parents which cannot be obtained by a review of the medical notes. Participants were asked to discuss a sample parental letter and feedback form, developed as a draft from the Sands/Department of Health PNMR Task and Finish group (2012-2015), which was set up to establish what information would be required for hospital reviews. The parental letter and feedback form were subsequently revised in the light of the PARENTS 1 study⁶ (Appendix S1). Fifty-nine percent (n=13) of stakeholders agreed that the language of the new form needed revision to provide more clarity to parents. It was important to participants that it was made clear in the information letter given to parents that being “involved in the review” process did not mean having to attend the meeting itself, however a parent representative can be present.

Individualised Parent-centred Approach

An individualised approach was preferred; to begin with, regarding the type of perinatal death that had occurred (for example stillbirth or neonatal death) it was thought that fundamentally most parents might ask some similar questions, for example: “Why did my baby die?” and “Was there something that I did to contribute to my baby dying?”. However, additional questions and comments from parents were likely to differ from case to case.

Stakeholders considered the implications of having free text boxes for parents to complete as opposed to structured feedback questions, including how it might lead to too many questions or questions that would not be able to be answered by the PNMR. Anonymised voting during the consensus meeting showed that 77.3% (17/22) of attendees felt that free text boxes should be included in the parental feedback form. Stakeholder

preferred a more inclusive, neutral terminology for the free text questions, for example, “How did you feel you were looked after?”. It was thought that there should be a responsibility to try and answer all questions that parents submit and to ensure there is robust system to address their questions, in line with current risk management procedures. However, parental expectations should be managed, and parents should be advised that for some questions parents submit there might be no feasible explanation agreed in the PNMR meeting.

Participants in the workshop discussed the challenges of obtaining feedback and questions about their care from families which may be more difficult to engage with, such as non English speaking parents, those with complex social situations or young people who prefer using technology to communicate. Offering parents the option to submit feedback and questions about their care via different formats such as email, smartphones and audio recordings were suggested as solutions to facilitate their input. An advocate or parent representative was recommended to be appointed as a person who could potentially support all parents through the process, answer any queries with regards to the feedback form, and represent them, their views and questions at the PNMR meeting when their baby’s death is discussed. In one group, it was considered essential that the parent advocate should not “wear two hats” and be fully independent to the healthcare professionals involved in the clinical management of the mother and baby. However, some thought this may not be practical within the clinical setting. It was agreed that parent advocate should be therefore at the meeting solely to represent the parents, however it was acknowledged that this may not be feasible due to resources in some hospital units.

Finally, additional content of the parents’ feedback was discussed. Upon voting, most participants (81.8%, n=18) agreed there should be the opportunity for parents to give positive feedback, and to comment on individuals and/or systems. We asked stakeholders if the feedback should explicitly differentiate between clinical and non-clinical care, for example by including specific questions and text boxes for each of these two aspects of care, and the majority (63.6%) disagreed or were unsure.

Workshop 2: Format of the perinatal mortality review meeting

Attendance

Stakeholders perceived that all healthcare professionals who have been involved in the care of the parents should attend the PNMR meeting. This should include as minimum the lead consultant obstetrician and neonatologist; midwives; nurses; a pathologist and an advocate representing the parents. Some

participants, but not all, felt that parents should be asked who they would like to be at the review meeting. It was perceived that involvement of staff should be mandatory for those involved in the case, so if unable to attend healthcare professionals should submit a formal report to read in the meeting or attempt a conference call.

Terms of Reference

The purpose of the review meeting should be stated clearly at the start of the meetings in the 'Terms of Reference'. Furthermore, the length of discussions around parental questions and feedback in the meeting should be flexible – 50% of attendees voted that the meeting should take “*as long as it takes*” to fully address parental questions and feedback. Participants discussed who should chair the meeting and whether the chair should be internal, external or independent to the hospital Trust or Health Board. Regardless of who this was, what was thought as vital was that the chair should be experienced with specific training to develop the skills for this role and that there should be external representation at the meeting as per the Perinatal Mortality Review Tool guidance¹⁶.

Workshop 3: Pathway

Adaptive structure

The stakeholders discussed that the PNMR process should be adaptive to individual parent needs; enabling parents to engage and contribute if and as much as they prefer. Stakeholders unanimously voted that after the review meeting takes place, parents should be offered feedback on the summary findings from the PNMR meeting. Parents should be given the choice of how that feedback is given to them, i.e. face-to-face, written, or by email communication. Eighty-six percent of attendees agreed there should be a written report of the meeting produced for the parents in plain English. Stakeholders discussed how parents should have access to a follow up meeting or appointment with their lead consultant or bereavement midwife or nurse. Follow up should continue for as long as required for parents, including if necessary into subsequent pregnancies.

