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[Hospital Patient Safety: A Realist Analysis]

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Hospital Patient Safety: A Realist Analysis

1. Aims/Objectives:

The influence of organizational features on hospital patient safety programmes cannot be understood from evaluation methods such as randomized controlled trails. This study is the first to employ insights from institutional theory within a realist analysis framework (Pawson and Tilley 1997) to analyze which contextual factors matter, how they matter, and explain why they matter in order that processes and outcomes may be improved. The study has five main aims:

1. To identify and analyze the organizational factors (e.g., structure, culture, and managerial priorities) pertinent to the health outcomes of hospital patient safety interventions.

2. To identify and analyze the contextual mechanisms (logics, or belief systems) that interact with organizational factors to generate the health outcomes of hospital patient safety interventions.

3. To develop and test hypotheses concerning relationships between organizational factors, mechanisms, and the health outcomes of hospital patient safety interventions.

4. To produce a theoretically-grounded and evidence-based model of which organizational factors matter, how they matter, and why they matter.

5. To establish and disseminate lessons for a broad range of stakeholders concerned with patient safety policy and management.

Achievement of these aims will generate profiles of each case site specifying how a particular configuration of organizational factors influences the mechanisms that lead to more or less successful health outcomes of the three focal safety interventions (improving leadership, reducing infection rates, and implementing surgical checklists). This will provide a platform for comparing across cases to establish generalisations about organizational factors that are likely to work in particular situations as a basis for informing practitioners. The final model may serve as a diagnostic tool to be used as a precursor to the design of more differentiated and context-sensitive interventions in future. These outputs will present a major breakthrough to the patient safety agendas nationally and internationally as hospitals strive to implement and sustain programmes of improvement. Crucially, the findings will empower stakeholders to develop improvement interventions that are more likely to 'work' in their local, contingent circumstances.

2. Background:

It is estimated that one in ten National Health Service (NHS) hospital patients are harmed during their care, and one in 300 die as a result of adverse events such as acquired infection (Donaldson 2009). Along with these human costs, safety incidents are a drain on NHS resources, costing an estimated £3.5 billion a year in additional bed days and negligence claims (National Audit Office [NAO] 2005, 2008). As awareness grows about the systematic nature, scope, and costs of these problems, patient safety has been driven to the top of the NHS agenda, and improvement programmes have been introduced (Department of Health [DH] 2006).

Evidence that the outcomes of NHS patient safety innovations vary across hospitals demonstrates that the organizational context of their implementation matters (Grol et al. 2008, Pate et al. 2008, Health Foundation 2011). However, relationships between features of organizational context (e.g., structure, culture, and managerial priorities) and the health outcomes of safety programmes are both under-theorized and poorly understood in empirical terms (Shortell et al. 2007). As a result, recent studies report that safety interventions such as incident reporting programmes fail to deliver the expected improvements because of 'unanticipated' organizational features such as competing managerial priorities (Waring et al. 2010).

The proposed study will employ insights from institutional theory (concerning the role of competing views, or 'logics' as mechanisms for change and resistance) within an innovative approach (realist analysis) to the study of patient safety research. The main aim is to examine the relationships between organizational context, mechanisms, and the health outcomes of NHS hospital patient safety interventions. Specifically, the study will examine the introduction of three safety interventions (improving leadership, reducing infection rates, and implementing surgical checklists) in nine comparative-intensive case studies of hospitals in the Welsh national *1000 Lives* + programme. The research team is uniquely qualified to conduct this analysis; it comprises an expert in the organizational analysis of healthcare, a leading UK social science researcher of patient safety, an experienced researcher of patient safety, and an ex-director of the *1000 Lives* + programme.

Overall, the study's combination of expertise, conceptual framework, research approach, and natural laboratory setting will enable the development of an evidence-base that is generalisable to the improvement efforts of policy makers and managers locally, nationally, and internationally.

Hospital Patient Safety: The Problem

Despite improvement activity, considerable and systematic NHS hospital patient safety problems endure. Over the last decade, awareness has grown about the number of patients harmed in the course of hospital treatment (Sari et al. 2007). Global estimates of harm vary but are normally reported to be around 10% of all inpatient admissions with a range of 3.8 - 16.6% (De Vries et al. 2008). A study using retrospective case note review in an English hospital provides the most reliable estimates of harm in a UK health system; one in 10 patients were harmed with around half of these being surgery and drug related (Sari et al. 2007). Further estimates suggest that one in 300 inpatients die as a result of errors or omissions in care (Donaldson 2009). While it is estimated that 22% of adverse events and 39% of near misses remain unreported, the reported incidents cost the NHS £3.5 billion a year (NAO 2005). Additionally, in 2003-04 provisions for outstanding clinical negligence claims were in excess of £2 billion (NAO 2005).

Following the seminal reports from the U.S. Institute of Medicine (1999, 2001), patient safety research has surfaced a number of common themes internationally including a lack of clarity in scoping the safety issues (Batalden and Davidoff 2007, Bates 2008), poor communication between healthcare strategists and frontline clinical teams and managers (Pate et al 2008, Parker et al. 2009), under resourcing of academic safety research (Grol and Berwick 2008, Sung et al. 2003, Tetroe et al. 2008), and problematic dissemination of empirical work (Grol and Grimshaw 2003, Grimshaw et al. 2004, Greenhalgh et al. 2004).

A significant development has involved the re-conceptualisation of the sources of risk and safety in the organisation of clinical work. Specifically, it is argued that the threats to patient safety stem, not simply from individual error or poor performance, but from the influence of upstream systemic factors (Reason 2000). These factors are seen as located in the clinical environment, teamwork, management and culture, organisational configuration and wider institutional pressures (Vincent 1997). Yet, despite this growing attention to the latent, organisation threats to patient safety, there has been a comparative lack of attention to how these same organizational factors influence the implementation of safety improvements including large-scale safety programmes. Indeed, recent reviews of the patient safety research literature conclude that knowledge of relations between organizational factors and safety improvement initiatives remains under-developed (Waring et al 2010).

