Report Supplementary Materials 11 (17-99-85-supp11)

Realist Data Extraction Table 2			
Improvements in 'Being Open'/Open Disclosure: What Works and How for Services (Bolded Program Theories Have Been Included in CMO Configurations)			
'BEING OPEN' PATHWAY	SITUATION	Indications of Mechanisms (forces, interactions, reasoning and resources)	OUTCOMES for Services
EVENT IDENTIFICATION	Incident uncertain/unfolding	Routine invitation to discuss felt harm prior to discharge or during an assessment of reported symptoms[1]; standardised checks on women's experiences embedded across maternity care pathways[1] and family perspective included in clinical records and incident analysis[2]	Leads to the development of trauma-informed maternity service[1]; Reduces the possibility of litigation by families who feel ignored[1] and the loss of vital information for patient care[2]
		Extension of thresholds of harm ('less' serious incidents)[1 3]; wider interest of improvement leads/committees in 'trigger' incidents[4] (with possibility of extension of these thresholds over time)[5]	Enhances view of service areas requiring improvement[1 3-5]
		Following 'Being Open' guidance and Regulation 20(Duty of Candour)[3 6] with all reviews including a systematic and critical review of care[7]	**Increases reporting of incidents[3]; improves discussions with families[6]; meets regulatory requirements; meets regulatory requirements [3]; creates more opportunities to learn from mistakes and substandard care[3] [7]and meets drive to improve maternity safety[6]**
ONGOING CARE AFTER EVENT	When the incident has happened and during ongoing maternity care	Organisation-wide[8 9]staff training in Being Open purpose[9],policy/principles[10], and communication skills[8]	Leads to fewer possible repercussions for Trust (aggrieved families)[10]; workforce competencies are more widespread[8]; becomes more likely for disclosure to be enacted in local practice[8 9].
DISCLOSURE PROCESS	Improvement Strategies and Infrastructures	**Specialist, multi-disciplinary 'event response team' manage processes across service[8 10]and immediate response to trigger events[8]; team selected by peers[8]**	**Disclosure processes will be more consistent/coordinated, there will be clear accountability[8 10]; leadership**

			positions/expertise will be developed[8]; a 'tenants of disclosure model' can be operationalised[8]; duplication likely to be reduced[10]and advice and standards more likely to be consistent[9]
		Concerted and resourced implementation strategy (including policy, guidelines, training, and evaluation of effect)[9 11], maximum use of IT[12]with whole service engagement[5]/capacity to integrate patient experience intelligence[4]	**Will meet the broad objectives of a pilot[11]; OD more likely embedded in organisation (not a discretionary activity)[5 9 12]; more effective identification of improvement focus possible[4]**
		Comprehensive protocol/guidance (identification, disclosure, investigation, appropriate resolution)[8]	**Meets one condition of programme implementation[8]**
		Dedicated, senior person to implement disclosure guidance (n Trust[4]; in regional partnerships[13])	Ensures clear and consistent leadership for implementation[4 13]
		Gaining and sustaining senior medical 'buy-in' (with responsibilities for implementation and case reporting[8])[4 9 14] and by local site engagement,(with benefits evidenced to them [8] and local services opportunities to adjust protocol to meet their own service conditions [8]	Encourages support by senior medical staff (required to promote uptake by colleagues; [4 8]; reassures junior staff[14]; crucial to ongoing practice[9] and policy implementation[8]
		Disclosure identified as more than clinical competence and as a service organisational issue about workload, supervision, rapid organisational change[9]; documentation[8]; administration and co-ordination[14]; communication/discussion and coordination of protocol and practice across units[8])	Embeds organisation-wide practice of openness[8 9]; reduces burden of disclosure in individual clinicians; and enhances possibility of patient-centred disclosure practice y[9]
		Trusts' prompt referral of/comprehensive information on incident to external body[6]	**Possibility of reduced litigation (parents get answers and/or assistance more quickly)[6]**
		Organisational regulation[15 16] with accommodation of differences in organisational maturity (how well systems support practice)[17]	Enables clear accountability for disclosure[16]; but variations across units are expected during early implementation[17]