Dedicated Resources

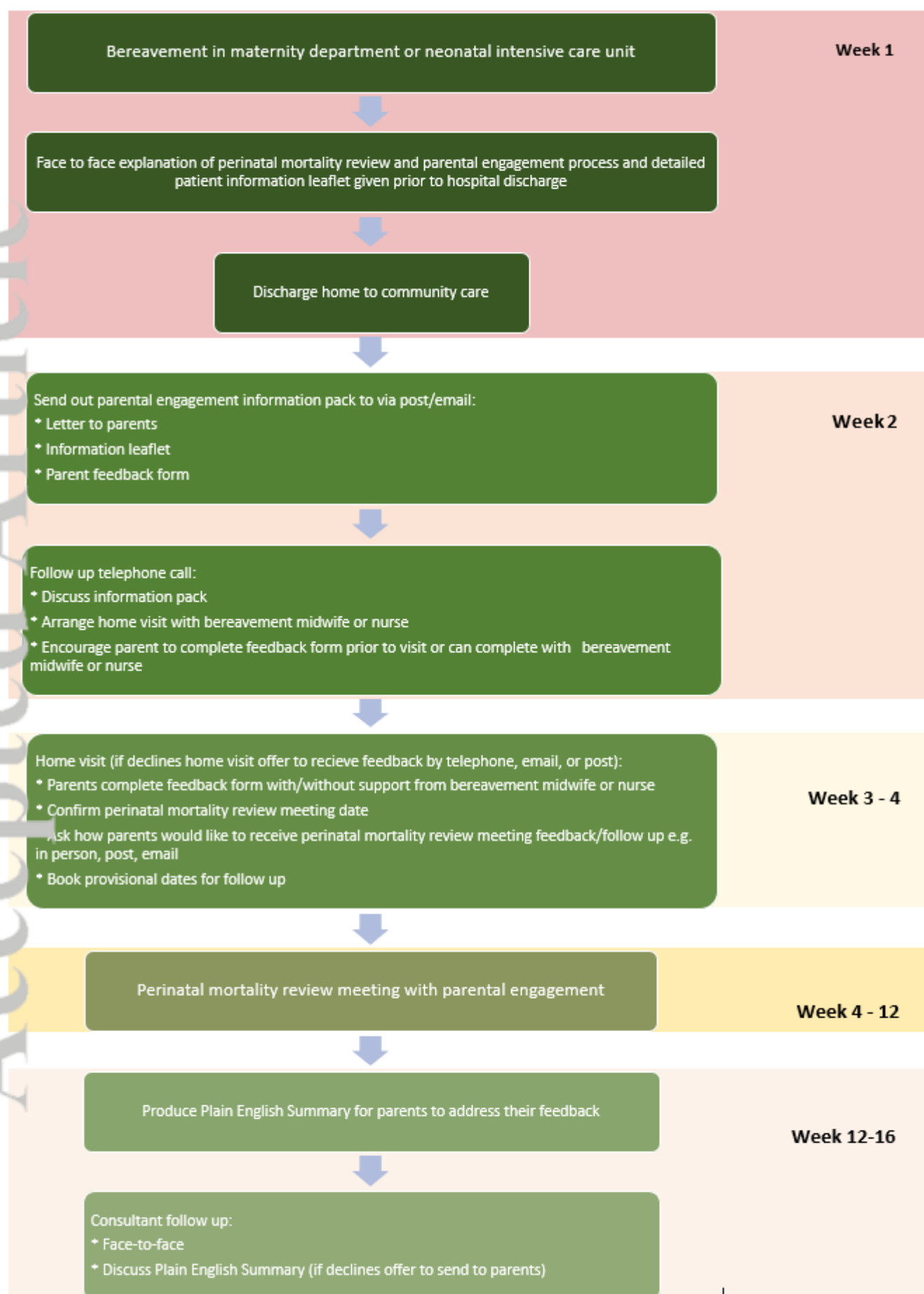
Participants contemplated the additional financial resources required to support parents through the process and whether funding to support parental engagement could be commissioned at every hospital. Additional resources would include a dedicated bereavement midwife or nurse to provide a continual point

of contact for bereaved families, active participation in their care, bereavement support and personalised, continuity of care, so parents “*do not have to repeat their story lots of times to health professionals*”. In addition, a senior administrator to ensure formal reports and investigations are available for the PNMR meeting would create a high-caliber process that is more robust and meaningful to parents. One stakeholder suggested a health economic assessment may be necessary to facilitate the commissioning of such a service.

