Report Supplementary Materials 9 (17-99-85-supp9)

IMPROVEMENTS IN 'BEING OPEN'/OPEN DISCLOSURE: WHAT WORKS AND HOW FOR FAMILIES

(BOLDED PROGRAM THEORIES HAVE BEEN INCLUDED IN FINAL CMO CONFIGURATIONS)

'BEING OPEN' PATHWAY	Context	Indications of Mechanisms (forces, interactions, reasoning, and resources)	Outcomes for Parents/Family
EVENT IDENTIFICATION	Incident unconfirmed/uncertain/unfolding (12 references)	Timely and reliable confirmation of incident[1]	Reduces prolonged anxiety[1]
		Identification of incident type/severity[2-4] in meetings and record-keeping[2,4]; follow professional duty of candour[5,6] Routine invitation to discuss felt incident pre-discharge/systematic assessment of reported symptoms[2]; standardised checks embedded across maternity care pathways[2]	**Shows respect for parents' views and experiences[2-4]; promotes timely referrals[2] by ensuring that subsequent providers have information for care/referral account of incident to other providers[2,4]; may include disclosure of incidents with lower thresholds of severity[5,6]**
		Sensitive timing of news[7,8]; partner involvement[9]; acknowledgment of religious and cultural preferences; use of tools with informed guidance[8,10] to enable decision-making for investigations (e.g. post-mortem)[1]	Seen as necessary for ongoing involvement[1]; reduces psychological demands[7]; enables best decision-making that helps later coping[8-10]
		Co-ordinated communication with original provider/across facilities when event later identified in a different facility[11]	Reduces need for repeated explanation[11]
		Uncomplicated and supported access to own health records and information[3]	Reduces suspicion that the service is hiding things behind 'patient confidentiality'[3]
ONGOING CARE	When the incident has happened	Positive interactions with healthcare	Efforts are highly valued by families who are facing

AFTER EVENT	(7 references)	staff, via acknowledgment and prioritisation of the patient's situation[1,7,9,10]; not to feel ignored or have the event overlooked; emotional[7] and respectful care[3]; continuity/consistency of expert care[1] and information from all staff [7] required; information on how to navigate unexpected/unusual clinical situations[7]	the unknown[7]; care needs are met[1]; reduces confusion/distress or felt/expressed frustration towards immediate care staff[7]; reduces sense of isolation, confusion, and vulnerability[4] and decreases long-term negative consequences of bereavement[10]; reduces loss of confidence in HCPs[7]; sets a positive tone at the start of reviews/investigations[3]
DISCLOSURE PROCESS	Structures and Strategies (8 references)	**National guidance, mandates, and programmes drive and routinise formal disclosure procedures and translate these into clear unit policies to include: proactive family engagement; sensitivity to diversity and individual needs[11,12]; prompt triggering for all severe adverse events[5,8,11,13-15]; possibility of consent to further investigations[12] and early discussion of review/investigation decisions[13,16]**	**Avoids demands on family to 'chase' providers for information[5,8,11,15]; changes their perception of events ('self-preservation' of service less often assumed)[3]; families feel treated as partners[11,12,16] (however these formal directives do not, in themselves ensure involvement of families in all events as regulations may be infrequently followed)[13]**
	Ethos (3 references)	**Ongoing/established practices that embed and sustain 'taken for granted' involvement[17,18]; involvement/engagement reinforced by wider service/organisational practice and ethos[19]**	**Involvement becomes routine practice in incidents/situations[17-19]**
	Governance (references)	**Representation of families via review/investigation committee membership[18]; service/Trust oversight of family involvement[16]**	**Sustains awareness of family in meetings[18]; increases a sense of entitlement to involvement[16]; families are able to inform or oversee improvements[16]**