Our proposed study provides the novel multidisciplinary research (combining institutional theory and realist methods), to generate context-sensitive insights that the patient safety literature states is required to improve the safety of hospital care in the 21st Century (Grol et al. 2008, Health Foundation 2011). More specifically, as demanded by Berwick (2008), our study is designed to assess both the implications of organizational factors, and the 'local wisdom' (understanding) of those factors.

A Problem with NHS Hospital Patient Safety Programmes

There has been a range of patient safety interventions in the UK ranging from 'hard'

technological solutions (e.g. in the use of intrathecal drugs), to softer forms of staff training, safety guidelines and alerts. However, research shows variability in the implementation and success of these programmes, and evaluations rarely take a whole-system approach that considers the influence of organisational factors (Waring et al. 2010). While organizational factors are acknowledged to be important to the health outcomes of hospital patient programmes, there is little evidence of which factors matter, where, and why. Early NHS policy responses to the growing awareness of patient safety problems identified the need to introduce programmes that aid 'a just culture', build local capacity, and sustain change through performance improvement monitoring (DH 2001, NAO 2005). Since the establishment of the National Patient Safety Agency (NPSA) and the introduction of the National Reporting and Learning System in the early 2000s, these policy goals have been pursued, in England and Wales, through the four main hospital safety programmes summarized in Table 1.

Table 1: NHS Hospital Patient Safety Programmes in England and Wales

Programme	Agency	Participants	Programme Summary
***Safer Patients Initiative Phase 1*: 2004-2008**	The Health Foundation (£4.3 million)	Four Trusts, one from each nation: Luton & Dunstable, Conwy & Denbighshire, Down Lisburn, & Tayside	1. Evidence-based interventions in five clinical areas. 2. Teaching methods for quality improvement 3. Executive role development
***Safer Patients Initiative* Phase 2: 2006-2008**	The Health Foundation (£165k per Trust plus support)	20 Trusts working in pairs including Southmead with Bristol Royal Infirmary	As phase 1 with aim to reduce mortality by >15% & adverse events by > 30%
***1000 Lives/1000 Lives +*: 2008-2015**	Collaboration including National Leadership and Innovation Agency for Healthcare, Wales Centre for Health, Clinical governance Support Unit &partnerships including National Patient Safety Agency and IHI	All Welsh NHS Health Boards	Evidence-based interventions in 6 'content areas' including: leadership & medicines management. Use of resources including: central support structure, & 'how to' implementation guides.
Safety First	Collaboration under National Patient Safety Forum	English Strategic Health Authorities & National Leadership and Innovation Agency for Healthcare	Formation of Patient Safety Action Teams to support the delivery of the national patient safety agenda by local NHS organizations.

Source: Summarized from Health Foundation 2008

Inspired by safety approaches in other industries (e.g., airlines) and the work of the US-based Institute of Health Improvement (IHI), NHS hospital patient safety programmes aim to improve service reliability by implementing evidence-based clinical practices, and enhancing performance monitoring systems (Sutcliffe and Weick 2001). In each of the NHS hospital patient safety interventions, organizational factors are acknowledged to be 'critical'. However, in contrast to the evidence-base supporting the clinical interventions, relations between organizational factors and the outcomes of hospital patient safety interventions are both under-theorized, and not well understood in empirical terms (Shortell et al. 2007, Grol et al. 2008). Despite important work sponsored by the Health Foundation, there has been no systematic and independent analysis of the relationship between organizational factors and

the health outcomes of patient safety interventions in NHS hospitals (McKee et al. 2008, Bate et al. 2008, Bates 2008). This is the crucial gap in knowledge that this study is designed fill. Despite the lack of a robust evidence-base, the designers of hospital patient safety programmes prescribe various combinations of the organizational features outlined in Table 2.

Table 2: Prescribed Organizational Factors in Patient Safety

1. Establish Priorities, Structure, Culture & Knowledge	
Priorities	(a) Ensure Execs have safety in 'front of mind': place safety prominently on board agenda, monthly review of performance, boards to hear patient stories
	(b) Monthly board-level tracking of hospital performance measures e.g., mortality rate, adverse drug events
	(c) Demonstrate executive commitment through WalkRounds
	(d) Develop 'rational portfolio of projects' with required scale & pace
Structure	(e) Assign executives to improvement teams, link with review & remuneration
	(f) Develop senior safety officer post & committee reporting to executive
	(g) Resource projects with capable strategic & operational leaders
	(h) Data-driven monitoring of project roll-outs & effectiveness
	(i) Emphasize safety during hiring, orientation & promotional activity
Culture	(j) Develop 'just culture' holding managers & clinicians accountable for safety, assess and monitor culture using surveys
Knowledge	(k) Develop executives' knowledge of improvement methods and tools
2. Engage Key Stakeholders	
Boards (Exec & non-Exec)	See a,b,c & d above
	(a) Develop Finance Director as safety champion, safety consideration within all efficiency goals e.g., promote view of poor safety as inefficient
Clinicians & staff	(b) Establish common purpose e.g., improve safety (c) Frame values e.g., individual & organizational safety responsibility (d) Segment implementation plan e.g., identify champions, educate 'laggards' (e) Engaging methods e.g., selective standardization & data use (f) Engaging style e.g., early inclusion, communicate candidly
Patients & families/culture	(g) Boards to hear patient stories at every meeting (also 1a) (h) Include patients & families on improvement teams
3. Communicate & Build Awareness	
	(a) Monthly executive WalkRounds (also 1c)
	(b) Implement Safety Briefings
	(c) Improve communication using Situation Background Assessment Recommendation (SBAR) mechanism
4. Track & Measure Performance Over time	
Measure, report & analyze harm over time	(a) Measure & report mortality and adverse events at the hospital level
Shared learning	(b) Identify triggers of adverse events from records reviews
	(c) Improve analysis of adverse events
	(d) Strengthen incident reporting mechanisms

Source: Summarized from Reinertsen et al., 2008, Botwinick et al., 2006, Davies et al., 2008

The nature of relations between organizational factors and patient safety outcomes, as anticipated in Table 2, is problematic in two respects. First, relations between organizational

factors and the outcomes of hospital patient safety interventions lack an appropriate evidence base (Shortell et al. 2007). As a result, Table 2 currently represents a set of hypothesed relationships between certain organizational factors and the health outcomes of patient safety programmes.