Following the conclusion of the Delphi process a flowchart was developed by the research team, depicting a pathway for a pilot of parental engagement. The draft pathway, approved in two UK Units (Bristol and Manchester) for local pilot implementation, is depicted in **Figure 2**.

Figure 2: Draft pathway for parental engagement in the perinatal mortality review

Parental engagement in perinatal mortality review flow chart



Workshop 4: Challenges

Stakeholders discussed challenging aspects of parental engagement including the financial implications; medico-legal issues; dealing with complaints; managing long complex questions; and supporting parents as well as staff during the process. When discussing the medico-legal aspects, stakeholders thought that embedding an open and transparent culture could prove helpful to parents and potentially reduce the number of complaints and litigation in the future. It was agreed that when dealing with complaints, the pre-existing separate formal procedure will still be followed to ensure the parents' concerns are addressed and not dismissed. The link person or bereavement care midwife or nurse could provide ongoing communication with parents and facilitate both the review and the complaints processes. The participants discussed that staff could be supported with specific bereavement care training, and by having protected time to attend the PNMR meeting and to address any feedback received on their behaviour and care. Furthermore, emotional support for staff was discussed in detail by stakeholders.

Round 2 - Results from web-based survey

Twenty-nine stakeholders including attendees of the consensus meeting, invitees who did not attend, the Project Advisory Board and research team were invited to rank 14 recommendations generated from the content analysis of the consensus workshops. Twenty-five stakeholders completed the web-based questionnaire (86.2% response rate). Respondents included patient and charity representatives, clinicians, commissioners, and researchers. Results from the web-based survey are displayed in **Table 2**.

Recommendations

Twelve out of the 14 recommendations were scored as "critical" or with a Likert score between seven and nine. There were two 'borderline' consensus principles which included 'there should be four different feedback forms (for stillbirth, neonatal death, coroner's case and termination for fetal abnormality)' and 'the meeting should take place within approximately 12 weeks from the baby's death'.

Based on the findings of the Delphi Study, the Project Steering Committee agreed on 12 core principles for parental engagement in the PNMR process (see **Table 3**). These principles reached consensus based the pre-defined criteria that 'Consensus' would be achieved 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). **Table 4** displays the two 'borderline' principles from the Delphi Study.

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Table 3: Core principles for parental engagement in the perinatal mortality review meeting

Core Principles	% of respondents scoring principle as 'not important' Score 1 to 3 (n)	% of respondents scoring principle as 'important but not critical' (n)	% of respondents scoring the principle as of 'critical importance' (n)	Consensus reached
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.	0 (0)	4 (1)	96 (24)	Yes
2. The form to obtain parental feedback should be completed in a face-to-face consultation at a private location of the parents' choice (if the parent declines offer by telephone, email, or post).	12 (3)	16 (4)	72 (18)	Yes
3. The parents should be offered the opportunity to nominate a suitable advocate or bereavement care midwife or nurse; a person who completes the feedback form with the parents and attends the perinatal mortality review meeting.	12 (4)	16 (4)	72 (18)	Yes
4. All healthcare professionals involved in the case should be notified of the perinatal mortality review meeting in good time and attend where possible.	4 (1)	0 (0)	96 (24)	Yes
5. Staff involved in the case who cannot attend the perinatal mortality review meeting should submit their comments at the very least.	4 (1)	4 (1)	92 (23)	Yes
6. Responses to the parental feedback should be formally documented in the perinatal mortality review meeting.	4 (1)	4 (1)	92 (23)	Yes
7. Action plans should be made from the parental responses if necessary and monitored.	4 (1)	0 (0)	96 (24)	Yes
8. A plain English summary should be produced following the perinatal mortality review meeting for the parents.	8 (2)	4 (1)	88 ()	Yes
9. The feedback from the perinatal mortality review meeting should be discussed at the consultant follow up consultation, supported by the plain English summary.	0 (0)	0 (0)	100 (25)	Yes
10. The consultant follow up meeting should take place as soon as possible after the perinatal mortality review meeting (approximately 2-4 weeks).	0 (0)	16 (4)	84 (21)	Yes

11. 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.	8 (2)	20 (5)	72 (18)	Yes
12. If the parents decline attending a consultant follow up meeting, then the written plain English summary should be offered to be sent to the parents instead.	8 (2)	0 (0)	92 (23)	Yes

