HS&DR Project 17/99/85 - DISClosing Harm in MatERNity [DISCERN study]

PROTOCOL TITLE:

Strengthening the Implementation and Operationalisation of 'Open Disclosure' with Women and Families After Unexpected Harm in NHS Maternity Care

SHORT TITLE:
Strengthening the Disclosure of Harm with Woman and Families in NHS Maternity Care

STUDY ACRONYM:

DISCERN

The project is funded by the NIHR HS&DR programme (project number 17/99/85)

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Title	Strengthening the Implementation and Operationalisation of ‘Open Disclosure’ with Women and Families After Unexpected Harm in NHS Maternity Care
Protocol Short Title/Acronym	DISCERN study
Funder Reference Number	NIHR HS&DR project number 17/99/58
Study Sponsor	Professor Reza Razavi, King’ s Health Partners
Chief Co-Investigators	Professor Jane Sandall and Dr Mary Adams
REC Number	IRAS ID: 262197
Medical condition or disease under investigation	Maternity Services Research
Purpose of the study	To identify and investigate the critical factors required to improve the disclosure and discussion of harm with affected women and families in maternity care and examine the consequences of these improvements.
Study Objectives	1. Conduct a realist evaluation study of open disclosure improvement work in NHS maternity services to identify what works, for whom, in what circumstances, in what respects and why. 2. Generate actionable findings for maternity providers and NHS trusts on how to strengthen disclosure policies, processes and practices. 3. Produce accessible guidance (documentary and filmed) on disclosure processes for women and families and for frontline clinical teams.
Study Design	A 36-month qualitative study in 3 related study phases: Phase 1: Scoping: a realist literature review and a telephone survey of 60 national and regional key stakeholders in open disclosure/candour improvements in NHS maternity care Phase 2: ethnographic case studies of open disclosure work in 3 maternity services or networks located within 2 NHS Trusts Phase 3: multi-stakeholder meetings organised in provider service forums (4); women and family forums (2) and a national forum (1).
Endpoints	Exploratory Study
Sample Size	Approximately 100 people (of which 48 are NHS staff or volunteers and 12 are members of the public)
Version and date of final protocol	tbc
Version and date of protocol amendments	V.1. 29.07.19 V.2. 14.09.19 V.3. 30.09.19 V4. 06.06.21
Statistical Methodology and Analysis	No statistical methodology will be used (this is a qualitative study)
Human Tissue Samples (if applicable)	Not applicable
Data collected/storage (if applicable)	Not applicable

DISCERN STUDY

Strengthening the Implementation and Operationalisation of 'Open Disclosure' with Women and Families After Unexpected Harm in NHS Maternity Care

(NIHR HS&DR Project: 17/99/85)

Detailed Project Description

Summary of Research

Open disclosure [OD] is the disclosure and discussion of harm that has happened during healthcare with the affected patient or family. Since the early 2000s this practice has been increasingly advocated as a patient or family entitlement. More recently OD has also been identified as an opportunity for healthcare professionals and NHS services to learn from unexpected events of harm to improve the quality and safety of healthcare and to enhance public trust in care provision.

In the NHS, the principles of effective OD were established in the 2009 updated 'Being Open' policy framework (National Patient Safety Agency 2009). These principles now underpin the legal duty of candour that applies to all health and social care organisations (Care Quality Commission 2016). NHS providers, and particularly maternity services, are the focus of central government attention to enhance candour and learning when things go wrong in healthcare. International and national research has highlighted that OD policy is not being adhered to or the quality of OD falls short of patient and family expectations.

The barriers to improving the extent and quality of OD in healthcare are widely documented. They range from professional and organisational concerns with litigation; workplace cultures of blame and distrust; and differing perspectives on particular events of harm. Additionally, in the NHS until recently, there has been a noted lack of effective local policies and procedures to support OD and limited staff training and support. There is limited evidence of procedures to support patients or families through OD events and processes.

This study will examine how OD can be strengthened and supported within NHS maternity services, and the trusts within which these services are located. We will identify the critical factors required to improve OD in maternity services, and wider trusts, and explore the actual and anticipated consequences of these improvements. We will do this by approaching OD as a complex social intervention. Taking a realist evaluation approach to recent OD improvements within maternity services/trusts we will investigate these as interventions to understand 'what works, for whom, in what circumstances, in what respects and why'.

In Phase 1 [Scoping] we will develop initial hypotheses of the critical factors required to optimise OD by a scoping review of the literature and consultations with our project advisors. Then we will undertake an interview study with national and regional stakeholders in OD improvement (professional and organisational bodies; maternity clinical network representatives; service-user groups; Maternity Voices Partnership members; NHS patient representatives; and Freedom to Speak Up Guardians representatives) in order to refine our initial hypotheses; establish the scope of OD in maternity services and explore reasons for variations. We will also consult with our interviewees, and our project advisors, to identify those services, trusts or networks where OD improvements are ongoing and where engagement in our study would be welcomed.

In Phase 2 [Ethnography] we will use qualitative research methods in 3 purposively selected services or local maternity networks located in 2 NHS Trusts to further refine (or revise) initial hypotheses on the critical factors required to optimise OD. We will focus on the context and contingencies in which different aspects of the OD intervention is being improved or supported. We will examine how the approach to enhancing OD within the service or trust are received, interpreted and acted on by intervention recipients, particularly with respect to the actualities of OD practices. We will also explore the actual and anticipated consequences for different recipients (frontline clinicians; women and family representatives from trusts and services; practice supervisors; service support staff; directors of services; risk managers; quality or safety improvement staff). Women and families' views will be sought directly and through their representatives (such as peer-support workers; patient liaison staff and patient representatives).

In Phase 3 [Interpretation and Outputs] we will hold a series of structured meetings with hospital managers, frontline staff and women and families to discuss the findings from our study and to develop practical recommendations for NHS managers and decision makers, for clinicians and for the public. One meeting will be held at each of the case study sites (and will involve, when possible, women and family representatives). Two meetings will be held with women and families drawn from two established PPI groups (organised through the Royal College of Obstetricians and Gynaecologists, Sands, Birthrights and Birth Trauma Association). A final meeting will be held with invited national policy-makers and key stakeholder organisations; representatives from the national Maternity Clinical

Networks; Maternity Voice Partnerships and NHS organisational and professional bodies, participating services/trusts and women and families. This meeting will explore how recommendations from the study findings can be aligned with regional and national policy developments relating to OD.

Study outputs in addition to academic publications and conference proceedings will include briefing documents and guidance for service and trust managers; and support materials (short guidance sheets and video animations) for both NHS staff and for women and families on OD events and processes. A tailored approach for the dissemination of our study findings, supported by a stakeholder analysis, will ensure that the study both enhances women and families' empowerment in OD events and processes, and supports frontline and management staff with this work by providing accessible information and co-produced guidance on the ways that OD can be improved.

Background and Rationale

Principles of and Rationales for Open Disclosure

In the past decade, open disclosure [OD] – the disclosure and discussion of harm that has happened to a patient during healthcare – has been identified as important in health services. OD is now publicly recognised as an entitlement of harmed patients and families (Wu 2017). Internationally and nationally, there is in principle agreement by service-users and some healthcare professionals that harmed individuals or their families should be told when something has gone wrong and why (Iedema 2008a; Larizogitia 2013; Birks 2014). Research suggests the potential benefits of disclosure and discussion of events of harm for affected patients and families as well as for affected clinicians (Iedema 2008a). Potential benefits have been identified as reduction of emotional harm and distress caused to patients or families, and to healthcare staff involved in the event (Berlinger 2005; Iedema 2008a; Manser 2011; Dekker 2013); opportunity for learning about the event from a patient or family perspective to inform future practice or service improvement (Vincent 2016); creation of new equities in patient-practitioner relationships (Berlinger 2005); a strengthening of a service ethos of public accountability; and, ultimately, enhancement of public trust in a health service (Iedema 2008a; Glasper 2016;). The emotional impact on patients and families of absent or poor OD is now recognised as extensive and long-lasting (Bell 2018); the costs to staff and to their employers has been highlighted (Harrison 2015; Santomauro 2014). Research of OD in Australian and other international health systems notes the potential reduction in public expenditures on settlement claims and investigatory and legal processes has also been proposed (see Piper 2011).

Patients and families themselves have identified the need for services to notify them of harm done and to give an immediate and honest apology and to contribute their views and experience to a timely explanation of why harm happened, its likely effects. The need for health care organisations to take responsibility for harm done (by seeking to repair the damage or offering adequate compensation) and to show that lessons have been learned from the event is also often important for those affected (Iedema 2011a). In the NHS, these principles are established in the revised National Patient Safety Agency 'Being Open' policy framework (2009). This framework underpins the Statutory Duty of Candour (SDC) that has applied to NHS bodies since November 2014 (Care Quality Commission [CQC] 2017). This duty applies to any incident the appears to have caused, or has the potential to cause, significant harm. This harm includes events that result in unplanned surgery, service or trust transfer, hospital readmission, prolonged pain or psychological harm (that lasts more than 28 days) in addition to more serious events of death and serious harm to patients (such as permanent disability) and events defined as 'moderate harm'. However, an independent investigation of CQC inspection reports on NHS acute trust compliance to the duty found significant disparities between these trusts and identified examples of good or poor systems and practice within and across services (Action Against Medical Accidents [AMVA] 2016). This investigation also noted the poor quality of regulators' inspections of trust compliance. Subsequently, the CQC has honed guidelines on regularity inspection of acute trusts and services for compliance to this duty (CQC 2017b).