		Commissioners' pro-active in investigation/action plan oversight[13]; Board-level responsibility for Candour regulations (and for inclusion of parents and staff in investigation processes)[6]; networked governance structures to enhance disclosure practices (Board-level, Membership Councils, QI Steering Groups; Patient Leads)[20]; annual reporting of national bodies to include lay summaries[21]	**Ensures better involvement/candour [6,13]; reduces variability of investigations[13]; embeds an expectation of family involvement in routine management[20]; engages public sector in quality improvement processes[21].**
	Accessibility and Availability (12 references)	**Routine and timely invitation for parents' views, concerns and questions after incident[3,5,11,19,22] (including what action to be taken) offered multiple times[8,19,22]**	**Reflects best practice as agreed by families[11]; reduces felt mistrust[3] (but invitation does not, in itself, result in parents asking questions)[19,22]; Gives time to reflect on events[22] and plan questions[5]; increases awareness of opportunities to be involved[19] and opportunities to return until the family feels less dissatisfied[8]** **(However, systematic and routine engagement practices no guarantee of active participation[18])**
		Family-centred/personalised approach to disclosure discussion/follow-up[3,12,23] with staff freely available to respond to variability[5]; includes meeting specialist needs (eg language services)[23]; an open-door policy to when and how to contribute[12]	**Decisions on degree and nature of involvement are possible[3,5,12,23] and these rest with the family[3] or they have a voice in the process[23]; open-door policy may be retriggered in subsequent pregnancy[12]**
		Disclosure process explained[24,25] in understandable way[13]	**Leads to understandable information with minimal requirement of active involvement unless desired by family [13]; an opportunity for questions to be addressed[24]; the system feeling less ineffective or closed[24,25]; decisions being made with people[24]. Reduces anxiety and confusion over accountability issues[25]**

	Places Enacted (9 references)	**First and scheduled follow-up meetings are formal and planned by lead clinicians[5], in a comfortable environment with space and time for parent[5,19]**	**Shows event is taken seriously; responses to questions are considered/more reliable[5]; families feel more able to raise questions and concerns[19]**
		Conducted (ideally face-to-face) with nominated clinical expert[8,26],with awareness of family situation[9]; or with those originally involved in care[21] (or with further opportunity to meet with them)[5]	**Reflects agreed best practice by parents[26]; provides emotional support[9] and chances to ask questions and discuss events directly[21] (and not just as a recipient of information[8]); shows respect for personal situation[5]**
		Exclusion of legal and external/ 'arms-length' presence at meetings[3,14]	**Increases direct communication with clinicians[14]; feels less intimidating[3]; increases trust; tensions are reduced[3] (legal advice to providers should be on meeting candour and patient involvement principles)[3]**
	Early Disclosure Conversations (12 references)	**Staff skilled in active listening[11]; using 'carefully chosen words'; aware of effects of language[17], posture and conversational tone[27]; attuned to that family experience[5] (responsive to expressed needs and cultural preferences[11])**	**Seen as a crucial aspect of effective disclosure[11,17,27] that can lessen harm[5]. Improves human communication by health professionals, with the most significant change felt by patients[24]**
		Authentic[28], honest and direct[10,11,16] and timely apology[4] (uninhibited by felt litigation risk[14,16]; 'safe space' provision[3])	**Maintains trust in clinician[28] or service[11]; is valued by some parents[10]/evidences a partnership working with them[16]; can avoid damage to healthcare relationships[14]; enables openness after mistakes[3];**
	Explanations (5 references)	**Initial Clarifications/Explanations: not all investigations establish cause[1]; reviews/investigations might not answer all questions[23]; findings may be inconsistent across multiple investigations of same event[3]; focusing**	**Reduces disappointment, distress[1] and mistrust[3]; may facilitate helpful signposting to additional information or organisations[23]; the identification of an accountable person might be expected[23]**

		may focus on systems-change and not individual cases[23]	
		Exploring initial expectations: local review of care (including avoidability; future care issues) [8,10,19]	**Local reviews (event and findings) are a critical /'life shaping event' for many[8,10,19]. Families expect information on why (explaining past; planning future) and /or systems-wide improvement[21]**
	Consistency in Disclosure Process (7 references)	**Consultations/debriefings with experienced, nominated HCPs (ideally know to parents)[1,9,11,26], that are ongoing and supportive[5]**	**Improves the consistency of care and information[1,5,9]; leads to fewer staff asking the same questions[11]; shows that the event is not minimised or quickly forgotten[5]; provides opportunity for irreconcilable views to be explored[5]**
		Information-giving through course of multiple investigations (for same event for different purposes[3]); future possibility of a single, integrated report[19]; clarification of 'investigation hierarchy'[25]	**Reduces inconsistency/ experience of un-coordinated services[3]; avoids contradictory information and advice[19]; reduces felt disagreement[25]**
	Navigation Strategies (10 references)	**Named person for contact for ongoing support[11,26]/liaison/advocacy from initial disclosure to inquest[3,16,23,25,26,29]; continuity of contact where possible[23]; follow-on support arranged before discharge[16]**	**Agreed best practice by families[11,16,26]; positive effect on experience overall[25]; supports ongoing[3], flexible, and diverse[23] involvement (including family feedback on investigation process)[26]. NB [however stakeholders not agreed on if this support person should be independent of, or embedded in, investigating or clinical service][29]**