		Disclosure, apology, and early redress embedded in quality improvement work[18]	**May reduce the need for the regulation of organisations[18]**
		National frameworks/guidance on programmes for all Trusts and services[4 13] (including for Board leads; staff skills; protected time; minimum data collection and reporting requirements)[4]	**Promotes a clear and consistent policy for family engagement and its requirements[4 13] (combining specificity with flexibility)[13]**
		Education to address gap between disclosure guidelines and clinicians' practice[19], including supported space for clinicians and patients to negotiate the practical demands/contradictions of disclosure[9]	**Effective disclosure becomes part of patient safety programmes[19]; and becomes more than 'in principle' agreement[9]**
		Risk management formalised/embedded in improvement work/aspect of cultural change[10 18] committed risk managers identified to embed disclosure protocol in each unit[8]	Incidents of disclosure are likely to increase[18]; evidence of impact of disclosure on reduction of incidents will be collected [10]; implementation of disclosure will be successful[8].
		Staff commitment to disclosure (notably, risk managers[18]; senior clinicians[20]; board and medical director/nominated consultant) with time and resources[4]; consistent communication of commitment[8]	**Continuity of disclosure practice will be possible[8 18 20]; financial and HR investment in high-quality systems and processes more likely[4]**
		Established provider service team reporting in Board and Commissioners into the divisions; and 'down' to wards and local forums[10]	Develops high-quality safety assurance with grassroots identification of risk and improvement implementation[10]
		'Joined- up' intelligence from reviews/incidents, patient experience, complains and support services by Trust Boards[3]	**Enhances insights for safety improvement[3];**
		Adoption/development of legacy interventions (e.g., review tools, training, and engagement methods)[4 12 21 22]	**Creates a shorter/easier journey to improvement; interventions are more reliable[4 12 21 22]**
	Ethos	**Disclosure communication enacted as moral-ethical obligation of clinicians (not an administrative task)[15]; enacted in service-wide early response teams to encourage disclosure[8]**	**Embeds disclosure as an aspect of care s in each clinical service[8 15]**

		Parents central in guidance[3 21] and practice development[4]	**Enhances effectiveness of guidance[3 21]; strengthens partnerships with families[4 21]**
		Change in NHS safety culture (with holistic work programme on structure, skills, capacity, and cultural reform)[17]; culture change in 'healthcare micro-systems' (over wider systems reform)[18]	Refocuses SI management from punitive/political process to learning for improvement[17](52% of 2017 survey respondents said not yet achieved"[17]); different programs for Trust settlement after incidents possible[18]
		Change in inspection and Board priorities from how investigations conducted and completed (within timeframe) to learning disseminated and embedded[3]	**Practice will be valued for learning and improvement (not for meeting short targets)[3]**
		'High-level' leadership in promoting 'Just culture[3 6]; desire to learn a central organisational value[4] (e.g. Provider Boards; Commissioners and Regulators); embedded and consistent culture of openness/candour[7 10]	**Change more likely to happen within units[3 6] when incidents, complaints, and concerns are seen as learning opportunities[10])[4 17] and when service-user experience if part of this learning [7]**
	Organisation/Unit Legacies	**When implementation approaches recognise the different capacities of organisations to drive attitude and practice change so that gradual and uneven change expected in organisations[8]and varying degrees of foundational systems and expertise in organisations anticipated[4 17 21]**	**Differentiated systems for support of staged implementation plans can be developed [17 21]**
		Established success/experience in other family engagement practices[21]	**Disclosure is more successful[21]**
	Governance	**Local Maternity Systems[13] and Health-Board/Trust buy-in[5] (with trained [17]Executive and non-Executive leading these processes)[23]; resourcing available[12]; with clear and consistent guidance/standards/processes/tools[3] and time for development of expertise in their application[12 21]; Board-level family advocate[4] and minimum standard of training for all Board members[17]**	Consistent disclosure improvements and learning are possible[3 5 12 23]; investigating and learning emphasised[13 17] in time (with variations between services expected)[21]; staff implementing family engagement are held to account[4]