Internationally, as well as in the English NHS, there is a lack of certainty or agreement on the principles, purpose and impact of OD, from service-users and from healthcare professionals (Wu 2017). OD is often not routinely practiced and, when it is, it often falls short of both patient and family expectations and of professional or organisational guidelines (Gallagher 2006; O'Conner 2010; Iedema 2008b; 2011; Birks 2014; Harrison 2014; Carranza 2014). A discrepancy exists between what service-users say they require from OD and what clinicians as well as healthcare organisations say they provide (Gallagher 2006; Piper 2011; Birks 2014; AVMA 2016). These discrepancies result from the multiple societal, professional, procedural, workplace, financial and resourcing issues that often stymie effective OD within health care.

Barriers to Open Disclosure

Fear of litigation, by health care professionals and healthcare managers, has been widely noted as a barrier to their reporting harmful events and, particularly to their disclosing them to harmed patients and families (Iedema 2011b; Piper 2011; Birks 2014). In England and since the introduction of the SDC, a further aspect of professional concern has been emerging. Distrust between professionals and their employing organisations or service managers, who might dispute accountability, has been noted (Quick 2014). The risks of litigation involve, at the extreme, professional liability exposure and criminal prosecution. Recent adjustments in legal protection of health professionals involved in OD events include the extension of apology laws and widening orbits of 'qualified privilege' (Quick 2014). These protect the content of disclosure conversations from being used as evidence in law courts. However, these protections have to be applied and tested in particular cases, often in high-profile civil or criminal court cases and under extensive media commentary or scrutiny. Such cases as well as their commentaries evoke notable collective professional concerns about the risks of practicing OD (Cohen 2017). When managers and clinicians engage with patients and families in OD conversations they tread a difficult line between the guarding of uncertain or compromising knowledge of events (and litigation risk) and relational practices of giving information and offering emotional care (Iedema 2009).

However, it is widely agreed that litigation fears are not the only barrier to improving the incidence and quality of OD in healthcare (Iedema 2011b; Piper 2011; Birks 2014). Health care professionals might avoid OD events for many reasons. These include actual and anticipated risks of negative repercussions on relationships with colleagues as well as patients, and of harm to future employment and career progression (Garbutt 2007; Birks 2014). The emotional risks, and sometimes longstanding psychological consequences, of involvement in adverse incidents, their disclosure and their review or investigation (feelings of guilt, shame, anxiety, loss of confidence, incompetence and depression) have been found to deter OD by medical professionals (Wu 2000; 2012) and by maternity care professionals (Wahlberg 2017; Zabari 2018). The mistrust of staff in service or organisational systems that support OD processes and outcomes for future service quality and safety will also influence decisions that are seen to involve some personal and professional risk (Harrison 2014; Quick 2014).

Not surprisingly, punitive workplace values and practices, leading to fear of workplace reprisals, are associated with lower incidences of OD (Bunting 2016; Wolk 2014). Some recent commentaries on NHS reforms note a signalled shift from 'blame culture', as well as from an adversarial risk management approach to patients and families, to the fostering an ethos of openness and honesty, resolution and systems-based learning (Glasper 2016). However, recent research in the UK describes more complex and nuanced relations between workplace cultures, innovations and outcomes than those implied by healthcare inquiries and subsequent policy drives to promote 'culture change'. As recently summarised (Jones 2018), a consensual definition of 'workplace culture' is notoriously difficult to reach. Workplace culture has been depicted as how new members are inducted into the norms, values and taken-for-granted practices of a group to the point at which these become 'the way things are done around here' (Dixon-Woods 2013a). It has also been defined as 'the way things are done around here when no-one is watching' (The King's Fund 2014). Within apparently common or cohesive 'workplace cultures' a series of cross-cutting tensions over the protection of public reputation for safety and public reputation for candour can be anticipated (Wu 2017). The contingent and 'ripple' effects and negotiations of these tensions on OD – and the possible effects of OD interventions on wider workplace vales and practices has yet to be understood. Also, in less serious events, the assessment of harm in healthcare; of the effects of this harm; and of who has the right or the capacity to 'know' are informed by a series of assumptions about what the care of patients means (Gallagher 2006; Vincent 2016).

More immediate challenges to OD improvements in the NHS include the lack of developed or evidence-based training and support provision for staff (Birks 2014). Since 2017 evidence of training and staff support for OD work within each core service (including maternity) was noted in the next phase method guidance of the CQC inspection framework. There is, however, limited evidence of the scope, resourcing and auditing of necessary training and staff support structures for OD processes within NHS acute care provision. International evidence suggests the value of organisational or service investment in 'second victim' support programmes to enhance the resilience of individual professionals and healthcare teams that contribute to ongoing patient care (Wu 2017). A further reported barrier to improvements in OD are inadequate OD procedures, including inflexible procedural guidance (Iedema 2011b; Birks 2014), or inadequate audit and reporting systems (see Piper 2011). OD is particularly complicated when events of harm in healthcare are accumulative, extending over time and sometimes involving different services, organisational systems and healthcare professionals (Vincent 2016). In such circumstances, there may be complex and poorly aligned formal and informal processes and relationships that influences decisions about if, how and when to initiate OD.

The impact of service users' expectations and experiences on the ongoing incidence and quality of OD within an organisational or service has been rarely examined. Some individuals and families are reluctant to voice their suspicions of harm caused to them, sometimes fearing damage to their relationship with clinicians and so poorer care (Mazor 2012). Staff and services might not inform them that potential harm has happened until much later in their care (Hannawa 2013). Some patients or families' lack of confidence in review and investigation systems; the time consuming and emotionally challenging processes of pressing for OD, or of engaging in these processes, are factors affecting some people's insistence on candour (Hannawa 2013). Also, patients' views and experiences of what constitutes harm often differs from those established following clinical guidelines and documented in clinical records. Patients and families may also value OD for different reasons to those of clinicians and managers. Iedema (2011a) found that families and patients wanted shared dialogue rather than one-way information giving from health providers.

In sum, there is abundant evidence of the challenges to improving the incidence and quality of OD in NHS provision. Indeed, it has been noted that even if all structural barriers were surmounted, OD will always be challenging, uncertain and difficult work for those involved (Iedema 2009; Piper 2011). Nevertheless, there is a need to understand how this difficult work can be best encouraged and supported within services. Since 2017 a scattering of innovations to strengthen the implementation and/or operationalisation of OD in NHS acute care – including designated trust-level staff for DoC; 'candour guardians'; the use of specialist bereavement midwives or midwifery consultants; and parent peer-support systems following stillbirth – exist (Birks 2014; AMVA 2016; Ellis 2016). There is a need for research to establish what can be learned and generalised from these various interventions. This research needs to identify the critical factors that underpin their introduction, development, use and support, taking account of both their context and their consequences for those involved. To date there is limited evidence of how, and in what ways, the difficult work of OD can be encouraged and supported within healthcare provision, and of the various actual or anticipated consequences of OD.

Open Disclosure in NHS Maternity Care

Since the Morecombe Bay Investigation Report (Kirkup 2015) the case for involving women and families in reviews and investigations of their own harm in NHS maternity care has been increasingly recognised (see particularly Cumberlege 2016). In 2017, the Secretary of State for Health reiterated the particular need for improving the quality of reviews and investigations in NHS maternity care, and for involving women and families in these processes. The emphasis on maternity care has happened at a time when there are significant increases in the costs of childbirth litigation claims (Magro 2017) and when parent lobbies for organisational candour and accountability for harm have been influential (see, for example, Titcombe 2015). One central aspect of maternity review and investigation improvement that has been identified by the Secretary of State is communication with families, including explanation of events of harm and assurance that lessons have been learned (Department of Health 2017).

A raft of measures is being rolled out under the 'Safer Maternity Care' strategy (Department of Health 2017). They include the introduction of external investigation systems to enhance learning from some cases of severe harm (https://www.hsib.org.uk) and the local perinatal review tool development to standardise the review of perinatal deaths). These measures are expected to include explanations to, or discussions with, women or parents. Additional changes designed to both enhance the quality of incident review or investigation practices – and to foster public trust in them - are reforms to professional training and registration criteria (Glasper 2016), the ongoing introduction of the Medical Examiners system (https://improvement.nhs.uk/resources/establishing-medical-examiner-system-nhs/) along with the proposed strengthening of CQC inspection criteria (as noted above) and the proposed plans (in consultation) for coroners to investigate stillbirths (https://www.gov.uk/government/news/new-powers-to-investigate-stillbirths)

Within this busy landscape of high-level policy drivers - designed to enhance openness, honesty and 'systems-learning' - maternity providers and family support groups need to organise for responding to these measures. There is a need for evidence to understand how the implementation and operationalisation of OD can be improved by maternity providers both in relation to the raft of national innovations (that address some of the most serious events of harm) and to the ongoing care of the wider population of patients who are protected by the SDC.

Evidence Explaining Why This Research Is Needed Now

The need for healthcare organisations to foster and support practices of OD in healthcare is now widely recognised, nationally (Birks 2014; AMVA 2016) and internationally (Wu 2017). In the UK, this responsibility is now a legal requirement, subject to regulatory inspection (CQC 2014). Recent reviews and NHS guidance highlight missed opportunities for professionals and managers to learn from avoidable harm to patients. The limited opportunities available to patients and families to either understand what has happened, or to contribute to this understanding, has also been noted (Redshaw 2014; Shah 2017; Magro 2017).