Second, general management research on the relationship between organizational factors (e.g., structure, culture and management) and performance has moved beyond notions of universal 'best' practices to recognize the context-dependent and negotiated nature of such relationships (Pettigrew and Whipp 1991, Delbridge et al. 2008). Supporting this view, Sheaff and colleagues' (2003) review of the literature on organizational factors and performance in healthcare demonstrates that the relationship is complex and contingent. It is clear that there are few, if any, simple levers that can be pulled to influence performance. However, three relatively consistent themes emerge: (1) an organization's socio-political and historical environment (including its parent organization e.g., the Trust for a hospital) influences health outcomes, (2) hierarchical organizations tend to work better in stable conditions, whilst organizations based on 'networks' or other horizontal structures are often better able to adapt to contexts of rapid change, and (3) organizational cultures (e.g. professionally 'clannish' or managerially 'rational)' may be associated with some positive performance outcomes. Thus, we need to know more about the assumptions governing patient safety practice within and across the NHS hospital field.

While Sheaff and colleagues' review did not specifically consider patient safety programmes, it underscores the context-dependent and negotiated nature of the outcomes of improvement programmes. The failure of incident reporting in the NHS to secure the improvements achieved in aviation demonstrates this point (Waring 2005). However, this lesson is not evident within much of the patient safety literature. Critically, the role of organizational culture is much stated but typically under-specified. In contrast to institutional analyses of other issues in healthcare, little attention has been given in patient safety research to the role of supra-organizational logics (belief systems) and their variants within hospitals which have significance for variations in hospital processes and outcomes (Kitchener 2002). Specifically, institutional analysis emphasizes that *logics operate as the mechanisms* that combine with organizational features to produce local variations in the outcomes of change programmes.

While the role of supra-organizational logics as generative mechanisms has not been explored directly within patient safety research, suggestions of their importance can be deduced. For example, it is known that NHS hospital patient safety initiatives have been promoted strongly by supporters who assert both the programmes' moral legitimacy (to save lives), and their functional legitimacy to deliver organizational and clinical improvements (Berwick et al. 2006). NHS hospital managers are, however, faced with the challenge of implementing the programmes in a context in which both their moral and functional legitimacy is questioned (Grol et al. 2008). As with other attempts to improve service reliability, the hospital patient safety programmes present a dual lever for co-ordinating (standardizing) clinical practice and accounting for professional work (Waring 2010). While this appears rational within managerial logics, conflicting clinical logics – emphasizing the need for professional autonomy and peer review – may provide the moral basis for clinicians' resistance to implementation (Kitchener 2002, Waring and Currie 2009). Additionally, the transferability of American safety approaches has been questioned and doubts have been raised about the data quality and analytical methods used in their promotion (Wachter and Pronovost 2006).

In summary, in patient safety research there is growing recognition of the need to dig below the headline pronouncements of 'what works', to investigate the role of organizational factors and the mechanisms (logics) through which influence is exerted (Waring et al. 2010). This requires assessing the impact of patient safety interventions in different hospitals in order to develop theories to explain the variation in adoption and patient outcomes. As noted, previous work tends to have listed organizational factors associated with change but there is a paucity of empirical work examining how factors interact and the contexts in which they occur (Bate et al. 2008, Bates 2008). This requires the research proposed here to provide evidence on what organizational features work, where, and why to help improve the safety of healthcare.

3. Need:

Achieving the aims of the proposed study will address at least three of the main needs outlined in the call for proposals.

Capacity to generate new knowledge. Evidence that the health outcomes of patient safety initiatives vary across hospitals demonstrates that organizational context matters. However, relationships between contextual (organizational and cultural) factors and the outcomes of hospital patient safety interventions are both under-theorized, and poorly understood in empirical terms. This study is designed to develop new knowledge to plug that gap (Aims 1-3). Achievement of these aims will generate profiles of each case site specifying how a particular configuration of organizational factors influences the mechanisms that lead to more or less successful health outcomes of the three focal safety interventions (improving leadership, reducing infection rates, and implementing surgical checklists).

The study findings will provide a platform for comparing across cases to establish generalisations about organizational factors that are likely to work in particular situations as a basis for informing practitioners. The final model may serve as a diagnostic tool to be used as a precursor to the design of more differentiated and context-sensitive interventions in future. These outputs will present a major breakthrough to the patient safety agendas nationally and internationally as hospitals strive to implement and sustain programmes of improvement. Crucially, the findings will empower stakeholders to develop improvement interventions that are likely to work in their local, contingent circumstances.

This study is designed to extend knowledge in ways that are designed to have high levels of impact on policy makers, practitioners, and academics. We will build on our excellent relationships with stakeholders including senior policymakers through ongoing engagement, both formally through an *advisory board*, and informally through a *programme of regular consultation and interim dissemination* activities, augmented towards the end of the project with a *knowledge transfer programme* for practitioners.