		Strong governance structures: e.g., review groups, including regular executive reviews[4 5]; promotion of unit reporting for external benchmarking[13]; monitoring of training effectiveness[5 13]and involvement guideline compliance[13];	**Essential for service improvement/learning and acting on lessons[4]; improvement monitoring[13]**
		Commissioning that includes: lead for incident reporting and process improvement[3]; for maternity safety[6]; and commissioners have time and training to quality assure disclosure and investigations[13]	**More coordinated improvement work[3]; clarification of accountabilities[13]; family participation more likely to be achieved[13]**
		Commissioners' responsibility for investigation reporting/action plans with family involvement[13]; Board-level clarification and resourcing of Candour regulations (and inclusion of parents and staff in investigation processes)[6]	**Regulation will be met[6 13]; variability of investigations will be reduced[13]**
		Inspection bodies include: mortality reviews/investigations[3]; compliance to family involvement guidelines[13] (e.g. to benchmark Trust leadership)	**Improvements in national oversight and support for learning from failings; improvements in family involvement in national oversight would improve[3 13]**
		Local Maternity Systems, supported by strategic partnership Boards, responsible for improving investigation process (and MVP involvement in it)[13]	National recommendations can be co-designed and included in local SI processes[13]
		Royal College clinical leadership and guidance to Trust/service investigators[3]; professional-led national quality improvement introduced[23]	Costs of external investigations teams(c£100k per investigation) will be reduced[3]; national standards and objectives will be established[23]
		Value of user-voice already established in organisation/clinical governance (co-production-user forums)[4 24]	**Reduction in the cultural resistance to involving families in making improvements in reviews/investigation processes[4] (however practice of user-involvement will always be more challenging that other aspects of clinical governance, especially where addresses difficult issue of 'poor outcomes')[24]**

		Networked governance structures to enhance disclosure practices (e.g. Board-level, Membership Councils, QI Steering Groups; Patient Leads)[10 13]; annual reporting of national bodies to include lay summaries[23]	More effective learning and engagement for Sis and involvement of families[10 13 23]
	Accessibility/Availability	**Family-centred approach to engagement in reviews and investigations[3], including information materials noting multiple opportunities to engage[22]; and staff training in this perspective[24]**	**Increases satisfaction of families [3]; family engagement improved[22], along with care planning and delivery[24]**
		Culture that supports meaningful apology for any harm[3 10 25]; explanation of circumstances without blame[25], including legal protection[18]	**Reduces likelihood of escalation or legal claim[3 10 25] NB: [limited potential to reduce malpractice claims by US families with birth-injured infants][18]**
	Explanations	**Comprehensive assessments of care during review[13]; Correspondence in care standard assessments (between services and external bodies)[6]**	**Delays in settlements for families are mitigated[6](possible reduction of costs)[6]; learning from cases for care systems improvements are increased[6 13]**
		Inclusion of family and carer understandings of events[3 16], with understanding that common understanding of what happened might not be reached [16]	**Increases opportunities for learning from family experience of care across complete care pathway)[3 16]; reduces possibility of ongoing conflict if family listened to[16]**
		Investigations include clinical and legal experts (examining all relevant documents)[6]	**Investigations can bridge 'claims, safety and learning functions of the organisation'[6]**
	Consistency in Disclosure Process	**Formal, family engagement guidance (shared between services and between external organisations)[6 16](and review tools[23]) co-developed with staff and parent advisors[12 22]**	**Leads to more consistent information; shared resources[16]; that are relavent[22 23 12]and avoid duplication[6] are available to the service**
	Navigation Strategies	**Named professional/patient representative or advocate to manage co-ordination of information between parents and clinicians[5 26]**	**Leads to the provision of crucial infrastructure for improvement of 'Being Open' guidance[6] (more information and relational consistency between Trusts and**