Despite the recent government policy emphasis on the value and benefits of OD, there is a very limited evidence of how OD can be improved and supported by NHS providers (at trust and service levels). The 2017 CQC inspection framework for NHS acute hospitals, core services (including maternity), requires sector specific evidence of the Duty of Candour as recorded in incident investigations and in processes and procedures to support DoC (training, staff support, policy and audit). Since 2015 NHS maternity services have been at the forefront of government policy initiatives to improve local reviews and independent investigations of serious harm to women and babies, and to improve communication about, or explanations of, harm to those affected (National Quality Board, NHS England 2017; Royal College of Obstetricians and Gynaecologists [RCOG] 2017). Research studies highlight the overall limited incidence of OD in maternity care: only 7% of local reviews of a baby's death involve parents (Kenyon 2017) and only 15% of local reviews into severe harm of a mother involve her or her family (Shah 2016). The ongoing gap between what women and families expect from OD and how they experience this has been highlighted after stillbirth or the death of a baby (Redshaw 2014; Bakhbakhi 2017). Since 2017 OD practices and standards in NHS maternity services have been driven by regulatory frameworks and, in some cases of severe harm, by external case-by-case investigations and by the standardisation of some local review tools. Improvement, possibly leveraged by the standardisation of incident reviews and investigations, is expected to involve the introduction of new mitigation and resolution strategies. These are expected to reduce the excessive costs of litigation and settlement for harm within this service (Shar 2016; Magro 2017). Improvement in the reduction of avoidable and serious incidents in maternity care is now an NHS priority with maternity claims equating to 40% of the £1.1bn paid by the NHS in 2016 and escalating to 50% in 2017 (Magro 2017).

Our focus on NHS maternity provision will contribute to learning about OD beyond NHS maternity provision in two ways. First, we approach our project as a case example of a series of generalisable challenges to OD that arise from the particular characteristics of maternity service use and service organisation. Here events of harm often involve complex and episodic care pathways that involve multiple professionals with contested views of risk and hazard. Moreover, women and families are often astute observers of their own safety (Sandall with Rance 2013; Sandall with Rainey 2015). Investigation of the challenges of OD in maternity services and, more importantly, of some interventions that have sought to negotiate them, will be relevant for non-maternity managers dealing with some of these problems. Additionally, OD in a local maternity service is likely to involve policies, procedures and practices that extend beyond this service and that interconnect with the wider trust, other service areas (such as A&E), and other organisations (such as the ambulance service).

The research will add to work in this area by identifying the critical factors required for the strengthening OD in maternity services in the UK but will also have international relevance. As far as we understand there is no research focusing on how OD improvements can be made in NHS service provision or of the consequences of improvement. As we have noted, while the barriers to OD have been extensively documented, the question of how, why and how far some services or trusts are managing to have negotiate these barriers to improve OD policies, procedures and practices has yet to be answered. Our study will seek to answer this question and, in so doing, will establish the generalisable critical factors for improving OD in NHS maternity services and trusts.

There is documented and reported evidence that OS improvement work exists in NHS acute trusts and maternity services (AvMA 2016; Ellis 2016; Professor G. Martin, personal conversation December 2017) however the organisation and consequences of this work is not understood in-depth. Our study will be of significant strategic importance to NHS maternity services, and to women and family groups, providing evidence of the organisational, service and team requisites for implementing, supporting and resourcing OD. By focusing on maternity services and trusts where improvement efforts are ongoing, we will examine why and how OD improvements might be happening here, and the possible or actual intended consequences of this improvement work for different participants.

Study Aims and Objectives

Aims:

The research will address the overarching question ‘what are the critical factors that can improve the incidence and quality of Open Disclosure in NHS maternity services?’. We will ask what the actual or anticipated consequences of these improvements are likely to be for different participants and in what contexts. The main aim of the study is to generate actionable evidence to inform maternity providers and the trusts in which they are located on how to strengthen Open Disclosure in NHS maternity services. A further aim of the study is to co-produce outputs (including support materials for women and families and for frontline staff and managers; and practical recommendations for NHS organisations) to support the improvement of OD for the benefit of women and families; clinical teams and the quality and safety of maternity care.

Objectives:

OBJECTIVE 1: To establish initial hypotheses to focus the realist investigation of Open Disclosure improvements in NHS maternity services; METHOD: Literature review and stakeholder consultation on OD interventions in maternity care (Published as an output); MONTHS:1-12

OBJECTIVE 2: To establish the scope of OD in NHS maternity services in England. METHOD: Telephone interviews of National and Regional Stakeholders (n=18). MONTHS: 7-21

OBJECTIVE 3: To refine our initial hypotheses and conduct stakeholder analysis with national and regional stakeholders. METHOD: Telephone interviews of National and Regional Stakeholders (n=18) MONTHS: 7-21.

OBJECTIVE 4: Conduct In-Depth Study of OD improvement interventions. METHOD: Comparative ethnographic case studies. MONTHS 22-30.

OBJECTIVE 5: Conduct data interpretation and study output development with stakeholders. METHOD: Interpretive Forums. MONTHS: 29-36.

Research Plan/Methods

Design and Conceptual Foundations

We will approach Open Disclosure [OD] improvement as a policy-led, complex intervention undertaken in services, trusts or networks in the expectation that incidence and/or quality of OD will be improved. These improvements might be the introduction of OD procedures into established or recent incident reporting systems; the development of specialist professional roles or peer-support interventions. Complex interventions are difficult to implement and evaluate in part because they are composed of many elements. Each element might involve a range of activities and interactions that extend across and beyond actual incidents of OD. These interventions are likely to include a range of team, service, organisational or extra-organisational priorities. It is known that there are significant disparities in OD practices, and in interventions to improve OD, across the NHS (Birks 2014; AVMA 2016).
A realist, theory-driven approach (Pawson 2006) will inform the study design. The aim of realist evaluation is to understand when, how and why a programme [in this case Open Disclosure improvements] produce effects for different participants (Kirst 2012). Realist evaluation asks, 'what works, for whom, in what circumstances, in what respects and why?' (Pawson 2012). Our approach tackles this question by identifying the critical factors (in realist terms, 'mechanisms') that produce – or do not produce - different effects for different participants. Using this approach to understand when, how, why and for whom OD improvements have effects, we will examine the consequences of different OD improvements for those involved (for example, women and families; individual staff and staff teams; different professionals; risk managers; quality and safety improvement leads in units, services and trusts, patient liaison services).

Realism, as developed for use in health service research, examines the interaction between a complex social intervention or 'programme' (such as a policy implementation, a program of work or an operational system), the context in which it is implemented in everyday practices, and the intended or unintended outcomes that are produced for different participants (Wong 2013). The approach recognises the non-linear and contingent qualities of interventions and their effects and seeks to understand patterns of failure as well as success (Pawson 2004). A key aspect of a realist approach is the identification and development of a working theory or initial hypotheses (in realist terms, 'preliminary programme theories') of how interventions have effect. One or more initial hypotheses will be identified, refined, reworked or challenged in the course of iterative data collection. Initial hypotheses are identified by literature scoping and, significantly, in discussion with different topic experts. The point of hypothesis development is to establish some common principles by which particular improvements might generate effects, how, for whom and in what circumstances.

The focus of a realist evaluation is not to understand how singular interventions generate effects, but to identify the critical factors (in realist terms, the 'generative mechanisms') that produce effects in particular circumstances (Pawson 2012). A realist evaluation is likely to generate a series of interconnected hypotheses on the critical factors that drive and direct improvements in the quality and incidence of OD work within maternity services, and more widely (Rycroft-Malone 2015). As described above, a realist approach involves the identification of an initial or working hypothesis by literature scoping and discussion with experts. This initial hypothesis draws from one or more middle-range theories (such as behaviour change models; or strategic or operational change models). For our study, we anticipate that we will use a theoretical approach that guides an in-depth investigation of the socio-structural contingencies and cultural qualities of work and the workplace to understand how front-line staff and service managers interpret and enact the values, risks and benefits of OD improvement work and OD practices.

Normalisation Process Theory (NPT) (Murray 2010; May 2016) may offer a useful theoretical lens to guide hypothesis development. This is because NPT is a sociologically informed approach that attends to how and why different individuals and collectives are motivated (or not motivated) to implement as well as to establish practice change (May 2018). NPT focuses attention on the anticipated and felt effects of interventions on front-line recipients; on the work, skills and commitment required of them to accommodate, operationalise and legitimate such interventions; and on the service and organisational investments required for these staff contributions. NPT would allow in-depth focus on the perceived 'workability' of OD interventions and OD practice (and the possibilities for it to become part of routine care practices); on the required organisational social support and resourcing of OD work; and on the influence of workplace norms and professional roles on OD practices and their value.