Table 4: 'Borderline' principles for parental engagement in the perinatal mortality review meeting

Borderline Principles	% of respondents scoring principle as 'not important' Score 1 to 3 (n)	% of respondents scoring principle as 'important but not critical' (n)	% of respondents scoring the principle as of 'critical importance' (n)	Consensus reached
1. There should be four different parental feedback forms (for stillbirth, neonatal death, coroner's case, and termination for fetal abnormality)	24 (4)	12 (3)	64 (16)	No
2. The meeting should take place within approximately 12 weeks from the baby's death	8 (2)	24 (6)	68 (17)	No

DISCUSSION

Main Findings

Using a modified Delphi method, we reached consensus on 12 fundamental principles of parental engagement in the PNMR process with 25 key stakeholders. This is the first consensus process to date on this topic. The recommendations give specific guidance on how best to involve parents in the United Kingdom (UK) in the review of their baby's stillbirth or neonatal death. Recommendations focus on: when to provide information to parents about the PNMR process; how to obtain feedback and support parents; who should represent the parents at the PNMR meeting; the outputs of the meeting (including action plans, lessons learned and a plain English summary); and how to follow up with parents. As a next step, these recommendations should be piloted and evaluated.

Strengths and limitations

This is the first study to our knowledge where recommendations for parental engagement in the PNMR process have been developed using consensus techniques. In fact, this is to our knowledge also the first study of patient involvement in learning from deaths across disciplines. The involvement of multiple stakeholders, including bereaved parents and their representatives, increases the reproducibility and generalisability of the developed recommendations in the UK. Furthermore, a range of methods including evidence from parent and healthcare professional focus group interviews and the stakeholder consensus meeting were used to develop the recommendations in the web-based prioritisation survey^{8,6}. Interestingly, content analysis of the stakeholder consensus meeting workshops revealed broadly similar findings to the parent and healthcare professionals focus group interviews we had previously carried out^(6,7). Parallel themes included: the provision for an individualised flexible approach to receiving feedback from parents; the necessity for feedback to be inclusive; opportunity for parents to give positive feedback; the importance of communicating to parents the lessons learnt from their engagement; and the need for a parental advocate. The consensus workshops provided an opportunity to explore these themes in more detail, for example as to who could or could not take over the role of the parent advocate. In keeping with our findings, the UK National Child Death Review guidance published in October 2017, recommends a 'key worker' or advocate to represent the 'voice' of the parents at professional meetings, to ensure that their questions are effectively addressed, and to provide feedback to the family afterwards¹⁷. Our consensus studies have provided detail to help operationalise this recommendation.

A limitation of the consensus study is that the stakeholders were purposively sampled and included members of the research team introducing the possibility of selection bias, however a balanced range of type of stakeholder participated. To mitigate bias the research team took part as facilitators or transcribers rather participants in the workshops. Although the number of participants in the web-based survey was relatively small, it is similar to previous Delphi technique studies¹⁵. There is no standard method for the calculation of the most appropriate sample size in Delphi studies¹⁰. Moreover, we had a very good response rate from a diverse range of stakeholders, including parent representatives. Another potential limitation was that we used a modified Delphi method opting for an open in-person work instead of anonymous voting Round 1. Anonymity in the Delphi process can counter balance the influence of experts or more influential personalities. We attempted to counteract this by anonymised voting in the workshops and anonymous voting in Round 2. Even though the participants were practising across all different regions of the UK, the principles generated may not be applicable to other countries or lower- and middle-income settings, compromising the external validity. Future research should address other settings and

involve an even broader range of stakeholders, including perinatal pathologists, representatives from the coronial system, and medicolegal experts.

Interpretation

The recommendations developed as part of this consensus study show a possible way for engaging parents in the review of their baby's perinatal death. The general principles could also be applied to learning from deaths in other medical specialities and other serious incident reviews. Public enquiries in the UK found that in many hospitals learning following deaths was not taking place, and opportunities to improve care were missed^{2,18,19}. The National Quality Board in the United Kingdom published its 'Learning from Deaths' guidance in 2017, which proposed that learning from deaths should be critical to clinical governance and parental/patient engagement should be integral to such a process². What has not been previously shown is how parental/patient engagement should be implemented. The PARENTS 2 consensus study has given preliminary evidence on how parental engagement could be implemented following a perinatal death.