Generalizable findings and prospects for change. The study's combination of expertise and mid-level theorizing within a natural laboratory setting will enable the development of an evidence-base that is generalizable, and hence useful, to the improvement efforts of policy makers and managers locally, nationally, and internationally. The outcomes of the study will be generalizable to the extent that the study is designed to enhance understandings of context; something that is often left undefined, and when considered is frequently conceptually limiting because it does not sufficiently stress the interactions between the elements of context (Dopson et al. 2008: 214). In undertaking nine comparative-intensive case studies of hospitals this study enhances the transparency of the given context by penetrating beneath the surface of observable policy inputs and outputs of the focal interventions using the techniques of analytical abduction and retroduction (see method section). These techniques are fundamental to the generalizability of the study, as they draw into detailed consideration both: (1) an actor's 'dominant logic' and professional orientation (Reay and Hinings, 2009: 648), and (2) an actor's positional level, the remit of their role, and the power dynamics embedded within the operational arena (Mouzelis 2008: 204-205). A pertinent contribution of such a penetrating realist lens is its potential to reveal the depths of organizational contextual complexity, thereby fostering insightful circumspection and further investigation.

Our empirical findings will provide a significant addition to the evidence base on (a) the health outcomes of patient safety programmes, and (b) their relationships with local context and mechanisms. This evidence will assist policymakers who are designing patient safety programmes and policies, and managers who are implementing them (Aims 3-5).

Health need. This research is designed to identify what organizational factors work, where, and why. The field of patient safety needs this information to enhance the outcomes of patient safety programmes, and the hence the safety of patients (Aims 1-3).

4. Methods:

Conceptual Framework: Realist Analysis

Health services researchers, and notably those within the field of health policy, have begun to employ realist analysis as a foundation for studies that seek to move beyond asking—'what works?'—to investigate the more intellectually-challenging and practically relevant questions of 'what works, for whom, why, and in what circumstances?' (Pawson and Tilley 1997, Greener and Mannion 2008, Brown et al. 2008, Greenhalgh et al. 2009).

Built upon realist philosophy, realist analysis provides a conceptual framework that comprises the three central components of theoretically-founded social science: context (C), mechanism (M), and outcome (O). In short, it is proposed that patient safety interventions (e.g., improving leadership, reducing hospital acquired infection rates, and implementing surgical checklists) work (have successful 'outcomes') only in so far as they introduce the appropriate ideas, subliminal assumptions and practices ('mechanisms') in the appropriate organisational conditions ('contexts').

Importantly, with respect to the analysis of hospital patient safety interventions, there is open acknowledgement that other research methods, such as randomized controlled trails (RCTs), cannot produce the required knowledge (Berwick 2007). Indeed, the need for research that examines 'what works, for whom, why, and in what circumstances?' is reflected in the foreword of the recent evaluations of the Safer Patients Initiatives Phases 1 and 2 (Health Foundation 2011). Thus, the proposed study's design and methodology have been purposively chosen to address these issues.

Study Design: Comparative Case Study

As the realist conceptual model used in this study involves a search for explanation in the phenomena studied, we will adopt a comparative case study approach (Pettigrew and Whipp, 1991).

The proposed study aims to examine the local implementation of three safety interventions: (i) improving leadership, (ii) reducing hospital acquired infection rates, and (iii) implementing surgical checklists within nine NHS hospitals participating in the Welsh 1000 Lives Plus programme. Thus, the unit of analysis in this study is the process of local implementation of these content areas (not the campaign itself, which forms part of the context).

There are four main reasons for selecting the process of local implementation of the 1000 Lives Plus programme. Firstly, it is a Welsh national safety campaign, and one of only a very few in the UK. Hence, it represents a natural experiment in national quality improvement that has attracted growing international recognition and interest (Berwick 2007). Secondly, historical data, useful to our study, have already been collected within the predecessor 1000 Lives programme, including: (i) patient stories, (ii) a robust hospital-level performance measurement strategy, and (iii) a hospital culture survey. Thirdly, we have provisional access to sites for our data collection (through programme co-director Janet Davies, who will sit of the research study's advisory board). Finally, within the 1000 Lives Plus programme itself, there is no intention to conduct a targeted examination of organisational features and no capacity to conduct the form of realist analysis proposed here. Therefore, without this study, a great opportunity for research informing these improvement efforts will be missed.

Case Selection Criteria and Two Stage approach to Case Sampling

As noted earlier, realist analysis rests on the core proposition that the intended and unintended outcomes (O) of change are explained by mechanisms (M) - stakeholders' ideas (logics) about change - that are embedded in contexts (C), which trigger or fail to trigger certain changes rather than others (Kitchener and Leca 2009). The case selection criteria used in this study therefore follow the realist study design principle, and seek to ensure theoretical variation in emergent and underlying context-mechanism-outcome (CMO) configurations (Ackroyd 2009). Hence, clear and readily operationalisable criteria, used in previous organisational analyses of hospital behaviour (e.g., Sheaff et al. 2003), were employed to define the purposive sample of the first wave of case sites.

These operationalisable criteria encompass:

(i) Corporate parent — we include case sites from each of the seven newly-formed Local Health Boards to gain insight into how such organisations have responded to the 1000 Lives Plus campaign and have influenced the activity of their constituent hospitals;

(ii) Geographical coverage across NHS Wales — case sites were also selected to display a metropolitan, urban and rural mix of organisational locations, with a geographical balance across south, mid and north Wales;

(iii) Organisational complexity — in order to enhance the theoretical variation in underlying CMO configurations, we explicitly sought to engage with healthcare organisations that displayed a different mix of organisational complexity. Therefore, organisations were selected by: (i) size, thereby examining the impact of tiers of command, and intra-organisational interfaces across corporate and professional groups; (ii) the provision of regional specialist healthcare services versus generalist healthcare services versus the restricted service scope of a small cottage hospital; and (iii) university teaching hospitals versus smaller hospital facilities with limited teaching capacity.