We also anticipate that our literature scoping and discussion with experts will require us to consider the impact of wider social and professional debates (such as those relating to legal privilege and legal risk) on OD improvement work and OD practices. An Institutional Logics approach (Thornton 2015; Anderson 2015; Harris 2015) might guide our identification of these emergent issues. This approach focuses attention towards understanding how public beliefs and social values shape attitudes and practices in the workplace. Depending on our literature scoping and discussion with experts, was may use an Institutional Logics as a theoretical lens for understanding how various social valuations (such as assumptions about professional expertise or vulnerability; the nature and effects of organisational efficiency;

the significance of public accountability or of patient or family entitlement) are evoked as organisations, services, teams and individuals negotiate OD improvement work. We also expect to draw on theories of trust decline in contemporary healthcare and healthcare relationships (Taylor-Gooby 2006; Calnan and Rowe 2007). We will also seek to enrich 'second victim' research (Wu 2012; Dekker 2013) by situating these debates about workplace practices and relationships and notions of resilience.

Our study plan is structured according to realist evaluation principles (Pawson and Manzano-Santaella 2012).

- In Phase 1a we establish our working hypotheses by literature scoping and in consultation with experts (the members of our project advisory group).
- In Phases 1b and 2 we refine or begin to question and revise these hypotheses in the light of our iterative analysis of interview and ethnographic findings.
- In Phase 3 we work with different interest groups and experts to collectively examine how our data and hypothesis informs understanding of the critical factors required for OD improvements, and to explore the generalisability of findings across NHS maternity care and NHS care.

Study Plan and Methods
The 27-month study uses a multi-methods qualitative design organised in three phases.

Phase 1: Scoping: **(Months 1-21)**

Phase 1a. Theory Building (months 1-12) **[to meet Objective 1]**
This phase is to generate initial hypotheses of what critical factors might be required for OD improvement; what factors will influence the effects and consequences of OD; and how OD 'works' (or does not work) for different participants. The hypotheses generated will be organised and developed using conceptual frameworks drawn from Normalisation Theory, an Institutional Logics approach, and wider sociological approaches to explore perspectives on second victims; trust decline in healthcare relationships; and team and organisational resilience.
Following realist methodology, we will develop our initial hypotheses by scoping the literature and by stakeholder consultation. Some members of the research team (JS, RI and MA) are already undertaking a realist synthesis of OD interventions in generic healthcare settings and in maternity (JS). The literature review for this study will be on OD interventions in maternity care. Literature will be identified from social science, nursing and medical and health service management electronic data bases. Scoping searches will help with the identification of key words, synonyms, spelling variations. Searching will include both free text and database-specific subject headings (such as MeSH terms); use of advanced Boolean truncation; 'explode' and other techniques. Library and information specialists at KCL will advise the team on relevant search terms and key word revisions and additions. We will supplement the data base search with additional 'snowball' strategies, relevant papers will be scanned for reference list and citations to extend our search and requests for advice from subject experts.

Following realist methodology, we will have no specific pre-determined inclusion and exclusion criteria in terms of research methods or quality. We will, however, report on areas of study design and evidence weakness. Grey literature, including that relating to policy, service reports and public and professional commentary on OD in maternity services, will be retrieved. We will limit our search to English language documents. We anticipate that the overall volume of papers retrieved will be under 50 documents. Since the purpose of the review is descriptive, if a larger number of papers are identified we will select those most relevant to our study aims and objectives. We will identify papers and documents that are relevant to OD description and evaluation in maternity services; OD implementation or improvement strategies; the experiences of staff, managers, policy makers, harmed women and families and the public in the implementation, organisation and practice, or observations of OD. The abstracts of all identified papers will be screened for suitability; two members of the research team will screen all potentially relevant papers. A structured data extraction form will be used, and the completed data extraction forms will each be examined by two members of the research team. We will appraise selected documents following RAMESES project guidance.

We anticipate that the data extraction form will document for each paper:

i. literature item (and, if relevant, study methods, design and sample size)
ii. the context of the OD work/OD intervention (national/regional policy setting; regional or local service setting(s)
iii. details of the OD intervention (intervention components along methods of organisational, staff and family involvement and support)
iv. outcomes (such as family and staff experiences of OD process) and unexpected effects
v. factors that have supported, inhibited or reshaped the intervention during its implementation and actual use.

A thematic analysis will be conducted on the extracted data in order to build a series of pictures of likely critical factors that influence the strengthening of OD in maternity care and the consequences of this for women and families, staff and services/organisations when these mechanisms are and not present.

We will hold one face-to-face meeting, with telephone conversations as required, to consult our project advisory group (PAG) that comprises a range of academics, policy-makers, patient and public advocates and front-line professionals to seek their views on the critical factors that are likely to challenge or support the strengthening of OD in NHS maternity care [in month 2].

The data from literature analysis and this stakeholder consultation will be synthesised to develop:

1. initial hypotheses on what the critical factors that underpin OD in maternity services might be, in what circumstances, to what effect and for whom. These hypotheses will be 'tested' (refined and possibly overturned) in Phase 1a and Phase 2 of the study.
2. an interview topic guide for Phase 1b. The interview topic guide will be piloted with two research-active maternity managers who are not connected to the study. Piloting will ensure that the topic guide encourages in-depth responses to questions and still addresses realist evaluation objectives.

Phase 1b: Telephone Interviews of National and Regional Stakeholders (months 7-21) **[to meet Objectives 2 and 3]**
The Phase 1b (interview study) research will:

i. build a national picture of the scope of OD in NHS maternity services (from perspectives of national leads in professional and NHS organisational bodies; maternity clinical network representatives; service-user groups; NHS patient representatives; Freedom to Speak Up Guardians representatives; Maternity Voices Partnership leads; service-user activists with a national profile).
ii. explore with interviewees our different perspectives and experiences of OD so that initial hypotheses on how, when and for whom OD works (or does not work) can be refined.
iii. assist with identification of OD intervention sites for sampling for Phase 2.
iv. conduct a stakeholder analysis to understand stakeholder interests and to inform the research impact plan.

Method
One-to-one, semi-structured audio-recorded telephone interviews [n=60] will be conducted with

(a) national groups and networks with a significant stake in OD in maternity care [representatives of different parent action groups; professional bodies; NHS, research and audit bodies] [n=43]
(b) regional and national leads whose work more directly overlaps with OD issues (e.g. maternity safety or women and family experience or complaints) located across the 12 Maternity Clinical Networks] [n=17].

We will structure our interview guide following realist evaluation principles. The purpose is to explore participants' views and experiences of an intervention. This includes asking interviewees about the initial hypotheses being used in the study and focusing their explanations and reflections on what they think works within an intervention, in what sorts of ways, when and for who. It is expected that a series of interviews, will capture varied perspectives and experiences on OD in different service settings and conditions (Manzano 2016).

Given this approach our topic guide will be developed on the basis on our Phase 1a. findings and may accommodate significant emergent findings from previous interviews undertaken during Phase 1b. However, we expect to collect interview data on:

- the implementation and ongoing improvement in OD policy, procedures and practice within NHS maternity provision (how this is structured and resourced; supported, audited and reported)
- if and why there are variations in OD quality and quality improvement between services, trusts and regional networks.
- the consequences of new national policy measures to increase OD in maternity services
- the actual and anticipated consequences of OD within maternity provision (for example, for women and families, staff and services; for service ethos; on complaints and compensations; reputations; staff wellbeing)

Sampling
Phase 1b. study participants will be identified by snow-balling though our co-applicant and advisory group networks and approached by research team to ask for an expression of interest in the study and study participation. Our PPI co-applicants and study advisors will support the identification of service-user groups and networks who will then be approached by the researchers who will give them further study information.

Data Collection and Analysis

With interview participants' consent, interviews will be digitally recorded and transcribed verbatim, in preparation for analysis. The realist interview data will be analysed using a framework approach, a method that involves the systematic analysis of verbatim interview data within a thematic matrix (Spencer and Ritchie 2003). Following familiarisation with the interview transcripts, emergent themes will be identified and explored in relation to our initial hypotheses of the critical factors that support OD improvements, to what effect and for whom (as identified in Phase 1a). Phase 1b data analysis and integration will allow us to refine our understanding of these critical factors, particularly those relating to extra-organisational structures, processes and relationships.

Depending on the interview findings, we may use cross-tabulations and scattergrams to examine the relationships between apparently anomalous aspects of some areas of OD implementation or operationalisation and other variables (such as distinctive service or organisational histories, resourcing agreements or public involvement in OD implementation work). We will also conduct a stakeholder analysis using the RAPID AIIM matrix (Mendizabal 2012) that will assist in mapping each participants' position in relation to their interest in, and influence over, OD improvements at regional and national levels. This approach will help us to understand the span on interest and influence in OD at local organisational and national (organisational and policy). Our findings might also inform the tailored dissemination of study outputs.

Phase 2: Ethnography (months 22-30) **[to meet Objective 4]**

In this phase, we examine a selection of services, trusts and/or networks where interventions for improving or supporting OD are ongoing. Three ethnographic case studies will be conducted in two NHS Trusts to further refine or to revise our initial hypotheses on the critical factors that shape the implementation and the actual practice of OD work. Through the case studies we will examine, more directly, how different contingencies shape ideas and practices of effective OD, and the various consequences of these ideas and practices for women and families, front-line staff and services.

Ethnography is an approach most suitable for understanding the context and practices of healthcare and healthcare relationships, and for eliciting the situated and often taken-for-granted qualities of these practices, their negotiation and legitimation (Leslie 2014). It is a key aspect of successful design, implementation and evaluation of interventions in healthcare delivery in terms of local viability (Dixon-Woods 2013b; Iedema 2013). A case-study approach will provide detailed data that enables the comparison of the implementation and operationalisation of complex interventions in actual settings where the relationship between context and the activities of individuals is particularly dynamic, and where competing demands as well as values are in constant negotiation.