			family[26]) **NB: [unclear if that person should be 'fully independent' of clinical team][5] [26]**
DISCLOSURE DURING REVIEWS AND INVESTIGATIONS	When incident review and/or investigation initiated	**Investigation Leadership that is expert in family liaison and includes risk management /governance team (not consultant in charge)[10 22]**	**Enhances the reliability and consistency of findings[10]; the incorporation of action plans into clinical governance plans d[22] and findings more likely to be underpinned by ethos of candour[4]**
		Robust review/investigation process including whole care pathway (multi-agency[27]; cross-department[22]; multi-discipline[21-24 28]); parents' perspective[22]; external or independent peer-review[13 22], and adequate RCA methodology[13];	**Enhances learning from the incident by more comprehensive for improvement planning[21-23 27]; encourages care variation and grading from a multi-disciplinary perspective[22 28], along with the use of 'fresh eyes' to identify systems issues[13 22 23] to identify active and latent failure)[13] and the wider development of cross-sector relationships[24].** **NB [but 17% reported PMRs 2018-19 completed by 1-2 same discipline clinicians)[22]; 1:5 PMRs 2018-19 had external member input[22]**
		Planning[3] and training[28] for multi-disciplinary/sector review/investigation (establishing ToR, leadership, expectations of contributions and time-lines reflecting complexity[3 22](and building of cross-sector relationships)[3]; investigators trained in RCA techniques[3]	**Enhances reliability of review/investigation processes and completion in a realistic timeframe[3] [22 28]**
		Independent, structured peer-reviews underpinned by just culture approach[13]	**Reduces risk of 'political highjack'; increases possibilities for the identification of systems-factors in development of action plans[13]** **NB [costs estimated as £2,100 per**

			peer-reviewed case][13].
OUTCOMES OF DISCLOSURE PROCESS	System-Wide/QI Resolution	**Board and trusts governance teams invested in action planning for post-review improvement[22]**	**Shared ownership of actions and system-level changes more likely[22]**
		Focus of national bodies on improvement processes rather than completion deadlines[3]	**Reduces focus by Boards on more immediate targets and greater focus on longer-term systematic change [3]**
		Integration/standardisation[3] of (internal; external) data collection/surveillance systems11; robust mechanisms to disseminate learning from investigations or benchmarking beyond single Trust[3] (e.g. across local maternity system); beyond single external bodies[6]; administrative support for Trusts to engage[6]	**Increases opportunities for national learning from local reporting[11]; possible reduction in repeated mistakes[3]; more rapid learning[6]; engagement possible[6]**
		Ongoing review process/audit spirals or cycles[29]	Supports (re)evaluation of recommendations and their implementation[29]
	In-Case Resolution	**Meeting ongoing care requirements[16] (including offer of fair compensation, if admission of fault[18]; costs payments[25 30]; and informed sign-posting for expert follow-up[16]**	**Diffuses anger towards individuals or service and may help to preserve relationship with family[16 18 25 30]**
		Trust/employer recognition of duty of care to affected staff[6]; investment in dedicated joined-up post-incident support[6]; changed perspectives staff HR during investigation (e.g. time off work not a penalty)[17]	Leads to the development of joined-up and dedicated systems for effective post-incident staff support /workforce wellbeing/OH improvement[6]; staff less traumatised/likely to feel penalised[17]; staff more likely to be retained[6]
	Wider Social Influences	Professional insurance policies support participation in disclosure procedures[8]	Impact/use of disclosure protocols increases (and organisations promotion of disclosure work (and systems/team perspectives on issues for improvement not undermined)[8]
		Litigation fear and costs managed[8 31] (e.g. protected spaces[3]); external agency interventions[6 18]	More reviews happen[31]; open communication is more likely (expected to reduce complaint and litigation need[3 6 18]; evidence that decreases malpractice costs[8]; legal

			duty not breached[3]
		Consumer-perspective on incidents (personal/psychological[1]), disclosure, involvement routinised[15]	Consumer experience is incorporated into wider patient safety issues[15]; 'cultural shift' from bio-medical perspectives on incident[1 15]
		Increasing public pressure on policy makers[11]; costs of clinical negligence claims (connected to marginalisation of families)[6]	High-level drivers on organisations to secure disclosure improvements[6 11]

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