		Family nominated advocate or HCP (such as bereavement midwife) to attend review meeting; ask questions on family's behalf[18,26]; explain particular circumstances in that review/investigation (e.g. delays)[15]	**Leads to representation[18,26]; information-giving and reassurance on progress of progress[25,26]; advocacy relationship might diffuse anger and harm resulting from event or poor or delayed investigation process [3,15]**
		Joined-up systems (PALS; complaints; incidents)[16]	Reduces points-of-contact for families[16]
DISCLOSURE DURING REVIEWS AND INVESTIGATIONS	When incident review and/or investigation initiated (24 references)	**Family pro-actively included in decisions on review/investigation from outset [3,13,16,19]; nonclinical range of questions, opinions for establishing facts; perspectives and comments accommodated (and independent investigator 'checks' this opinion-seeking has happened)[3]; centrality of family views embedded in review/investigation process[22] and process design[12,26,29,30];**	**Includes and discusses experience and perspectives [3,12] and reviews are more meaningful[13,19] and effective[13][however est. 59% of reports where questions of family not addressed][3]. Reduces distrust; accuracy and credibility of investigation are enhanced[3,16]; involvement in finding explanations may alleviate harm[22]; engagement could be extended to other services[26]**
		Use of nationally agreed standards[13], with policies and local guidance with co-ordinated, consistent, and explicit	Reduces variation in involvement across cases and units[3,16]; involvement more central to investigations/ investigation quality assessment[13];

		rationale and approach for parent involvement[3,18,31]; standardised mortality review tools incorporate family involvement[19,21,22] standardised communication process (that allows tracking of progress)[31]	more co-ordinated and consistent communication possible[31]; More likely to be informed of review and invited to raise questions, concerns[19,21,22] (concerns/questions raised by 58% of parents). NB [policies do not necessarily guarantee respectful and caring family involvement][9].
		Comprehensive reviews/investigations include whole care pathways [1,12,19] with multi-disciplinary/cross-service representation[24] and subsequent sharing of knowledge of events/effects beyond that service[4]	**Incorporates overall experience of care[1,24]; prevents loss of information[24]; could avoid further investigations with costs to family[19]; enhances learning for system-improvements[12,19] encourages other service responsiveness for ongoing or subsequent care requirements[4]**
		Structured and accessible general information on steps and timescales of review/investigation with family-centred design and delivery[1,6,9,13,15,22,25]	**Minimal requirement for family's active involvement[13]. For dealing with the process[9,25]; decision-making[1]; ability to ask questions[22]; and understanding reasons for investigation[6] or time it may take[3,15]**
		Clarification of the primary objective of that review/investigation for a family[23]	**Reduces misunderstanding and disappointment[23]; directs appropriate questions and defines expected limitations of review[23] NB [however families sometimesanticipate that review multiple purposes, from explaining what happened [7,19] to recommendations for wider learning and prevention [7])**
		Specialist (emotional and practical) support and advocacy provision for families (and information on this)[3,13]; user-groups advise on least harmful timings/approaches to family[26]	**Necessary if families to be included in investigations[13]; agreed best practice[26]**
		Individualised/flexible or 'open door' opportunities for Involvement[12,16] that are appropriately timed[5], high-quality review /investigation process (contribution to ToR, questions and	**Accommodates individual and changing needs[12,16]; best practice principles (as agreed by parent representatives[26];or expectation of active involvement[13,19]. Families are more likely to be involved in and satisfied with report[3,23]; There is**

		report drafts)[3,13,17,19,23]; with named support of, and formal documentation of, parent feedback on this process[26]	**an appreciation of honesty, openness, and detail[17]**
		Meaningful apology and explanation for avoidable harm[3,13,20,32] (that are timely[4]) with assurances of learning[20,32]; expression of regret from those accountable[5,32];	**Necessary recognition[13] and accountability[32]; trauma may be reduced[20]; personal resolution possible[5]; trust in health care provision might be sustained[32]; situation less likely to escalate to complaint about concerns or legal action to get answers[3,20]; however when apologies are offered too late (or family not ready to engage) trauma many be increased[4]**
OUTCOMES OF DISCLOSURE PROCESS	Reporting and Feedback (9 references)	**Informing /discussing with families as review/investigation continues[21,25] (including delays)[3], as well as discussion of final report findings and feedback on involvement process[3,23,25,33]**	**Prevents mistrust cause by either 'closed door' investigation (for ongoing discussion denied)[21]; enables contributions after time to reflect[25]; or information 'drip feed' (without possibility to ask questions)[3,33]; final report more likely to be satisfactory[3]** **NB: [however: 24% of respondents agreed with value of family feedback survey for ongoing quality improvement (may be onerous from families and should be optional)][25]**
		Reports are accurate, appear complete and without jargon[3,13]; (if external) are forwarded to families before Trusts[13,23],	**Indicates that report is reliable, understandable,[3,13]and impartial[23]**
	System-Wide/QI Revisions (8 references)	**Action (and accountability for this action) from review/investigation to prevent same event happening again[3,5,11,12,14]; selective in-depth investigations (including near-misses) to maximise learning[25].** **Leading/initiating change based on particular event/experience[3,4]**	**Want this to make sense of loss[3,12,14]** **NB: [however 83% families think that investigation had made no positive difference; 73% unclear on what learning had happened][3]; some families want personal accountability for events[23]; exclusion of family's own case from improvement programme might not be acceptable to them[25].** **Leading/assuring change may be adequate in some situations[3,4]**
	Family Resolutions (3 references)	**Offer of fair compensation (if admission of fault)[15]and payment of expenses/further access to services of**	**Appreciated by families[14]; may promote some family's involvement in disclosure processes32 ; diffuses anger and may preserve relationships[15].**