In our proposed study, the case sampling approach employed is informed by that used in the National Institute for Health Research, Service Delivery and Organisation (NIHR SDO) programme's funded, and on-going, study titled: 'A Formative Evaluation of Collaborations for Leadership in Applied Health Research and Care (CLAHRCs): Institutional Entrepreneurship for Service Innovation' (SDO Project 09/1809/1073), led by Professor Andy Lockett, University of Warwick. Hence, in alignment with the SDO Project 09/1809/1073, the proposed study adopts a two-stage sampling strategy.

In stage one, the primary goal is to establish the 'bigger picture' of relations among context, mechanism and outcomes concerning the implementation of patient safety programmes. We have therefore selected nine Welsh hospitals participating in Welsh 1000 Lives Plus programme, as defined in Table 3.

Table 3: Initial Case Sites

Case Site:	Local Health Board:	Contextual Features:
Morriston Hospital, Swansea	Abertawe Bro Morgannwg University • Area size 1,071 km^2 • Total Population 499,400	• Urban large district general hospital • Beds 750, wards 28 • General medicine, surgery, and associated sub-specialities; specialist tertiary services • *1000 Lives/1000 Lives +*
Neville Hall Hospital, Abergavenny	Aneurin Bevan • Area size 1,553 km^2 • Total Population 560,500	• Semi-rural mid-sized district general hospital • Beds 500, wards 25 • General medicine, surgery, and limited sub-specialities • *1000 Lives/1000 Lives +*
Glan Clwyd Hospital, Rhyl	Betsi Cadwaladar University • Area size 6,172 km^2 • Total Population 678,500	• Urban large district general hospital • Beds 684, wards 24 • General medicine, surgery, and associated sub-specialities; specialist tertiary services • *1000 Lives/1000 Lives +*; *Safer Patient Initiative* Phase 1 and 2 site
University Hospital of Wales, Cardiff	Cardiff and Vale University • Area size 471 km^2 • Total Population 445,000	• Urban large teaching hospital • Beds 1038, wards 39 • General medicine, surgery, and associated sub-specialities; multiple regional and specialist tertiary services • *1000 Lives/1000 Lives +*; *Safer Patient Initiative* Phase 2 site
Prince Charles Hospital,	Cwm Taf • Area size 535 km^2 • Total Population	• Urban deprived area mid-sized district general hospital • Beds 434, wards 15

Merthyr Tydfil	289,400	• General medicine, surgery, and limited sub-specialities • *1000 Lives/1000 Lives +*
West Wales General Hospital, Carmarthen	Hywel Dda • Area size 5,781 km^2 • Total Population 375,200	• Semi-rural mid-sized district general hospital • Beds 326, wards 18 • General medicine, surgery, and limited sub-specialities • *1000 Lives/1000 Lives +*
War Memorial Hospital, Brecon	Powys • Area size 5,196 km^2 • Total Population 132,000	• Rural small community hospital • Beds 61, wards 2 • Rehabilitation, care of the elderly, and intermediate care • *1000 Lives/1000 Lives +*
Gorseinon Hospital, Gorseinon	Abertawe Bro Morgannwg University • Area size 1,071 km^2 • Total Population 499,400	• Rural small community hospital • Beds 66, wards 2 • Rehabilitation, care of the elderly, and intermediate care • *1000 Lives/1000 Lives +*
Community Hospital, Colwyn Bay	Betsi Cadwaladar University • Area size 6,172 km^2 • Total Population 678,500	• Rural small community hospital • Beds 42, • Rehabilitation, care of the elderly, and intermediate care • *1000 Lives/1000 Lives +*

This initial case sample will optimise the description, interpretation and explanatory pattern analysis of context-mechanism-outcome (CMO) configurations whilst reducing chance associations (Eisenhardt, 1989; Fitzgerald and Dopson, 2009; Lee, 1999). However, after the analysis of the data collected at the initial sample sites, four main sites will be selected for more detailed study in stage two. Hence, the primary goal at this latter stage is to drill down from the bigger picture, established in stage one, to develop a more nuanced understanding of local CMO relations concerning the focal interventions. Following established critical realist research methods, the primary criterion for selecting the four main cases will be on the basis of the most promising emergent CMO configurations.

Data Collection (Interviews, Meeting Observation, and Document Collection)
During the first year of the proposed study, at each of the nine initial sites, fieldwork will include 10 exploratory interviews, meeting observation, and document collection. Such detailed fieldwork at our initial sample sites offers the potential for identifying CMO configurations which capture how the case sites operationalise the local implementation of three of the Welsh 1000 Lives Plus programme content areas: (i) improving leadership, (ii) reducing hospital acquired infection rates, and (iii) implementing surgical checklists.

After analysis of this data, in year two, further data will be collected at the four main sites. Again, this will include an additional 25 interviews per site, meeting observation, and document collection. We will therefore continue to identify, and then track, the mechanisms, contexts and outcomes of the three focal interventions, in real time, over the duration of the 27 month study.

