Report Supplementary Materials 7 (17-99-85-supp7)

Documents identified for realist review, organised by comparable interventions, publication details, realist quality appraisal ratings, and key study characteristics

Focus of Improvement	Lead Author & Publication Year	National Context	Publication type	Ranking (Relevance)	Ranking (Rigour)	Aims and objectives	Research Design	Improvement/ Intervention Specified
Family-Clinician Relations and Care Provision	Bakhbakhi D. (2017)[1]	High-Income countries	Peer-reviewed Research	1	1	Review of latest published research, guidelines, and best practice points	Evidence Review	Stillbirth Bereavement Care
	Ellis A. (2016)[2]	Western High-Income Countries	Peer-reviewed Research	2	1	Synthesis and meta synthesis of parents' and healthcare workers' experiences of maternity bereavement care in hospital settings	Systematic Literature Review	Practical learning points to improve research, training and ultimately care of parents who experience late stillbirth (>24 weeks)
	Downe S. (2013)[3]	UK	Peer-reviewed Research	2	2	Analysis of parents' experiences and views of interactions with hospital staff after perinatal death	Qualitative	Care of parents after perinatal bereavement
	Heazell A. (2013)[4]	International	Conference Proceeding Report	2	2	Evidence-based summary of international conference proceedings	Evidence Review	Bereavement support after stillbirth
	Make Births Better (2020)[5]	UK	Research Report	2	2	Findings on reported access to support after a difficult birth	Survey	Birth Trauma Care and Support for Women, Families and Professionals

						experience. Findings on professional training and service provision for this support		
	Redshaw M. (2014)[6]	UK	Research Report	3	2	Investigation of parents' experiences of care after stillbirth or death of their baby after birth, including offering and information of post-mortem and professional support to understand the report	National Survey	Bereavement care after stillbirth or death of a baby after birth
	Stanford S. (2016)[7]	England	Peer-reviewed Article	1	1	Narrative account of experience of harmful event during maternity care; difficulties with communication and outcomes for women and family	Qualitative	Communication and candour issues, women's story, and response by a professional college
Clinical Skills, Training and Post-Incident Support	Bonnema R.A. (2009)[8]	USA	Peer-reviewed Research	3	1	Post-intervention study of pilot training intervention to evaluate effectiveness of 'Being Open' training	Survey	'Being Open' and Breaking Bad News graduate training

Coughlan B. (2017)[9]	Europe	Peer-reviewed Research	2	1	Narrative review of phenomenon of 'second victims' and remediation systems in maternity services	Evidence Review	'Second Victims' of avoidable adverse events in maternity care
Karkowsky C.E. (2016)[10]	USA	Peer-reviewed Research	3	1	Assessment of trainee-assessed effectiveness of simulation training for breaking bad news situations in obstetrics	Randomised prospective trial	Simulation training with obstetric residents
Raemer D.B. (2016)[11]	USA	Peer-reviewed Research	1	1	Testing of best practice guideline for disclosure and apology to improve communication performance	Randomised Trial	Mixed-realism simulation
Bakhbakhi D. (2017b)[12]	England	Peer-reviewed Research	1	1	Analysis of bereaved parents' views on involvement in the perinatal mortality review process	Qualitative	Parents' Active Role and ENgagement in The review of their Stillbirth/perinatal death (PARENTS) perinatal mortality review design portfolio
Bakhbakhi D. (2018)[13]	England	Peer-reviewed Research	1	1	Exploration of healthcare professionals' views on acceptability of and support for parent engagement in the perinatal mortality review process	Qualitative	PARENTS perinatal mortality review design portfolio

Perinatal Mortality Review (Development & Evaluation)

Bakhbakhi D. (2019)[14]	England	Peer-reviewed Research	1	1	Development of core principles and recommendations for parental engagement in Perinatal Mortality Review Tool	Qualitative	PARENTS perinatal mortality review design portfolio
Boyle et al (2020)[15]	High-income countries	Peer-reviewed Research	2	1	Investigation of perinatal morality review meeting practices, including the extent of parent engagement, as reported by healthcare professionals in six countries	Survey	Perinatal mortality review meetings
Burden C.B. (2018)[16]	England	Report	2	2	Summary of evidence-based policy recommendations arising from the PARENTS studies	Evidence Summary	PARENTS perinatal mortality review design portfolio
Chepkin S. (2019)[17]	England	Research Report	1	2	First annual report on progress of implementation of the perinatal morality review tool	Thematic Review	Perinatal Morality Review Tool Progress Report
Kurinczick J.J. (2020)[18]	England	Progress Report	1	2	Second annual report of progress of the national perinatal morality review tool	Thematic review	Perinatal Morality Review Tool Progress Report
Sauvegrain P.	France	Peer-	1	1	Examination of	Mixed	District-level Perinatal