Each case-study will be undertaken on a face-to-face basis completed over 36 weeks (at 12 weeks per site). Between these visits the researchers and study team will meet to discuss emergent findings.

Case study Focus

We will approach OD improvements as a dynamic and generalisable process rather a series of fixed steps or stages. Therefore, we define OD implementation and actual practice pragmatically. For each case study (networks, unit, service or trust) we will trace the implementation, operational realities and actual and anticipated consequences of OD. Our initial hypotheses and their refinements or revisions will guide the comparative case-study focus. However, we will include investigation of:

- OD policy and procedures as promoted, managed and monitored as well as interpreted and evaluated by recipients (along with the challenges and opportunities to this)
- factors that influence the 'when and how' of OD as it is enacted and experienced in actual clinical settings by different participants including women and families, front-line professionals and administrative staff, risk teams, service and organisational managers.
- how OD interplays with aspects of formal and informal local workplace cultures and wider public and policy debates; and personal, team and service histories including its potential to effect revisions wider revisions in user-service relationships as OD (or some aspects of) becomes 'normalised'.

Sampling

Due to the sensitivity of the research topic for frontline staff as well as for services and trusts, and the anticipated challenges of organisational engagement in some trusts, services and networks, our sampling frame will follow Stake's (2013) principles:

(a) maximise chances of ongoing engagement of participants in the research
(b) provide diversity of cases across contexts
(c) ensure that all cases provide good opportunities to learn about complexity and context

We will only sample those services, trusts and networks identified as potential case study sites during Phase1.

We will sample these potential case study sites for maximum diversity at NHS trust level and at NHS service level that can be established using two public data sets with benchmarked scores:

- Trust-level scores on Transparency: 'Learning from Mistakes League'. This data set reports annually on variations between all NHS acute trusts (from outstanding levels of openness and transparency [level 1] to poor reporting culture [level 4]. This data set is established from selected metrics from the annual NHS staff survey and from the National Reporting and Learning System.
- Service-level scores from the annual NHS staff survey, '*Reporting on 'Errors and Incidents', selected items* [KF 29; 30;31] (see Box 1)
  These key findings are benchmarked against others trusts and for different locations [or divisions] within that trust. Women's Health is one location. Therefore, we will be able to establish a comparative picture of how staff experience incident investigation, across and between our listed sites in Women's Health and listed acute trusts.

Box 1: 'Errors and Incidents': items from the annual NHS staff survey (by trust and location)

Survey Item	**Error and Incidents: by Trust and by Trust Location (Women's Health)**
KF 29	staff reports of errors, near misses or incidents witnessed in last month (percentage score)
KF 30	staff reported fairness and effectiveness of procedures for reporting errors, near misses and incidents (scale summary score)
KF 31	staff reported confidence and security in reporting unsafe clinical practice (scale summary score)

After selecting 'highest' and 'lowest' performing services or trusts in relation to these public data sets, we will seek to select for maternity service type. We will seek to identify two tertiary and two non-tertiary units to be our organisational case studies. The rationale for this distinction are evidence-based differences in women's clinical needs or birth complexity, unit capacity and resourcing, team working; consultant presence and trainee development (Reid 2018). If necessary, we will also select for maximum variation between potential case studies by service and trust size and by regional location.

Recruitment Strategy

We will adopt a series of approaches to enhance service, trust and/or network recruitment in the Phase 2 research (ethnographic case-studies). These include:

1. <u>our sampling strategy for the potential case study sites</u>:
   The identification of any site for potential recruitment will be on the basis of their already being active in the strengthening of the implementation and/or operationalisation of Open Disclosure in NHS maternity care and on the basis of their likely interest in engaging with the study team (as identified by Phase 1b. interviewees and our PAG). We will therefore ensure that, prior to our sampling for diversity or context, we have sampled to maximise our chances of ongoing engagement of services, trusts and/or networks in the study.
   In addition, we will identify potential sites by internet including deepweb searches. These searches will assist in our closer identification of maternity safety and learning 'candour' collaboratives or working groups (for example, as developed in the Health Innovation Networks or as supported by local NHS staff or parent/ maternity support groups).
2. <u>use of a recommended framework for enhancing study participant recruitment:</u>
   We understand that the recruitment of organisations and networks, as well as of those who work within them, is a multi-layered process. We will draw on McDonald's (2011) adapted business-model approach to recruitment to inform our recruitment plan. We will undertake:
   (i) Early and widespread familiarisation of the research project (the study question, along with the ongoing promotion of study value, legitimacy and potential benefits) across NHS maternity services. We will initiate promotion of the study (and of the senior researchers involved) from study start date. This promotion will be established and sustained through social media (twitter; a project blog and, on the advice of our PAG, a study update newsletter) until project completion. Prior to Phase 1, and after the study has been contracted, our study team and PAG will be encouraged to 'spread the word' on the research through regional and national networks. This familiarisation and ongoing promotion will be underpinned by a simple message of 'what the study stands for' and how it can be recognised.
   (ii) Early identification of potential case study sites. We will be anticipating potential sites throughout the Phase 1 research. This will include establishing short 'case study' profiles to aid us with sampling following Stake's (2013) case study sampling principles as well as by making early contact with potential sites through gatekeepers identifiable on public websites. These initial contracts (and a response after one email contact and one email reminder) will aid our assessment of their interest in potential participation.
   (iii) Anticipation of multiple dimensions of recruitment: we are aware that access to services, trusts and/or networks will require successful engagement with multiple sponsors and gatekeepers, both formally and

informally. We will use tailored messages to engage different interest groups (for example, the potential benefits of involvement in the study for patient representatives will differ from those for a group of junior clinicians or managers). We will also identify the range of influential sponsors, champions and change agents within potential case study sites to enlist their ongoing support.

(iv) Assurance to potential participants (organisations and individuals) of the scope and limits of the research across and within case study sites. Macdonald (2011) highlights the necessity of clarifying the expectations of organisational participation and of the scope and limits of the research to be undertaken to all gatekeepers. This will be particularly important for the ethnographic case-studies as participants or gate-keepers will be concerned that they may have less control over information shared through survey or interview methods. We will reiterate in all communication materials, that our observations are focused on the contexts and routines that make OD possible and that we will not be expecting to observe actual OD meetings with women or families (see case-study methods described below). We will not be recruiting women or families from the case study sites as study participants.

(v) Emphasis on the actual and potential benefits of research participation to key gatekeepers as well as to individual study participants. We are assuming that there will be some reluctance of some potential participants to engage with this study topic. However, we have sought to enhance to benefits to participants by our study design (Phase 3 offers opportunities for networking, social interaction and sharing experiences both within the sites, from our Women and Family Forums and from our Summative Interpretive Forum). Our communications will highlight these opportunities.

(vi) The engagement of staff as potential and actual research participants will be facilitated by short presentations of the study and key study messages by the researchers at local unit meetings in different service areas; by identified quality and safety improvement champions and by snowballing through clinical or project teams. The ongoing development of ongoing research relationships, with two named and experienced health service ethnographers, will further support recruitment processes.

Case-study Methods

In each ethnographic case study, we will use:

1. **Focused Observations** [estimated 25 hours] of events and routines intended to secure OD improvement, and of events and routines that are likely to influence this (e.g. accessible incident reporting routines; quality and safety improvement events; relevant service, unit or team meetings; training activities; promotion and publicity work). Observations are likely to attend to the settings and social relationships that shape these situations and practices; views and values expressed formally and informally in relation to OD and the roles and positions of different staff as well as patient or family representatives in these events. Observations are not expected to include actual OD meetings with women or families and clinical or organisational representatives.
2. **In-depth Return Interviews** with 12 staff [at two time-points] with a maximum variation sample of clinicians; staff and patient support personnel (e.g. Patient Liaison Services; Occupational Health; HR); patient safety and quality improvement leads (service and trust); practice support supervisors; specialist personnel in disclosure (e.g. bereavement and consultant midwives; peer supporters) involved in OD. In the development of patient and staff information, interview guides and interview techniques, the researchers will follow current guidance on interviewing people about potentially sensitive topics or traumatic experience (Rakime 2011; Razzaghi 2018) and will seek specialist advise within our PAG.
3. **Documentary Data** such as redacted meeting minutes, action plans organisational and service bulletins, new archives; training reports; and quality and safety improvement reports to construct a retrospective picture of OD work within that network, service, unit or trust

Data Collection and Analysis

With participants' informed consent, in-depth interviews will be audio-recorded on encrypted devices and transcribed verbatim. The observational data will be recorded as low inference field notes in notebooks and later word processed. Encrypted audio files will be stored on university computers or encrypted portable devices. Transcripts will be analysed at the point of transcription. Any printed material containing personal information will be stored in a locked cabinet on Kings College premises. Data from documents, interviews and observations will be analysed in a triangulating fashion to develop concrete descriptions of the different factors, contexts and contingencies that foster and shape OD interventions and their various outcomes and effects. We will approach our data iteratively, reading and re-reading our transcripts with the intention of refining or developing (or undermining) our hypotheses. We will draw upon NPT and IL theory as we iterate explanations from our data.

Ethnographic Case studies will be undertaken in person (face-to-face).