The interviews undertaken during stage one and two will include individuals drawn from different organisational roles, including the:

(i) Executive Board—Chair, Chief Executive, Board Secretary, and Board Directors (Finance; Human Resources, Workforce and Organisational Development; Medicine; Nursing; Planning, Performance and Delivery; Therapies and Health Sciences);

(ii) Senior-Middle Corporate and Clinical Management—Chief Pharmacist, Consultants (Anaesthetist, General Medicine, Microbiology and Infection Control, and General Surgery), Directorate Managers (General Medicine, Operating Theatres, Recovery and Anaesthetics,

Surgery), and hospital leads for: Risk Management, Clinical Governance, Clinical Coding, Patient Advice and Liaison, Litigation and Complaints Management;

(iii) Clinical Arena (1): Operating Theatres, Recovery, Ward Departure and Return—Consultant Nurse (Surgery Assistant), Junior Doctors (Anaesthetist, General Surgery), Operating Department Practitioner, Radiographer, Theatre Sister (Operating Theatres, Recovery and Anaesthetics), Ward Sisters (General Medicine, Surgery, and Intensive Therapy Unit/High Dependency Unit);

(iv) Clinical Arena (2): Infection Control—Consultant Nurse (Infection Control), Junior Doctors (Elderly Care Medicine, General Medicine, Paediatrics and Neonatology, and Renal Medicine), Specialist Clinical Pharmacist (Antibiotic Management and Infection Control), Ward Sisters (Elderly Care Medicine, General Medicine, Paediatrics and Neonatology, and Renal Medicine).

Furthermore, these will be complemented by interviews undertaken with consumer champions and representatives of external bodies, including: policy-makers, the National Patient Safety Agency, and the Health Foundation. As indicted in Table 4 (below), at each site, the study of mechanisms and contexts will be conducted largely using qualitative approaches plus the results from a *1000 Lives* programme survey that included a validated measure of organizational culture.

Table 4: Realist Framework, Data Sources, and Research Aims Addressed

Element of Framework	Data Sources	Project Aims
Context		
(a) Features prescribed in Table 1,	Literature, review, Interviews, meeting observation, culture survey, internal documents, 'patient stories', programme data, secondary sources	1,3,4,5
(b) *1000 Lives* management practices e.g., Walk Rounds		
(c) Variables from literatures including contingency theory and health services (e.g., Sheaff et al 2003) e.g., size, management structure, culture		
Mechanism		2,3,4,5
Logics of patient safety programmes	Interviews, meeting observation, programme data, internal documents. Institutional theory	
Outcomes	A: Hospital Standardized Mortality Ratio (HSMR); (ii) the Risk Adjusted Mortality Index (RAMI); (iii) the established Trigger Tool (requiring 20 closed cases per major acute hospital, per month, using the method defined by the campaign team, as defined within NHS Wales' Annual Operating Framework (Welsh Assembly Government, 2010: 31); and (iv) other local methods of incident reporting. B: Intermediate process and outcome measures of the 3 focal patient safety initiatives as specified in Tables 5a-c	1-5

Data Collection (Research Participant Contact, Interview Process and Location)
A named senior ranking individual within each case site will act as the point of contact between the organisation and the research team. Working in close liaison with this individual,

the research team will identify potential research participants. Each potential research participant will be contacted by Dr Herepath via letter or e-mail (which ever is the most appropriate and effective means of communication), and given an information leaflet describing: (i) the aims of the project; (ii) interview arrangements, including the scope of the hospital patient safety topics to be discussed; and (iii) information covering issues of consent, confidentiality, and secure data storage. Those interested in taking part will be invited to reply directly to Dr Herepath by e-mail or telephone.

Individuals who give their consent, and subsequently participate in the study, will be interviewed by Dr Herepath (face-to-face or, if preferred, via telephone) for approximately one hour at a convenient location within their employing organisation. It is anticipated that most participants will be interviewed once. However, key individuals who offer a great depth of insight into the focal areas of the study, will be approached to undertaken a follow-up interview. Contact with the proposed study's research participants will be maintained throughout the duration of the research via web based research updates and case site feedback workshops.

Data Collection (Organisational Process and Outcome Measures for the 1000 Lives Plus programme)

In addition, within each of the nine case sites, available documents containing organisational and clinical improvement data related to the local implementation of three safety interventions: (i) improving leadership, (ii) reducing hospital acquired infection rates, and (iii) implementing surgical checklists will be collected. This will encompass the following data.

(i) Case site-specific targets for harm and mortality reduction—Medical Directors in NHS Wales' hospitals are now charged with setting their own targets for harm and mortality reduction. Such autonomously defined targets are to be informed by a suite of self-selected performance measures, including: (i) the Hospital Standardized Mortality Ratio (HSMR); (ii) the Risk Adjusted Mortality Index (RAMI); (iii) the established Trigger Tool (requiring 20 closed cases per major acute hospital, per month, using the method defined by the campaign team, as defined within NHS Wales' Annual Operating Framework (Welsh Assembly Government, 2010: 31); and (iv) other local methods of incident reporting.

(ii) Case site-specific process and outcome measures for the three focal patient safety initiatives—defined in Table 5 below.

TABLE 5a	**1000 LIVES PLUS PROGRAMME:**
Patient safety intervention—*Leading the way to safety and quality improvement*	
PROCESS STEPS: **Driver (1)—Building the *will* to make measureable systemic improvements:** • Set aims, local targets, and monitor progress (via locally selected measure of hospital mortality rate and Trigger Tool) • Demonstrate visible leadership • Hear stories • Change the culture **Driver (2)—Encouraging and spreading *ideas*:** • Seek and share new evidence of best practice • Use relevant *1000 Lives Plus* clinical content area guides **Driver (3)—Attending relentlessly to the *execution* of an aligned range of improvement initiatives:** • Establish executive and organisational accountability (primary focus to be placed on indicators that measure process reliability, quality improvement, and outcome) • Use the *1000 Lives Plus* model for improvement • Focus on learning and development	
PROCESS MEASURES:	
• *Specified within the individual patient safety initiative*	
OUTCOME MEASURES:	
• *Specified within the individual patient safety initiative*	

This patient safety initiative is an overarching programme that is targeted primarily at board level organisational leaders. Within our study, we shall therefore seek objective evidence of the:

(i) definition of local organisational targets for mortality and harm reduction;
(ii) appointment of executive level leads to the *1000 Lives Plus* focal safety initiatives;
(iii) systematic use of process measure data to consistently monitor mortality, harm reduction, and thus the quality and safety of healthcare service provision;
(iv) sign-up to 'mini-collaboratives' at executive level, which seek to share and rapidly spread best practice within the organisation; and the
(v) executive level alignment to the delivery of the central theme of NHS Wales' Annual Operating Framework: 'to reduce harm, waste, and variation' in order to improve the quality and financial stability of healthcare service delivery across Wales (Welsh Assembly Government, 2010).