	(2020)[19]		reviewed Research			effects of implementation of mother's inclusion in perinatal mortality audit interviews	methods	Mortality Audit
Organisation or Service Level Pilots & Evaluations	Bennett J.B. (2016)[20]	Scotland	Conference Presentation	1	3	Summary of principles, requirements, and initial outcomes of the 'Being Open' project (for scalability of training package)	Progress Summary	'Being Open' Scotland
	Gluyas H. (2011)[21]	Australia	Peer-reviewed Research	2	1	Case study of hospital-level changes following an inquiry to review the quality of obstetric and gynaecological services	Qualitative	Clinical Governance
	Healthcare Improvement Scotland (2015)[22]	Scotland	Resources with evidence of effect	1	2	Checklists, resources, and outcomes evidence developed for 'Being Open' pilot	Qualitative	'Being Open' training and staff support pilot resource
	Hendrich A. (2014)[23]	USA	Peer-reviewed Research	1	1	Case study of implementation of full disclosure protocol in 5 pilot sites (one organisation)	Mixed methods	Labour and delivery units
	Pillinger J.P. (2016)[24]	Ireland	Research Report	1	2	Process evaluation of implementation of open disclosure	Qualitative	Trust Pilot Schemes

						pilot programme piloted in 2 acute hospitals (including maternity units)		
	Santos P. (2015)[25]	USA	Peer-reviewed Research	2	1	Evaluation of a multi-faceted model for managing malpractice in obstetrics, including a disclosure programme	Qualitative	Disclosure Programme
	Scholefield H. (2007)[26]	England	Peer-reviewed research	1	1	Organisational case-study of improvement in quality and risk management processes in obstetrics, including parent involvement in adverse events	Document analysis	Internal Trust Investigations/Local Review
National and Regional Interventions, Evaluations & Audits	Care Quality Commission (2016)[27]	England	Research Report	1	2	Review of processes and systems in NHS Trusts in England on how NHS trusts identify, investigate, and learn from the deaths of people under their care	Mixed methods	NHS Trust Investigations and Reviews of deaths of patients (including maternity units) Local Review
	Care Quality Commission (2019)[28]	England	Research Report	1	2	Review progress and examples of good practice in	Qualitative	Learning from Deaths guidance implementation

					implementation of the learning from deaths guidance		
Health Service Investigation Branch (2020)[29]	England	Progress Report	1	2	Report on progress of engagement of families in independent investigations	Survey	Family involvement in external investigations of serious incidents (including maternity incidents)
Iedema R.A. (2008)[30]	Australia	Peer-reviewed Research	1	1	Determination of which aspects of open disclosure 'work' for patients and healthcare staff (including maternity services)	Qualitative	Australian Open Disclosure pilot
Iedema R.A. (2008)[31]	Australia	Peer-reviewed Research	1	1	Exploration of patients' and family perceptions of Open Disclosure of adverse events that occurred during their health care (including maternity care)	Qualitative	Australian Open Disclosure pilot
Kenyon S. (2017)[32]	England	Research Report	2	2	Examination of local reviews of a random selection of eligible cases reported to the perinatal confidential enquiry on inter-partum and intra-partum related neonatal death, including parent	Thematic review	Trust-based local reviews of inter-partum and intra-partum related neonatal death

					notification and involvement		
Magro, M. (2017)[33]	England	Research Report	1	2	Thematic review of NHSR data to identify the clinical and non-clinical themes from cerebral palsy claim records that resulted in claim compensation and to highlight areas for shared learning and improvement, including family involvement in serious incident reviews	Thematic Review	Serious incident Investigation summaries submitted to NIHR for progression of cerebral palsy claim
NHS Improvement (2018)[34]	England	Research Report	1	2	National consultation (of patients, families, the public, commissioners, providers, and professional bodies) on factors affecting serious incident investigations (including maternity) in NHS Trusts	Mixed methods	Serious Incident Framework Implementation
NHS Resolution (2019)[35]	England	Progress Report	1	2	Analysis of a pragmatic sample of cases of potentially severe	Mixed-Methods Thematic Review	Early Notification Scheme progress report