In-case analysis and then cross-case comparison of the Phase 2 data will help us to establish how some critical factors may be fostered or sustained in different contexts and contingencies and produce different effects and outcomes (Rycroft Malone 2015). We will seek to identify convergent and contradictory evidence within and then across the three cases. Coding and data management will be aided using qualitative data analysis software, Nvivo (version 10).

Phase 3: Interpretation and Outputs (months 29-36) **[to meet Objectives 5 & 6]**

This study phase is to use our findings to work with hospital managers, frontline staff, women and family support personnel and representatives, and women and families themselves. With them we will enhance our understanding of the critical factors that support OD and to co-develop practical recommendations and actionable guidance for strengthening OD implementation and practice. We will organise and facilitate up to 7 interpretive forums to achieve this. The interpretive forum approach is underpinned by the principles of reflective learning and will support a collaborative process of reflection and encourage the active engagement of participants in different systems of value and meaning (Argyris 1993). Therefore, these forums will bring together stakeholders with different views on the key research findings and encourage their translations of findings into actionable outputs.

Sampling

One forum will be held in each of the selected case study sites [n=3]. They will involve frontline staff, managers and, where possible, women and family representatives from within the service and trust or network. Dedicated women and parent forums will be held for women and parents recruited through the already established women's groups run through Sands, Birthrights, the Birth Trauma Association or the Royal Colleges [=2]. One summative forum will be held for a stratified sample of representatives from Study Phases 1b and 2 and from the previous 6 forums; from the women and parent forums; national policy makers and commentators on OD work; policy-makers and influential organisations (e.g. the AvMA and the Health Foundation); and representatives from the national Maternity Clinical Networks and NHS organisational and professional bodies. The event will be hosted through the Department of Women and Children's Health at KCL. We will also ensure wider consultation of the interpretation of study findings through ongoing online forums (for example Maternity Outcomes Matter closed Facebook site for women and families) and by email correspondence (with the PAG and our Stage 1b study participants)

Data Collection and Analysis

All interpretive forum discussions will be audio-recorded and transcribed verbatim. These transcripts will be analysed thematically and in relation to our findings. Thematic analysis will further inform our understanding of the critical factors, contexts and contingencies) that foster and shape OD, and its consequences. An external facilitator will assist the research team at the summative forum. Also, the commissioned film producers will attend the women and family forums (if acceptable to participants) and the summative forum. This is for their development of the focus and narrative for the animation film storyboards. We will allow a 3-week window prior data analysis of the summative forum to allow for wider consultation of the interpretation of study findings through online forums (e.g. Maternity Outcomes Matter closed Facebook site for women and families) and by email correspondence (with the PAG and our Stage 1b study participants) NB: Throughout the study we will follow the MRC/HRA guidance 'GDPR and Data Protection Act 2018: key facts for researchers'.

Dissemination and Projected Outputs

Dissemination

A range of dissemination approaches will be used to target different research audiences. It will be supported by our Phase 1b stakeholder analysis. The development of a tailored strategy for the dissemination of research findings will ensure that the study findings are accessible to different groups of recipients.

We will produce a final research report for the NIRH journals library detailing the work undertaken and including an abstract and executive summary focused on results/findings. This will be suitable for separate use as a briefing document for NHS maternity service and NHS managers. We will prepare a set of 10 PowerPoint slides presenting the main research findings and designed for us by the research team, the PAG and others in disseminating the study findings. The report and slides will be available on the HS&DR programme website and we will promote this availability through professional and organisational networks (twitter; updates through the South London and Greater Manchester CLAHRCS, the RMN and RCOG, Maternity Clinical Networks, NHS Improvement, and NHS Resolution) We will prepare at least two high-impact publications (one focused on the implications of OD improvements for maternity and patient safety and quality practitioners and one aimed at academics interested in OD structures, processes and practices). Abstracts of findings will be presented at national and international conferences related to safety and quality improvement in maternity services and health services (e.g. Health Services Research Network; International Society for Quality in Healthcare (ISQua); and Women's Voices conferences).

We will produce up to three academic publications in high-impact, peer-reviewed journals.

Press releases will be sent to the Health Service Journal and to health correspondents in the national media. Short articles will be prepared for release to the healthcare professional and NHS management press and we will work with our public communications leads at Birthrights, the Stillbirth and Neonatal Death Association (Sands), the Birth Trauma Association, Tommy's Charity, the University of Manchester and King's College London to enhance public awareness of the research findings through interview and/or commentary in the general press.

We will host a summative forum with key stakeholders from the three study sites; PAG members; and policy makers will be an important event for both the dissemination of findings as well as mutual learning and network building, within the field of maternity safety and quality improvement and beyond. The three forums in the case-study sites will also promote dissemination and mutual learning both within and beyond each maternity team, service, network or trust.

Two video animations (each of 4-5 minutes), one targeted at maternity providers and one targeted at women and families involved in OD, will be commissioned to convey main study messages. These will be produced by WOVENINK, and company experienced in producing films dealing with sensitive subjects in maternity care. With research participant's permission, the producers will attend the two forums for women and parents and the summative forum. These films will be available through links on the King's College London, Tommy's Charity, Birthrights, the Stillbirth and Neonatal Death Association (sands), the Birth Trauma Association websites. Links to the study report and the animations will be made available to all study participants and through social media (LinkedIn, Twitter and Facebook Groups, such as the MOMS group). The animations will also be shown by the study team at dissemination events. Professor Sandall has previously used films successfully in previous research.

Findings will be shared through wider NHS bodies (such as NHS Improving Quality; NHS Contact, Help, Advice and Information Networks (CHAINs)), NHS networks, patient organisations (such as the Patients Association, National Voices, the Campaign Against Medical Accidents (by PAG)) and staff support organisations (such as Public Concern at Work). We will also engage with organisations with a strong interest in policy development for healthcare safety and quality (e.g. Kings Fund; The Health Foundation; Point of Care Foundation).

Outputs

Outputs will be robust and actionable evidence about the organisational strategies, and team, service and network practices that can support and enhance the quality and extent of OD within NHS maternity care and wider NHS care provision.

Study emphasis is on the co-development of outputs so that different interests, values and subject positions can be negotiated and better aligned. The approach reflects current policy emphasis on participatory approaches to healthcare service quality and safety improvement. This emphasis on co-development is supported by:

(a) a multi-disciplinary and multi-sector research team (including experts from different women and family support organisations)
(b) use of interpretive forums for making sense of study findings. In these forums research participants with different experiences and interests will work with the researchers to both develop practical and generalisable recommendations for OD improvement, and together decide on what critical factors for OD improvement will be included in training and resource materials
(c) active collaboration with an extensive and varied Project Advisory Group (PAG), including their involvement in the summative forum.
(d) strategic organisation of PPI representation within and across the research team and the SAG to ensure effective and ongoing voice throughout the study.

Tailored and co-produced outputs will be:

- Local service/trust forums and a summative forum to support extensive contribution to, and learning from, the study findings.
- Briefing documents and guidance for maternity service managers and policy-makers that will include findings on the progress of OD improvement in NHS maternity provision and identification of the critical factors required to support this.
- Support materials (short guidance sheets and video animations) for NHS staff and for women and families who are involved in or might be involved in OD events and processes.
- in-depth understanding of the process of OD improvement and the mechanisms and contexts by which they are effective for different participants and in terms of their actual or potential impact on the safety and quality of maternity care. These findings will be available for the future planning and commission of on-line support tools for women and families and of training materials for staff teams.
- Accessible public information and ongoing lay summaries about the progress and findings of the research through a monthly blog and dedicated Twitter account
- Peer-reviewed academic journal articles (e.g. BMJ Quality and Safety; Implementation Science) and health professional and service user journals (e.g. HSJ, Midwifery, Women and Birth).
- Presentations at NHS and academic national and international conferences
- Final HS&DR report
- A summary of findings sent to all study participants who have consented to receive this information.

Our research plan is underpinned by all RCUK identified factors that help to generate academic and societal impact. The research will enhance the evidence base for improving the use and quality of OD in NHS maternity care, influencing policy and practice; produce theoretically informed knowledge of the critical factors for fostering, enhancing and sustaining OD; and will support the growth of networks and knowledge exchange between NHS maternity providers, women and family interest groups and associations, OD policy-makers and non-maternity NHS providers.

Overall, the study will contribute to improvements in the NHS safety and care quality agenda within, and beyond, maternity services and at three different levels:

- micro-level of OD practices, interactions and processes (the production of accessible guidance in text and video format for improving service-users' and staffs' experiences of involvement in OD
- meso-level of service management and organisation (documenting management responsibilities for OD systems and processes, and the factors that facilitate or undermine the involvement of women and families in OD, both for their own learning and for organisational learning)
- macro-level (policy and public drivers) that shape, and might be shaped by, OD implementation and actual practice in NHS maternity care and other NHS services.