TABLE 5b	**1000 LIVES PLUS PROGRAMME:**
Patient safety intervention—*Reducing healthcare associated infections*	
PROCESS STEPS: **Driver (1)—Prevention of Transmission:** • Standard precautions—e.g. hand hygiene and decontamination of the environment • Isolation precautions • Use of antimicrobials • Management of medical devices (via the implementation of care bundles for: (i) central venous catheter insertion and maintenance; (ii) peripheral vascular catheter insertion and maintenance; (iii) urinary catheter insertion and maintenance; and (iv) the prevention of ventilator associated pneumonia) **Driver (2)—Prevention and effective treatment of infections:** • Use of antimicrobials • Management of medical devices **Driver (3)—Patient engagement:** • Patient information and education • Patient awareness of risks • Patient empowerment and involvement in care	
PROCESS MEASURES (Exemplars)**:** • % compliance—e.g. hand hygiene protocols, decontamination protocols • % compliance with recording the duration of the antimicrobial treatment course on the drug chart • % compliance with care bundles • Incidence of episodes of 'failure to isolate'	
OUTCOME MEASURES:(1) • Incidence of Clostridium difficile disease • Incidence of Staphylococcus aureus bacteraemia • Incidence of infections related to medical devices: – ventilator associated pneumonia – central line infections – urinary catheter associated infections – bacteraemias related to peripheral intravenous lines	

(1) Supplementary measures stated within NHS Wales' Annual Operating Framework (Welsh Assembly Government, 2010: 57-59):

Local Health Boards are to demonstrate a minimum of 20% reduction over the next 12 months in the number of cases of *Clostridium difficile* in patients over the age of 65, (based on figures published in the All-Wales *Clostridium difficile* report for 1/7/08-30/6/09). In addition, Local Health Boards are required to achieve over 95% compliance with the mandatory Welsh Healthcare Associated Infection Programme (WHAIP). [Data sources via WHAIP Surveillance Data Report (quarterly) by Public Health Wales].

TABLE 5c 1000 LIVES PLUS PROGRAMME:
Patient safety intervention—*Reducing surgical complications*
PROCESS STEPS: **Driver (1)—Prevention of surgical site infections:** • Administer prophylactic antimicrobials appropriately • Use of recommended hair removal methods • Maintain glycaemic control of known diabetics • Maintain peri-operative normothermia **Driver (2)—Creating a team culture attuned to detecting and rectifying intra-operative errors:** • Use team briefings at the beginning of the list • Use WHO surgical checklist for each patient **Driver (3)—Patient involvement:** • Patient education • Patient awareness of risks • Patient involvement in care
PROCESS MEASURES (Exemplars)**:** • % antimicrobials administered on time • % antimicrobials discontinued early • % surgery patients with appropriate hair removal • % diabetic patients with good glucose control (within range) • % patients with peri-operative normothermia • % daily team briefings • % completing the WHO surgical checklist for each patient
OUTCOME MEASURES: • % of surgical patients with surgical site infections (to be reported monthly to the Board)

(iii) 1000 Lives and 1000 Lives Plus archived data on (anonymous) 'patient stories', and a validated measure of organisational culture. (Please note: the hospital-level performance measurement strategy used in the earlier 1000 Lives programme is no longer applied to the 1000 Lives Plus programme, due to local determination of targets for harm and mortality reduction.)

Data Analysis and Programme Theory (Hypothesis) Development

From year one, we will begin to elicit and formalize preliminary programme theories (stated as 'CMO configurations') concerning the three focal interventions (improving leadership, reducing hospital acquired infection rates, and implementing surgical checklists). These hypotheses will be drawn from multiple sources including: meta-search of electronic databases for information of three focal interventions (e.g., Metalib), a systematic review of research literatures (e.g., patient safety/health services research, and organization and management theory), documentary analysis (e.g., policy papers and annual reports), patient stories, and stakeholder interviews. We will explicitly build upon the findings of the evaluations undertaken across different facets of the Health Foundation's Safer Patients Initiative, (SPI) and those of other noted patient safety and healthcare quality programmes (e.g. those published by the National Patient Safety Agency). Crucially, the SPI Evaluations report: (i) the importance of aligning safety programmes to features of local context, and (ii) a failure to appreciate the importance of the programme theories. In contrast, this study explicitly examines context-mechanism-outcome (CMO) relations as programme theories. Accordingly, SPI evaluation findings will be integrated throughout our study, especially in the development of CMO configurations, and the refinement of our intellectual argument. This will help expose the complex interactions between programme interventions, the local context, and the ensuing organisational theory of change; a critical knowledge deficit, and research challenge, openly acknowledged by the Health Foundation (2011).

Data Analysis and Programme Theory Testing

Following best practices in comparative case study work (Miles and Huberman 1994), data

collection, analysis and theorisation will be conducted simultaneously to generate and explore emergent themes. From year one, the analysis will begin to explore the assembled programme theories concerning relations among context, mechanisms and outcomes. The interview and other qualitative case study data will be coded, electronically catalogued and warehoused prior to systematic, iterative cycles of thematic analysis and review to explore sub-group comparisons (Greenhalgh et al. 2009). To avoid producing 'merely' rich descriptive studies, the evidence collected in our case studies will be analysed inductively and grounded in existing knowledge by framing the analysis according to the elements of the analytical model, their inter-relationship, and development over time.