Two principles were deemed 'borderline' including 'there should be four different feedback forms (for stillbirth, neonatal death, coroner's case and termination for fetal abnormality)' and 'the meeting should take place within approximately 12 weeks from the baby's death'. Although these recommendations emerged as being important from the previous parent and healthcare professional focus groups⁶, and most consensus survey participants classified these recommendations as 'critical' they did not reach the a priori threshold to be included in the final set of principles. Reasons behind this could have been that stakeholders could have thought having four feedback forms would be too complex or conversely not specific enough. Also, having a PNMR meeting within 12 weeks of the perinatal death might not be feasible in all hospital units in the UK as this may not allow for completion of the post-mortem examination and multidisciplinary case discussion.

Stakeholders discussed the challenging aspects of parental engagement including the prospect of litigation. There is good evidence to suggest that poor communication and complaints or litigation are associated²⁰⁻²². Data on written complaints in the National Health Service in the United Kingdom (2016-2017) found that the largest proportion of complaints was attributed to communication issues²³. The Communication-and-Resolutions program in the United States, aims to promptly offer financial and non-financial resolution when adverse events are caused by substandard care²⁴. Patient and family involvement is extensive and integral

to this program. A study by the University of Illinois found that by encouraging transparency and taking a proactive approach with patient engagement, the Communication-and-Resolutions program may help to resolve malpractice disputes faster and at a lower cost²⁴. By enhancing the quality of communication with parents through engaging them in the process of the review, communication with parents could be improved with potential to reduce the number of complaints or litigation.

A six-month pilot of parental engagement in the PNMR at two geographically distinct hospital trusts in the United Kingdom is currently underway⁷ and has had over a 75% recruitment rate so far. The findings of this pilot will directly inform the UK national standardised PNMR tool and national bereavement care pathway^{16,25}. Future studies can explore the impact of widespread implementation of the tool and parental engagement on complaints and litigation.

Conclusion

In summary, stakeholders in this consensus project were very supportive of parental engagement, and recommended ways to make it both feasible and meaningful to parents, staff and patient safety. What is now needed is a comprehensive assessment of the effectiveness and cost-effectiveness of parental engagement, before wide-scale national, or even global, implementation.

COMPETING INTERESTS STATEMENT

None declared

AUTHORS' CONTRIBUTIONS

DP drafted the manuscript and was involved revising the manuscript critically for important intellectual content. CB, DS, CS, AH, ML, CBE, JJE, KL, and LT were involved in revising the manuscript critically for important intellectual content. All authors read and approved the final manuscript.

CB is the grant holder, DB is the principal investigator, and DS is the chief investigator and guarantor.

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References

1. Kirkup B. The Report of the Morecambe Bay Investigation. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/408480/47487_MBI_Accessible_v0.1.pdf (Accessed 27th September 2018)
2. National Quality Board. National Guidance on Learning from Deaths - NHS England. Available from: <https://www.england.nhs.uk/wp-content/uploads/2017/03/nqb-national-guidance-learning-from-deaths.pdf> (Accessed 27th September 2018)
3. Maternity Safety Programme Team Department of Health. Safer Maternity Care. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/560491/Safer_Maternity_Care_action_plan.pdf (Accessed 27th September 2018)
4. Royal College of Obstetricians and Gynaecologists. Each Baby Counts: 2015 Summary Report. Available from: <https://www.rcog.org.uk/globalassets/documents/guidelines/research--audit/each-baby-counts-2015-summary-report-june-2017.pdf> (Accessed 27th September 2018)
5. MBRRACE-UK. Perinatal Confidential Enquiry. Term, singleton, normally-formed, antepartum stillbirth. November 2015. Available from: https://www.npeu.ox.ac.uk/downloads/files/mbrrace-uk/reports/MBRRACE-UK_Perinatal_Report_2015.pdf (Accessed 27th September)
6. Bakhbakhi D, Siassakos D, Burden C, Jones F, Yoward F, Redshaw M, Murphy S, Storey C. Learning from deaths: Parents' Active Role and ENGagement in The review of their Stillbirth/perinatal death (the PARENTS 1 study). *BMC Pregnancy Childbirth*. 2017 Oct;17(1):333. Available from: <https://doi.org/10.1186/s12884-017-1509-z>
7. Bakhbakhi D, Siassakos D, Storey C, Heazell A, Lynch M, Timlin L, Burden C. PARENTS 2 study protocol: pilot of Parents' Active Role and ENGagement in the review of Their Stillbirth/perinatal death. *BMJ Open*. 2018 Jan 1;8(1). Available from: <http://bmjopen.bmj.com/content/8/1/e020164.abstract>
8. Bakhbakhi D, Christy B, Storey C, Heazell A, Lynch M, Timlin L, Gold K, Siassakos D. The PARENTS 2 Study - A qualitative study of the views of healthcare professionals and stakeholders on parental engagement in the perinatal mortality review: from "bottom of the pile" to joint learning. *Submitt Publ. BMJ Open* 2018;
9. Dalkey N, Helmer O. An Experimental Application of the DELPHI Method to the Use of Experts. *Manage Sci [Internet]*. 1963 Apr 1;9(3):458–67. Available from: <https://doi.org/10.1287/mnsc.9.3.458>
10. Black N, Murphy M, Lamping D, McKee M, Sanderson C, Askham J, Marteau T. Consensus development methods: a review of best practice in creating clinical guidelines. *J Health Serv Res Policy*. 1999 Oct;4(4):236–48.

