

Report Supplementary Materials 10 (17-99-85-suppl0)

Realist Data Extraction Table 1			
IMPROVEMENTS IN ‘BEING OPEN’/OPEN DISCLOSURE: WHAT WORKS AND HOW FOR STAFF (BOLDED PROGRAM THEORIES HAVE BEEN INCLUDED IN CMO CONFIGURATIONS)			
‘BEING OPEN’ PATHWAY	Context	Indications of Mechanisms (forces, interactions, reasoning, and resources)	OUTCOMES for Staff
EVENT IDENTIFICATION	Unclear/unfolding severity of incident (6 references)	Confidence in reporting systems (equity of response; learning from event); feedback on outcomes of incident reporting ¹⁻³ ; confidence in colleagues leading disclosure/investigations ⁴ ; non-punitive reporting environment ^{3,5} ; systems for identifying good practice formalised ³	Will increase confidence in when to trigger a formal response to an adverse event ^{1-3,5} ; with less anxiety over possible impact on reputation, relationships, and career) ⁴
		Recognition of different views of incident severity¹	More frequent reporting of adverse events¹
		Protocols to support consistent decisions on when to investigate ¹ ; availability of decision-making tools for use with anxious/bereaved parents ⁶	Will clarify expectations (including involving the family) ¹ ; the supported consent process will be less difficult ⁶
ONGOING CARE AFTER EVENT	When the incident has happened (4 references)	Capacity (resources, skills, behaviours, attitudes ⁷) of staff to respond with emotional intelligence to needs/requests and choices of bereaved/traumatised parents ⁶⁻⁸ and sufficient opportunity to reinforce this across teams ⁷	Reduces likelihood of expressions of anger and aggression toward staff ⁷ ; staff more able to understand women’s requests ^{6,8}
		Availability of staff with specialist skills to share/model/disseminate responsive approaches to injured families	Leads to dissemination of skills and recognition of this work ⁷
		Provision of support during/after care of avoidable/unavoidable serious incident ⁹	Reduces personal and emotional toll of the work (emotional difficulties that lead some clinicians to give up practice) ⁹
DISCLOSURE PROCESS	Structures and Strategies (8 references)	Disclosure processes supported and monitored by experienced colleagues⁴; embedded in robust clinical governance systems⁴; provided by skilled staff¹⁰ who	Reduces inherent uncertainties over disclosure practice (impact on own and organisational reputations or with a

		have ongoing support, advice, and practical help ^{5,11}	reduction in legal action by families searching for explanation ⁴ ; disclosure practices by individuals is better supported ^{5,10,11})
		National mandate (Regulation 20) with 'Being Open' guidance ^{10,11}	Emphasises organisational value of disclosure ¹¹ ; encourages organisational support for staff involved in this work ^{10,11}
		Collaborative Implementation of improvement work (e.g. new protocol) across service ¹² or organisation ¹³ ; demonstrated benefits of investment in specialist and senior support ^{12,13} ;	Decreases uncertainty of clinical staff and managers and decreases resistance about changes in practice ¹² / they are less likely to resist ¹³ NB: {collaboratively developed protocol revisions over 80% more likely to be implemented} ¹³
		Educational programs and staff support are critical elements of disclosure programmes ^{14,15}	Increases staff competence and confidence to involve family throughout process ^{14,15}
		Legally protected 'safe spaces' for disclosure conversations ¹	Decreases clinicians' fear around legal consequences and increases the likelihood that families will learn the truth from clinicians; increases open relationship with a family ¹
	Ethos (4 references)	Wider organisational landscape of trust between organisations and clinicians in which policies, tools, and programmes are operationalised ^{7,16}	Engages clinicians in an ethos of early reporting and disclosure ¹⁶ ; and improves positive relationships with injured patients ⁷
		Established practice that is supported consistently and clearly by local physicians and managers ¹³ ; senior doctors role-modelled disclosure with patients ² ;	Openness with families becomes 'part of the mind set of all practitioners' (about 3 months after initial implementation) ¹³ ; medical students and junior doctors will aspire to emulate disclosure practice ²
	Governance (3 references)	Implementation of disclosure widely supported by Trust leaders and managers (and government) ^{1,17} and modelled by Trust leads ³	Leads to the development of local cultures of reporting, openness, and learning ¹ ; reassures staff of this work ³ (will not rely on a