		involvement in disclosure process in all situations[14]32	
	Indirect Social Revisions (7 references)	Public awareness (and information) on rights to raise concerns and to support/advocacy after incidents[3,16]	Increases number of families informed/engaging[3]; decreases marginalisation after incident[16]
		Revisions in clinicians' awareness of effects of professional cultures on involvement and care[24]	Main barrier to involvement reduced for some; especially when more vulnerable and making decisions about involvement[24]
		Improvements in communication skills of doctors[4]	Increases ability to deliver care more generally[4]
		Wider awareness of value of family/patient insights along with clinical insights[3,23,25]	Recognition possible; reduces antagonism[3]; improves understanding of events[23]; view of families as disruptive is less likely[25]

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.
2. CIC MBB. The Make Birth Better Survey 2019: the circle of trauma for parents and professionals April 2020.
3. Care Quality Commission. Learning, Candour and Accountability: a review of the ways that NHS trusts review and investigate the deaths of patients in England2016.
4. Stanford SER, Bogod DG. Failure of communication: a patient's story. *International Journal of Obstetric Anesthesia* 2016; **28**: 70-5.
5. 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.
6. NHSR. The Early Notification scheme progress report: collaboration and improved experience for families, September 2019.
7. 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.
8. Redshaw M, Rowe R, Henderson J. Listening to Parents after stillbirth or the death of their baby after birth: University of Oxford, 2014.

9. 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.
10. 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.
11. Iedema RA, Mallock NA, Sorensen RJ, et al. The National Open Disclosure Pilot: evaluation of a policy implementation initiative. 2008; **188**(7): 397.
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. Magro M. Five years of cerebral palsy claims: A thematic review of NHS Resolution data, September 2017.
14. Quinn AM. The 3Rs Program: the Colorado Experience *Clinical Obstetrics and Gynaecology* 2008; **51**(4): 709-.
15. 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.
16. CQC. Learning From Deaths. A review of the first year of NHS trusts implementing the national guidance *Care Quality Commission* 2019.
17. J. B, Hacking B, Murdoch E. Being Open: communicating well with patients and families about adverse events 2016 (?).
18. 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.
19. Kurinczuk JJ, Thomas Boby, Sarah Prince, et al. Learning from Standardised Reviews When Babies Die. National Perinatal Mortality Review Tool: Second Annual Report. Oxford: l Perinatal Epidemiology Unit., 2020
20. 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.
21. S. K, F. C-S, C. K, T. J, 2017. Local review of intra-partum related death. In: Draper ES KJ, Kenyon S (Eds.) on behalf of MBRRACE-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.
22. Chepkin S, Sarah Prince, Tracey Johnston, Thomas Boby, al. MNe. Learning from Standardised Reviews When Babies Die. National Perinatal Mortality Review Tool: First Annual Report.: Oxford: National Perinatal Epidemiology Unit. , 2019.
23. HSIB. Giving Families a Voice: HSIB's approach to patient and family engagement during investigations Independent Report by the Healthcare Safety Investigation Branch September 2020.
24. 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.
25. NHSI. The future of NHS Patient Safety Investigation: engagement feedback. November 2018.

26. C. B, 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.
27. 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.
28. Coughlan B, Powell D, Higgins MF. The Second Victim: A Review. *European Journal of Obstetrics Gynecology and Reproductive Biology* 2017; **213**: 11-6.
29. 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.
30. 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.
31. Healthcare Improvement S. Communicating well with parents and families about adverse events and significance adverse events (SAE) reviews In: Lothian N, Scotland HI, Healthcare ECf, Babies SSC, editors.; 2016.
32. 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.
33. 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.