Plan of Investigation and Timetable

Table 1 outlines our plan of investigation and reporting. A concise summary of the plan of investigation for the study, by study phase [SP], is:

- SP1a (months 1-12): develop initial hypotheses (documentary evidence reviews and consultations with PAG members. Apply for Integrated Research Application System (NRES) and apply for R&D approval in one NHS organisation who will act as study co-sponsor.
- SP 1b (months 7-21): telephone interviews with national and regional leads and associations [n=60] to establish a national picture of scope OD in maternity services/their trusts; short-list, sample and invite services for comparative case study; complete and submit NRES draft with R&D approvals for SP2 study.
- SP 2 (months 22-30): three ethnographic case studies in two NHS Trusts for in-case and comparative case-study (if possible sample for maximum variation in approaches to error and investigation management and in provider purpose and structure to be conducted face-to-face).
- SP 3 (months 29-36): integration and final analysis of findings; local forums (n=4); women and family forums (n=2) and summative forum (n=1) as well as targeted consultations with online women and family forums (for example Maternity Outcomes Matter closed Facebook site) and by email correspondence (with the PAG and our Stage 1b study participants)
- to enhance our understanding of the critical factors that support OD and to co-develop practical recommendations and actionable guidance for strengthening OD implementation and practice.
- Outputs and Dissemination: tailored and timely outputs (publications, briefings, awareness raising are scheduled throughout the duration of the project.

Project Stages and Milestones	1-3	4-6	7-9	10-12	13-15	16-18	19-21	22-24	25-27	28-30	31-33	33-36
Research Ethics and R&D Approvals	x	x	x	x	x	x	x		x			
SP1a (months 1-12) [12 months]: develop initial hypotheses; develop interview tools for SP1b & SP2.	x	x	x	x								
SP1b (months 7-21 [14 months]: interview study; selection of cases for SP2; complete ethics and R&D for SP2			x	x	x	x	x					
SP2 (months 22-30) [7 months]: in-case & comparative ethnographic case study								x	x	x		
SP3 (months 29-36) [7 months]: integration of findings; interpretive forums; complete analysis										x	x	x
Study Team Meetings (six weekly)	x	x	x	x	x	x	x	x	x	x	x	x
Project Advisory Group meetings (six monthly)	x		x		x				x		x	
Outputs: forums and publications				x				x			x	x
Outputs: guidance (paper and video)											x	x
Outputs: progress reports and final report to NIHR				x		x						x

Project Management

The study will be co-led by Professor Jane Sandall (JS) and Dr Mary Adams (MA), who will co-ordinate management of the research team in KCL and in Manchester, London and Derby. JS, has a clinical background and is an NIHR Senior Investigator, will mentor MA. Professor Iedema (RI) is also an experienced investigator on previous NIHR studies. RI and MA are experienced ethnographers; JS, RI and MA are experienced social scientists and qualitative researchers; all have extensive experience working in this capacity on NIHR or other national projects. JS and MA have experience in realist approaches (JS is presently supervising a PhD realist evaluation). JS will be responsible for delivery of the project and final report, on time and in budget. JS and MA will organise R&D applications and direct the literature review, fieldwork, output design and dissemination and final report writing and submission. The core project team (research and PPI collaborators) will provide support and input at various stages; and two team members will take lead roles for the progression and team reporting on each of the study phases: JS will lead Phase 1; MA will lead Phase 2); and RI will lead Phase 3. These leadership roles reflect the interest and skills of project team members: JS has extensive research and professional experience working with national stakeholders and the Maternity Clinical Networks; MA is an experienced qualitative fieldworker and ethnographer with an interest in workplace cultures; RI has expert interests in patient engagement and facilitation skills and methodologies. Alexander Heazell (AH) will provide guidance to the project team on clinical and management issues through all study phases. One full-time research fellow (RF), already experienced in qualitative research on sensitive issues in healthcare and services, will be employed at KCL, and line managed by JS and MA, for the full duration of the study (27 months).
In Phase 2, MA will lead ethnographic fieldwork at site 1 and support data collection at site 3; RF will lead ethnographic fieldwork at sites 2,3 and 4, with support with data collection by MA (site 3). A project administrator based at KCL will support the research team with bookings; setting up meetings and the women and parents and summative forums; and study reporting. Project team meetings will be six-weekly throughout the study (face-to-face and/or by teleconference).

The project advisory group (PAG) will meet five times during the study to advise the project team on all aspects of the work, including as consultants for Phase 1a hypotheses development; and, for those able to attend, Phase 3 interpretation of study findings (summative forum).

Project Tasks are as follows:

-JS: 10%FTE to provide overall project coordination; supervise the qualitative researcher; contribute to Phase 1a theory development; data analysis and study outputs; support MA with summative forum facilitation; provide structured mentoring for MA.
-MA: 70%FTE to assist JS with overall project coordination and co-supervision of the qualitative researcher, lead on to Phase 1a theory development; contribute to Phase 1b interviews; carry out and complete fieldwork at site 1; facilitate forum at site 1; support data collection at site 3; facilitate one women and parent forum and summative forum; contribute to analysis; report writing and co-ordination of dissemination activities.
-RI: 5%FTE to help with examining OD and OD improvement issues within the broader policy context, to contribute to study design, data analysis and study outputs that relate our findings to staff training, women and family support and wider practice challenges raised by OD practice.
-AH: 5% FTE will provide ongoing input to the study and help to provide a frontline staff and service managers perspective and networks to support our access to interviewees and case study sites, framing actionable recommendations and support dissemination.
-RF: 100% FTE (Grade 7 to be appointed) to contribute to theory development; complete NRES ethics and R&D applications (with support by Jennifer Bostock); contribute to data generation and analysis for all Phases of the study; carry out and complete fieldwork at sites 2,3 and 4 (with support with data collection site 3 by MA); facilitate forums at sites 2,3 and 4; facilitation one women and parent forum; support MA and JS with facilitation of summative forum event; contribute to report writing, dissemination events and study outputs.
-Administrative Support 10% (Grade 5); to provide general administrative support to the project including support of the project team, advisory group meetings and all interpretive forums.
-Our charity/association co-investigators (Maria Booker, Charlotte Bevan and Maureen Treadwell) will ensure that the various interests of women and families is represented throughout. They will contribute, with the core research team, towards study focus (following a realist methodology); the identification of potential study sites and participants; research tool development and the co-development of findings into outputs and dissemination of these outputs.

Approvals by Ethics Committees and R&D

We are aware that the proposal will require NHS research ethical approval. We will seek full review because we will be:

- undertaking research with NHS staff and women or family members who are working on quality and safety improvement issues on a highly sensitive and potentially emotive topic.
- conducting two focus groups with women and families who are members of the public on this topic.
- interviewing and observing staff and managers whose care might have resulted in harm.

The primary ethical issues, and mitigation of them, will be:

- *non-consent or withdrawal of consent to study participation* (for example, by some staff during research observation of staff meetings and routines). In these situations, we will always respect withdrawal of study participation and we will state this in all participant information and consent forms. We will seek to also focus observations of collective routines on more public workplace activities (e.g. training events)
- *disclosure of negligence* (for example, during staff and during women and family representative interviews). We will make it clear in all participant observation that we have a duty to disclose the negligence of patients. We will establish a system for researchers concerned about negligence to alert the PI within an established time frame and for the prompt notification of the relevant Freedom to Speak Up Guardian.
- *participant engagement* (by trusts, services, units and teams who feel judged by the study sampling procedures and the study topic). The emphasis of the project, and of the two highly experienced researchers who will conduct fieldwork in the three case-study sites, is that all of these sites have been approached and invited because they are engaged in innovative work and that we want to learn from them. From previous HS&DR research, and from recent discussion with Professor Martin (PI on a Policy Research Programme project 'Building a Culture of Openness', we are aware that obtaining initial and ongoing engagement with participants is possible if it is done sensitively and ethically. We will reassure all trusts and services that we will not be approaching, interviewing or observing women and families directly.

4. *Non-malfeasance regarding study participants.* In the development of stakeholder and staff information and interview guides and interview techniques, as well as in the forum discussion guides, the researchers will follow both current guidance on interviewing people about potentially sensitive topics or traumatic experience (Rakime 2011; Razzaghi 2018) and specialist advise from our PAG.
5. *Non-malfeasance regarding PPI representatives* (study co-applicants; PAG members; forum participants). We have structured PPI representation across the study so that leadership and support roles are clearly defined. We have ensured that all PPI co-applicants and PAG members are highly experienced in research and engaging with diverse interest groups. We have also ensured linkage between the PPI PAG lead and the study PAG lead to ensure consistency of support as well as of representation.

The research will also require R&D approvals from the relevant trusts. Phase 1b ethics will be gained before the study commences. We will also draft some sections of the ethics application for Phase 2 before study commencement. We will complete applications for Phase 2 R&D/ethics as soon as we have a sufficient sample of potential organisational case studies. These applications will take priority in the later months of the Phase 1b work. Issues of anonymity, confidentiality and informed consent will be addressed in the recruitment of all participants, data collection processes and data storage. The principles of beneficence and non-malfeasance will be adhered to.

The team is experienced in NHS research and research ethics applications, including recruitment, access and data collection such as observation of practice, interviews and documentary analysis. Due to the sensitive nature of the study topic, an ethics specialist with a health service research background has reviewed the study application. We will draft NRES ethical approval for all stages of the project in Study Phase 1a and begin to seek R&D approvals from one NHS organisation at this time. We will seek the necessary further Phase 2 R&D approvals whilst the Study Phase 1b work is in progress.