			few champions ¹⁸); promotes disclosure work as a clinical priority for services and teams ¹⁷
Accessibility/Availability (5 references)	Managing parent expectations/questions (e.g. limited PMRT 'free-text') ¹⁹		Services are able to manage questions in the time available for reporting ¹⁹ and to provide answers to the questions that families are asking ¹⁹ NB [however 50% stakeholders voted against time limit set for addressing parent questions in PMRT meeting] ¹⁹
	Inclusion in staff in review meeting schedules and invitations ^{3,20,21} ; staff sensitively informed/kept informed of investigations involving them ⁵		Staff are able to attend panel discussions that involve them ²⁰ and feel less fearful and isolated during this time ⁵
Places Enacted (1 reference)	Time alone and with colleagues to prepare for disclosure conversation following a guide (who to contact; accommodating different understandings; what to say; body posture and proximity; how to respond; what required) ²²		Equips staff to plan the conversation and follow-up ²² and leads to better conversations with families ²²
Initial Disclosure Conversations (13 references)	Communication training^{12,21,23} for staff to acquire necessary interactional skills for difficult conversations^{21,24}; this training was offered to all labour and delivery clinicians¹³ and was part of the trainee curriculum²³, including multi-disciplinary training to prepare for the disclosure conversation²²		Staff who attend will have increased skills and confidence^{12,23} and greater willingness to be involved in discussions with families^{21,24}. Reduces levels of stress and risk of burn-out²⁴; with all team approaches^{13,23}. clinicians might develop wider collaborative relationships²²
	Time to prepare together for a conversation (plan private environment; contact with risk manager; share views on event; plan what to say; anticipate response and need)²²		Clinicians are better equipped for an effective conversation²²
	Clarification of difference between expressing regret and admitting liability¹; of the pressures arising from instructions to give a partial apology (when would prefer to give a full apology^{25,26}); management of risks associated with tort system^{16,27}		Apologies are given with less fear/sense of risk^{1,16} personal responsibility. Promotes that an apology is the right thing to offer regardless of review/investigation findings²⁵

		Knowledge of use of 'appropriate words' ¹³ /recognition of 'profound effects of subtle changes in language' ¹² in disclosure meetings; use of established cognitive aid as best practice guidelines ²²	Clinicians will be better able to integrate own feelings into an honest account for the family ¹³ guidelines will improve (simulated) disclosure conversations, notably, posture/ tone towards patient] by experienced practitioners ²² . Staff are more likely to have successful meeting ⁶ NB [Staff with best practice guidelines were more likely to apologise to patients [in simulations] however this training did not make the task of disclosure feel any easier for them]] ¹³
		Engagement of wider range of HCPs (e.g for co-design of communication training) ¹²	Different staff will realise that the challenges of disclosure work are common across health care teams(e.g. chaplains, clinicians, service managers) ¹²
	Explanations (2 references)	Approaches that identify learning and 'fair culture'(rather than apportion blame) ^{3,8}	Staff will be less reluctant to report and disclose events ³ ; the devastating effects of an incident that is hidden will be reduced; and opportunities for professional and service and personal learning are available ^{3,8}
	Navigation Strategies (3 references)	Named family contact/liaison has capacity (emotions and time) ²⁸ ; training and support ⁵ ; sufficient influence and experience ⁵	This contact will be able to work effectively ⁵ , responding to family needs throughout reviews/investigations (from routine updates to unmet expectations) ²⁸
		Clear pathways of contact/open communication with staff (raising concerns) developed by Trust ¹⁰	Staff will be less fearful of contact with families with more compassionate communication and possibilities for collaboration ¹⁰
DISCLOSURE DURING REVIEWS AND INVESTIGATIONS	When incident review and/or investigation initiated (11 references)	Standardised review tools and protocols that include communication with parents ^{29,30} ; Dedicated support materials developed with parents ^{29,30}	Staff will have guidance for when and how to involve a family ^{29,30} NB [Staff feedback indicates more structured approach to review improves staff communication with parents] ^{29,30}
		Chaired meetings with trained and experienced senior	Meetings will be more reliable and robust ¹⁹