11. Graefe A, Armstrong JS. Comparing face-to-face meetings, nominal groups, Delphi and prediction markets on an estimation task. *Int J Forecast*. 2011;27(1):183–95. Available from: <http://www.sciencedirect.com/science/article/pii/S0169207010000889>
12. Eubank BH, Mohtadi NG, Lafave MR, Wiley JP, Bois AJ, Boorman RS, Sheps DM. Using the modified Delphi method to establish clinical consensus for the diagnosis and treatment of patients with rotator cuff pathology. *BMC Med Res Methodol*. 2016 May;16(1):56. Available from: <https://doi.org/10.1186/s12874-016-0165-8>
13. Stemler S. An Overview of Content Analysis. 2001. Available from: <http://pareonline.net/getvn.asp?v=7&n=17> (Accessed 27th September 2018)
14. Grade Working Group. GRADE. Available from: <http://www.gradeworkinggroup.org> (Accessed 27th September 2018)
15. Williamson PR, Altman DG, Blazeby JM, Clarke M, Devane D, Gargon E, Tugwell Peter. Developing core outcome sets for clinical trials: issues to consider. *Trials*. 2012;13(1):132. Available from: <http://dx.doi.org/10.1186/1745-6215-13-132>
16. MBRRACE-UK. NPEU. National Standardised Perinatal Mortality Review Tool. 2018. Available from: <https://www.npeu.ox.ac.uk/mbrrace-uk/pmrt> (Accessed 27th September 2018)
17. HM Government. Child Death Review. Statutory Guidance. Available from: https://consult.education.gov.uk/child-protection-safeguarding-and-family-law/working-together-to-safeguard-children-revisions-t/supporting_documents/Child_death_review_stat_guidance.pdf (Accessed 27th September 2018)
18. Robert Francis. The The Mid Staffordshire NHS Foundation Trust Public Inquiry, 2013. Available from: <http://webarchive.nationalarchives.gov.uk/20150407084003/http://www.midstaffspublicinquiry.com/> (Accessed 27th September)
19. Care Quality Commission. Learning, candour and accountability: A review of the way NHS trusts review and investigate the deaths of patients in England 2016. Available from: <https://www.cqc.org.uk/sites/default/files/20161213-learning-candour-accountability-full-report.pdf> (Accessed 27th September 2018)
20. Hickson GB, Clayton EW, Githens PB, Sloan FA. Factors that prompted families to file medical malpractice claims following perinatal injuries. *JAMA*. 1992 Mar;267(10):1359–63.
21. Vincent C, Young M, Phillips A. Why do people sue doctors? A study of patients and relatives taking legal action. *Lancet (London, England)*. 1994 Jun;343(8913):1609–13.

22. Beckman HB, Markakis KM, Suchman AL, Frankel RM. The doctor-patient relationship and malpractice. Lessons from plaintiff depositions. *Arch Intern Med.* 1994 Jun;154(12):1365–70.
23. NHS Digital. Data on written complaints in the NHS, 2016-2017. 2017. Available from: <https://digital.nhs.uk/catalogue/PUB30080> (Accessed 27th September 2018)
24. Helmchen LA, Lambert BL, McDonald TB. Changes in Physician Practice Patterns after Implementation of a Communication-and-Resolution Program. *Health Serv Res.* 2016 Nov 28;51(S3):2516–36. Available from: <https://doi.org/10.1111/1475-6773.12610>
25. Sands. The National Bereavement Care Pathway. 2018. Available from: <http://www.nbcpathway.org.uk/> (Accessed 27th Septmber)