Study Oversight

The study will be overseen by Project Advisory Group [PAG] that will meet 4 or 5 times over the study period. This PAG will provide the study team with expert oversight and advice as well as support wider awareness of the project and the dissemination of study findings and outputs. PAG membership is: Professor Graham Martin (Director of Research, THIS Institute) [PAG Chair]; Anita Banerjee (Obstetric Physician, St. Thomas' Hospital); Professor Yvonne Birks (Health Policy Unit, University of York); Dr Chandrima Biswas (Clinical Advisor, Health Service Investigation Branch; Dr Denise Chaffer (Director of Safety and Learning, Maternity, NHS Resolution); Anita Dougall (Royal College of Obstetricians and Gynaecologists); Professor Jacqueline Dunkley-Bent (Head of Maternity, Children and Young People, NHS England); SIB); Professor Graham Martin (Mary Newburn (Public and Patient Involvement Consultant); Michele Upton (NHS Improvement); Ms. Birte Harlev-Lam (Executive Professional for Professional Leadership, Royal College of Midwives); Dr James Harris (practicing midwife and senior clinical lecturer); Professor Jenny Kurinczuk (Co-Director, Policy Research Unit in Maternity Health and Care); Sir Professor Jonathan Montgomery (Professor of Healthcare Law, University College London and Expert Advisor for Health Service Investigation Branch); Maxine Spencer (Director of Midwifery and Head of Gynaecology Nursing, Guy's and St Thomas' NHS Foundation Trust); Liz

Thomas (Policy and Research Manager, Action Against Medical Accidents); Ms. Suzanne White (Head of Clinical Negligence, LeighDay). Two women or family members with experience in disclosure processes following harm in maternity care will be appointed (tbc by September 2019).

Patient and Public Involvement

To ensure that the views and interests of women and families, and the wider public, remain the focus of the study, our PPI strategy supports representation at all study phases (study design, management, data interpretation, co-development of outputs, reporting of findings and dissemination of research findings, along with other outputs). We have followed the new National Standards for Public Involvement that provide a series of indicators to support structures and behaviours that support PPI in study governance and study impact. Our PPI strategy involves a variety of women and families, and a range of associations or charities that represent them, as follows:

1. Study Co-Application with three experienced representatives (Maria Booker (MB), Maureen Treadwell (MT) and Charlotte Bevan (CB) from three charities/associations that each represents a different perspective or range of experiences on Open Disclosure (see section on study expertise).
2. These PPI co-applicants will provide ongoing study advice and support including, when possible, participation in six-weekly co-investigator team meetings and the five advisory group meetings. During the team meetings MB, CB and MT will advise on issues to be considered in development of the realist working hypothesis and research tool development (Study Phase 1a); research engagement and participant recruitment (Study Phases 1b and 2); and research recruitment and re-engagement (Study Phase 3). A short, reflective summary of this PPI co-applicant work will be included in the final HS&DR report.
3. Independent PPI advice on the study will be through the Project Advisory Group that will engage two women/family members who have experienced harm and disclosure events in NHS maternity care. These two women/family members will be already experienced in engaging with multi-professional groups to discuss their interests and personal experiences.
4. Training and Advice for PPI representatives (co-applicants and advisors) will be provided as required.
5. Study Methodology to Facilitate Involvement: with consultations for theory identification (Phase 1a with PPI study co-applicants and advisors); research participation of national and regional public and patient stakeholders (Phase 1b); Phase 2 research participation, of women and families involved in OD improvements (if possible) and of their representatives in services or trusts; Phase 3 data interpretation and co-development of some study outputs (as described below), contribution to reporting (study co-applicants) and dissemination of outputs (study applicants and advisors).
6. Advice on data collection and interpretation that includes individual women and families by:
    a. Organising two interpretive forums dedicated to women and families (in already established groups supported by Sands, Birthrights, the Birth Trauma Association and, possibly, the Royal Colleges)
    b. If possible, consulting a dedicated online (closed) network of women and families whose interests on improving the care and safety of women in maternity care (Maternity Outcomes Matter)
    c. Including them in the interpretive forums at the case study sites (where possible) and in the summative forum.
7. Ethical Considerations that will minimise the risks of study and research participation to women and families have included advice from a commissioned ethics specialist who is also a PPI representative. (see section on Approval by Ethics Committee).

Measures of Success and Management of Risk

Measurements of success are:

1. Completion of Phases 1, 2 and 3 of the projects, fulfilling objectives 1-5
2. Adequate sampling sizes for Phase 1b (stakeholder interview survey) and, particularly for Phase 2 (three case studies from across the NHS in England).
3. Production of final report and other documented outputs, including the video films and guides for managers and for parents and families
4. Widespread dissemination and impact on OD policy, procedures and practice as experienced by women and families, health care professionals, maternity providers and wider NHS provider services.

Successful completion of the work requires support of and access to key stakeholders in Open Disclosure work. More significantly, it requires the ongoing engagement of sampled services, trusts or networks in the research study so that they will support the study. This support will allow access to intervention recipients (NHS staff), redacted documents related to the intervention and service, trust or network events where OD is promoted and discussed (for example, training events or policy reviews). The team has long established relationships with a wide range of national stakeholders in maternity services, quality and safety improvement, along with an extensive network of public, women and family support associations and charities. We anticipate that through these networks, and through our very extensive and well-connected Project Advisory Group, we will recruit sufficient stakeholders for the Phase 1b research.

A potential barrier to the completion of the proposed work to the high standard required is the potential for insufficient or inadequate engagement of services, trusts and networks for the comparative case study (Phase 2). We have taken several steps to guard against. As detailed above, we will adopt an organisational recruitment strategy to maximise opportunities to recruit trusts, services or networks as case study sites.

First, we are sampling and inviting only those services, trusts or networks where OD improvement is already underway (reported in grey literature or known to Phase 1b study participants or to PAG members). Second, we intend to study only cases of apparent OD improvement (rather than cases of OD inadequacy). Third, we are taking a pragmatic approach to the identification of potential case studies (prioritising capacity and interest over other sampling criteria). Also, we are conducting only three carefully selected case studies, in order to allow time for initial researcher engagement and the gradual building of relationships. We have planned for two highly experienced researchers (Research Fellows) both with experience of health service research on sensitive issues to conduct the case study work. Finally, our case study research does not include researcher observations of OD events or the direct involvement of women and families as we assume that some trusts/services would find this challenging. Holding the final interpretive forum at King's College, London, supported by the reputation and credibility of the three family and parent's associations, as well as Tommy's Charity, will enhance the uptake of the findings and facilitate widespread dissemination through website hosting of the film and other guidance materials.

Expertise and Justification of Support

We are an experienced team with relevant expertise in quality and safety improvement in maternity services, healthcare research and practice. Across the team, we have experience in midwifery and obstetrics; clinical management; team-based education in healthcare; health service improvement; communication studies; public and patient engagement with woman and families (including those traumatised by adverse healthcare events); sociology, anthropology and ethnography; realist approaches and improvement science. We have previously conducted research on Open Disclosure, patient safety, staff wellbeing, women-centered care, service-user involvement and staff training interventions.

Professor Jane Sandall CBE [JS], Professor of Social Science and Women's Health is a highly experienced PI and HS&DR investigator, midwife and sociologist. She will be senior PI on the study, co-ordinating the research team, overseeing study progress, ensuring the deadlines for study outputs are met and that the project budget is managed effectively. JS's extensive knowledge of maternity care policy and practice within services, trusts and wider networks will help us to frame our study within the broader policy context. Her access to national networks and policy makers will help will access to interviewees and case study sites, framing relevant recommendations and supporting dissemination. Professor Sandall will mentor Dr Mary Adams MA who will be co-PI. Dr Adams is a social scientist, anthropologist and midwife with expertise in women and patient centered care, service user involvement, staff wellbeing and qualitative research methods. MA has extensive experience conducting qualitative research, including ethnography, in NHS settings and on sensitive and emotive issues within healthcare and she will also be conducting fieldwork research on two of the three sites. This will be her first PI role on an HS&DR study. Both JS and MA have experience in realist studies, JS as a supervisor and MA with an ongoing realist synthesis.
Professor Rick Iedema [RI] has a background in communications studies and ethnography, health service improvement and team-based education. He will help to ensure that outputs are relevant to service users as well as to services and trusts; he will also support the dissemination of findings through international networks. RI has extensive research and theoretical expertise in OD, particularly of the experience of patients and families as well as frontline staff teams. RI will contribute to the framing of research questions and of data analysis. Professor Alex Heazell [AH], an obstetrician, senior clinical academic and Director of Tommy's Stillbirth Research Centre, is experienced in working with mixed-methods and qualitative research teams and is widely networked into relevant NHS organisations. Both RI and AH have extensive experience in the management of large research projects and grants, including NIHR awards.

Due to their organisational affiliations, Charlotte Bevan (CB), Maria Booker (MB) and Maureen Treadwell (MT) together represent different aspects of women and family interests in OD. MB is Programme Director for Birthrights, a charity that focuses on the human rights aspects of maternity care, particularly those faced by women with complex or multiple needs, and on maternity safety improvement. MT is co-founder and research lead of the Birth Trauma Association, that co-ordinates the MOMS project, a collaboration of user led charities and individuals who have experienced often serious adverse maternity events who are working, along with leading health care professionals, to improve safety. CB is Senior Research and Prevention Advisor for the Stillbirth and Neonatal Death Charity, that has extensive experience of supporting, conducting and participating in research on stillbirth and the effects of stillbirth on families and healthcare professionals. These three organisations have extensive experience in contributing to research studies and in working with other charities and associations to achieve this. All PPI representatives will be paid at INVOLVE guideline rates.

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