Comment [NS1]: Check that this one is right (the ref)

					brain injured babies reported into year 1 of the Early Notification Scheme, including notification and communication with families		
Quinn A.M. (2008)[36]	USA	Peer-reviewed Research	2	1	Description of origins and outcomes of 3Rs programme for patients, physicians, and programme officers (including maternity)	Qualitative	The 3Rs programme (early disclosure and resolution program)
Sakala C. (2013)[37]	USA	Peer-reviewed Research	3	1	Literature synthesis of policy strategies most likely to mitigate harmful effects of the liability (tort) system for families	Evidence Review	Liability Systems
Sorensen R. (2008)[38]	Australia	Peer-reviewed Research	1	1	Analysis of views on open disclosure of medical errors by health care professionals and managers and identification of workforce and systems capabilities required for embedding disclosure in units	Qualitative	Australian Open Disclosure Pilot

References

1. Bakhbakhi D, Burden C, Storey C, Siassakos D. Care following stillbirth in high-resource settings: Latest evidence, guidelines, and best practice points. *Seminars in Fetal and Neonatal Medicine* 2017; **22**(3): 161-6.

2. Ellis A, Chebsey C, Storey C, et al. Systematic review to understand and improve care after stillbirth: a review of parents' and healthcare professionals' experiences. *BMC Pregnancy and Childbirth* 2016; **16**(1): 16.

3. Downe S, Schmidt E, Kingdon C, Heazell AEP. Bereaved parents' experience of stillbirth in UK hospitals: a qualitative interview study. *BMJ Open* 2013; **3**(2): e002237.

4. Heazell AEP, Leisher S, Cregan M, et al. Sharing experiences to improve bereavement support and clinical care after stillbirth: report of the 7th annual meeting of the international stillbirth alliance. *Acta Obstetricia et Gynecologica Scandinavica* 2013; **92**(3): 352-61.

5. Make Birth Better CIC. The Make Birth Better Survey 2019: the circle of trauma for parents and professionals: Make Births Better CIC, 2020.

6. Redshaw M, Rowe R, Henderson J. Listening to Parents after stillbirth or the death of their baby after birth: University of Oxford, 2014.

7. Stanford SER, Bogod DG. Failure of communication: a patient's story. *International Journal of Obstetric Anesthesia* 2016; **28**: 70-5.

8. Bonnema RA, Gosman GG, Arnold RM. Teaching error disclosure to residents: a curricular innovation and pilot study. *Journal of graduate medical education* 2009; **1**(114-118).

9. Coughlan B, Powell D, Higgins MF. The Second Victim: A Review. *European Journal of Obstetrics Gynecology and Reproductive Biology* 2017; **213**: 11-6.

10. Karkowsky CE, Landsberger EJ, Bernstein PS, et al. Breaking Bad News in obstetrics: a randomized trial of simulation followed by debriefing or lecture. *The Journal of Maternal-Fetal & Neonatal Medicine* 2016; **29**(22): 3717-23.

11. Raemer DB, Locke S, Walzer TB, Gardner R, Baer L, Simon R. Rapid Learning of Adverse Medical Event Disclosure and Apology. *Journal of patient safety* 2016; **12**(3): 140-7.

12. Bakhbakhi D, Siassakos D, Burden C, et al. Learning from deaths: Parents' Active Role and ENgagement in The review of their Stillbirth/perinatal death (the PARENTS 1 study). *BMC pregnancy and childbirth* 2017; **17**(1): 1-6.

13. Bakhbakhi D, Burden C, Storey C, et al. 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. *BMJ open* 2018; **8**(11): e023792.

14. Bakhbakhi D, Siassakos D, Lynch M, et al. PARENTS 2 study: consensus report for parental engagement in the perinatal mortality review process. *Ultrasound in Obstetrics & Gynecology* 2019; **54**(2): 215-24.

15. Boyle F, Horey D, Siassakos D, et al. Parent engagement in perinatal mortality reviews: an online survey of clinicians from six high-income countries. *BJOG: An International Journal of Obstetrics & Gynaecology* 2021; **128**(4): 696-703.

16. Burden C, Bakhbakhi. D, Lynch M, et al. All parents should be offered the opportunity to engage with the review of their baby's death. *PolicyBristol*, 2018. https://www.bristol.ac.uk/media-library/sites/policybristol/PolicyBristol-report-oct18-engaging-parents-baby-loss.pdf (accessed.