		administrators ¹⁹	
		Dedicated/protected time for reviews and investigations (and part of job plans) ¹ ; administrative support for reviews ^{5,29,30}	This work will be recognised as a necessary clinical responsibility ¹ ; with sufficient time, the quality of reviews will be improved; e ¹ ; less burdensome for investigators ²⁹ (more time for discussion and identification of care improvements) ³⁰
		Professional duty of candour followed ¹	There will be more active participation in reviews (by staff as review leads and information-providers) ¹
		Systems that seek to reduce need for litigation against Trusts (eg, early notification/compensation of costs) ^{16,21}	There will be a reduction in fear of consequences of incident reporting and candour ^{16,21}
		Training and expertise development for family involvement in investigations ¹ ; specialist training for investigators ^{1,31} (national and mandated ¹¹); ongoing/facilitated team/peer-support programs ^{28,31}	The competency of investigators will be improved ¹¹ , including their confidence and resilience to effectively involve families ^{1;28,31} . These competencies of investigation and engagement skills ¹¹ .
		Staff emotional support that is routinised ⁷ , dedicated, joined-up ²¹ , during incident investigation ¹¹ and post-incident ^{21,7,11} . Trusts (OH, Workforce Wellbeing and Board) responsible for provision of range of flexible care packages and specialist referrals ²¹ .	Staff wellbeing will be better supported ⁷ ; staff will be more likely to report and disclosure to a family next time ²¹ ; trainee attrition might be reduced ¹¹ NB [evidence of staff support offered in about 60% of NHS claims; no evidence of uptake or quality/continuity of support offered] ¹¹ Support needs will be met as part of Trust-level duty of care to staff ²¹ .
OUTCOMES OF DISCLOSURE PROCESS	Reporting and Feedback (2 references)	Informed of investigation progress and findings by key contact/liaison (not 'kept in the dark') ^{5,21}	Staff uncertainty and stress will be reduced ^{5,21} .
	System-Wide Change /QI (3 references)	Evidence of corrective action/improvements from learning after incident (taken by teams/departments) ^{1,2} ; Regular updates on shared lessons from reviews/investigations ¹⁰	Leads to a reduction in staff trauma ² ; Staff will feel that organisation is open with them; and they will be involved in learning for improvement ¹⁰
	Resolution of Staff (5 references)	Permission to communicate truthfully' about event ¹³ ; Demonstrated effort by service to address harm to	Leads to a reduction in staff stress, concern and trauma with the possibility of a just

		patient (amelioration) (taken by teams/departments) ² with sincere apology and offer of compensation ³² ; new systems for early notification/settlement of costs ²¹ dedicated and confidential post-incident support for staff ^{3,21} ;	resolution ^{2,13} ; Reduction of fear of litigation ('barrier to safety') ²¹ , anger is diffused and relationships with family might be preserved ³²
	Wider Revisions in Social and Healthcare Relationships	New practices (views on fallibility/expertise/care decisions) entailed in disclosure ^{8,26,33}	Will encourage new ways of working with staff and patients ^{8,26,33}
		Parents/families central in post-incident events and care ^{28,34}	Will 'upskill' staff in new perspectives on user involvement in care planning ^{28,34}

1. CQC. Learning, Candour and Accountability: a review of the ways that NHS trusts review and investigate the deaths of patients in England December 2016.
2. Coughlan B, Powell D, Higgins MF. The Second Victim: A Review. *European Journal of Obstetrics Gynecology and Reproductive Biology* 2017; **213**: 11-6.
3. 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.
4. 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.
5. NHSI. The future of NHS Patient Safety Investigation: engagement feedback. November 2018.
6. Bakhbaki 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.
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. Stanford SER, Bogod DG. Failure of communication: a patient's story. *International Journal of Obstetric Anesthesia* 2016; **28**: 70-5.
9. 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 Obstetrica et Gynecologica Scandinavica* 2013; **92**(3): 352-61.
10. CQC. Learning From Deaths. A review of the first year of NHS trusts implementing the national guidance *Care Quality Commission* 2019.
11. Magro M. Five years of cerebral palsy claims: A thematic review of NHS Resolution data, September 2017.
12. J. B, Hacking B, Murdoch E. Being Open: communicating well with patients and families about adverse events 2016 (?).

13. 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.
14. 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.
15. 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.
16. Quinn AM. The 3Rs Program: the Colorado Experience *Clinical Obstetrics and Gynaecology* 2008; **51**(4): 709-.
17. C. B, Bakhbaki D, Lynch M, et al. All Parents Should be Offered the Opportunity to Engage with the Review of their Baby's Death *PolicyBristol*, 2018.
18. 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.
19. Bakhbaki 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.
20. Bakhbaki 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.
21. NHSR. The Early Notification scheme progress report: collaboration and improved experience for families, September 2019.
22. 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.
23. 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).
24. 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.
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. 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.
27. 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.

28. 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.
29. Chepkin S, Sarah Prince, Tracey Johnston, Thomas Bobby, al. MNe. Learning from Standardised Reviews When Babies Die. National Perinatal Mortality Review Tool: First Annual Report.: Oxford: National Perinatal Epidemiology Unit. , 2019.
30. Kurinczuk JJ, Thomas Bobby, Sarah Prince, et al. Learning from Standardised Reviews When Babies Die. National Perinatal Mortality Review Tool: Second Annual Report. Oxford: I Perinatal Epidemiology Unit., 2020
31. 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.
32. 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.
33. CIC MBB. The Make Birth Better Survey 2019: the circle of trauma for parents and professionals April 2020. (accessed.
34. 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.