17. Chepkin S, Prince S, Johnston T, Boby T, al. MNe. Learning from Standardised Reviews When Babies Die. National Perinatal Mortality Review Tool: First Annual Report: Oxford: National Perinatal Epidemiology Unit., 2019.

18. Kurinczuk JJ, Boby T, Prince S, et al. Learning from Standardised Reviews When Babies Die. National Perinatal Mortality Review Tool: Second Annual Report. Oxford: l Perinatal Epidemiology Unit., 2020.

19. Sauvegrain P, Zeitlin J. Investigating the benefits and challenges of including bereaved women in research: a multifaceted perinatal audit in a socially disadvantaged French district. *BMJ Open* 2020; **10**(9): e034715.

20. Bennett J, Hacking B, Murdoch E. Being Open: communicating well with patients and families about adverse events. 2016.

21. Gluyas H, Alliex S, Morrison P. Do inquiries into health system failures lead to change in clinical governance systems? *Collegian: Journal of the Royal College of Nursing, Australia* 2011; **18**(4): 147-55.

22. Healthcare Improvement Scotland. Being Open NHS Scotland: Guidance on Implementing the Being Open Principles. 2015.

23. Hendrich A, McCoy CK, Gale J, Sparkman L, Santos P. Ascension Health's Demonstration Of Full Disclosure Protocol For Unexpected Events During Labor And Delivery Shows Promise. *Health Affairs* 2014; **33**(1): 39-45.

24. Pillinger J. Evaluation of the National Open Disclosure Pilot. *State Claims Agency* 2016; (Health Service Executive. Ireland).

25. Santos P, Ritter GA, Hefele JL, Hendrich A, McCoy CK. Decreasing intrapartum malpractice: Targeting the most injurious neonatal adverse events. *Journal of Healthcare Risk Management* 2015; **34**(4): 20-7.

26. Scholefield H. Embedding quality improvement and patient safety at Liverpool Women's NHS Foundation Trust. *Best Practice & Research in Clinical Obstetrics & Gynaecology* 2007; **21**(4): 593-607.

27. Care Quality Commission. Learning, Candour and Accountability: a review of the ways that NHS trusts review and investigate the deaths of patients in England2016. (accessed.

28. Care Quality Commission. Learning From Deaths. A review of the first year of NHS trusts implementing the national guidance, 2019.

29. Healthcare Safety Investigation Branch. Giving Families a Voice: HSIB's approach to patient and family engagement during investigations: Independent Report by the Healthcare Safety Investigation Branch, 2020.

30. Iedema RAM, Mallock NA, Sorensen RJ, et al. The National Open Disclosure Pilot: Evaluation of a policy implementation initiative. *Medical Journal of Australia* 2008; **188**(7): 397-400.

31. Iedema R, Sorensen R, Manias E, et al. Patients' and family members' experiences of open disclosure following adverse events. *International Journal for Quality in Health Care* 2008; **20**(6): 421-32.

32. Kenyon S, Cross-Smith F, Keegan C, Johnston T. Local review of intra-partum related death. In: Draper Es KJJKSoboM-UK, ed. MBRRACE-UK 2017 Perinatal Confidential Enquiry: Term, singleton, intrapartum stillbirth and intrapartum-related neonatal death. The Infant Mortality and Morbidity Studies, Department of Health Sciences, University of Leicester: Leicester; 2017.

33. Magro M. Five years of cerebral palsy claims: A thematic review of NHS Resolution data, 2017.

34. NHS Improvement. Spoken Communication and Patient Safety in the NHS. In: Health Do, editor.; 2018.

35. NHS Resolution. The Early Notification scheme progress report: collaboration and improved experience for families, 2019.

36. Quinn AM. The 3Rs Program: the Colorado Experience. *Clinical Obstetrics and Gynaecology* 2008; **51**(4): 709-.

37. Sakala C, Y. Tony Yang, Maureen P. Corry. Maternity Care and Liability: Most Promising Policy Strategies for Improvement. *Women's Health Issues* 2013; **Volume 23, Issue 1**: e.25-37.

38. Sorensen R, Iedema R, Piper D, E. M, Williams A, Tuckett A. Health care professionals' views of implementing a policy of open disclosure of errors. *Journal of Health Services Research & Policy* 2008; **13**(4): 227-32.