Analysis will involve two modes of realist inference: (i) 'abduction', to define an initial elemental account of putative generative mechanisms; and (ii) 'retroduction', to further elaborate the mechanism and, pivotally, establish the distinctive contextual conditions for its manifestation (Ackroyd, 2009: 538). Such realist inference will be enhanced by close examination of the relational structures operating within the three selected interventions (improving leadership for quality, reducing infection rates, and implementation of surgical checklists) thereby maintaining the differentiation between structure, agency, and the health care practices that arise through their complex interplay (Fleetwood, 2008: 243).

The two main realist analytical techniques used in this project (abduction and retroduction) are fundamental to the generalisability of the study, as they draw into detailed consideration both: (i) an actor's 'dominant logic' and professional orientation (Reay and Hinings 2009: 648), and (ii) an actor's positional level, the remit of their role, and the power dynamics embedded within the operational arena (Mouzelis, 2008: 204-205). A pertinent contribution of such a penetrating realist lens is its potential to reveal the depths of organizational contextual complexity, thereby fostering insightful circumspection and further investigation.

In one development to standard realist analysis we will investigate the possibility of using Qualitative Comparative Analysis to help develop lines of enquiry concerning relations among context, mechanisms and outcomes (Kitchener et al. 2002).

Data Analysis and Interpretation

The final study stage centres on the assessment of the extent to which the derived programme theories are supported by the analysis. This necessarily involves the adjudication of alternative explanations (Miles and Huberman 1994). While it is anticipated that some outcome variations may be relatively intelligible, others may involve unanticipated effects that require further rounds of hypothesis generation and testing. The purpose is to draw closer to explaining the complex signature of health outcomes associated with hospital patient safety programmes. As Greenhalgh et al. (2009) demonstrated, drawing realist conclusions about the generative causality of particular CMO configurations is not an entirely logical-deductive exercise. Rather, it is an interpretive task and will only be achieved through much (resource intensive) negotiation and contestation. This will involve the analyses being presented to study participants and other practitioners during workshops designed to test interpretations and evaluate alternative explanations of the relations among context, mechanisms and outcomes.

When the five aims of the project are achieved, the study will have identified for each case site, an overall profile (stated as CMO configuration) that will show how a particular configuration of organizational factors influences the mechanisms that lead to more or less successful health outcomes of the intervention. This will provide the basis for comparison across cases, to come up with some generalisations about organizational factors that are likely to work in particular situations as a basis for informing practitioners. This will form the basis of a diagnostic model as a precursor to the design of more differentiated and context-sensitive interventions in future.

Procedures in place to Detect and Compensate for any possible "Researcher Effects or Bias"

To ensure the objectivity, rigour and generalisability of our research, the members of the project team each have pivotal roles to play. The Senior Researcher (Herepath) will undertake the primary analysis of the data. This will then be exposed to a triangulated challenge: one which will focus upon the underpinning clinical features of the emergent CMO configurations

(Gray); the social science aspects of these constructs (Waring); and the health service managerial and post-merger reconfiguration dynamics (Kitchener).

Time Frame and Key Events
The proposed study will run from Monday 3rd October 2011 for a period of 27 months. Key events, and associated durations, are listed below:

(i) Main literature review—months 1-12 (on-going thereafter);
(ii) Interview instrument development—months 1-9;
(iii) Initial site visits—months 1-3;
(iv) Interviews (Stage 1)—months 4-9;
(v) Interviews (Stage 2)—months 10-18;
(vi) Meeting observation (Stages 1 and 2)—months 4-18;
(vii) Performance data collection—months 4-18;
(viii) Data analysis)—months 7-27;
(ix) Interim report writing—months 10-12;
(x) End stage report writing—months 25-27;
(xi) Site feedback workshops—months 10-12, 22-27;
(xii) Policy forum seminars—months 25-27;
(xiii) Advisory board meetings—months 3, 15, 24.

5. Contribution of existing research:

This study will extend knowledge in ways that are designed to have high levels of impact on policy makers, practitioners, and academics. We will build on our excellent relationships with stakeholders including senior policymakers through ongoing engagement, both formally through an *advisory board*, and informally through a *programme of regular consultation and interim dissemination* activities, augmented towards the end of the project with a *knowledge transfer programme* for practitioners.

Our findings will provide a significant addition to the evidence base on (a) the health outcomes of patient safety interventions, and (b) their relationships with local context and mechanisms. This evidence will assist policymakers who are designing patient safety programmes and policies, and managers who are implementing them.

The targeting of policy and practitioner audiences within our dissemination plan will ensure that these empirical findings impact upon subsequent policy discussions. This will be evidenced by, for example, references made within the high-impact practitioner publications such as the *British Medical Journal* and *Health Service Journal* and by citation within documents produced by government bodies including the Welsh Assembly Government, Department of Health, national improvement agencies, and Inspectorates (such as the Audit Commission, Care Quality Commission, and the Healthcare Inspectorate Wales).

During each study year, half-day interim workshops will be held to check data, feedback initial findings and elicit comments. Findings will be disseminated to user communities through articles in practitioner journals, and presentations to research forums including SDO annual meetings and events. In the final year, knowledge transfer will take place through half-day final seminars to test the implications of key findings, plus a national, one-day *dissemination conference* in Cardiff for senior policymakers and practitioners across the UK.

A project website will be created at the outset of the project. This will contain project reports and updates, academic articles, conference papers, and other material publicising emerging findings. The website will also incorporate an interactive bulletin board dedicated to the study that will provide a further means of establishing a dialogue with stakeholders. In order to maximise use of the site we will publicise it through the workshops, conferences and short reports that we produce and publish.

Additionally, knowledge transfer will include the production of short *briefing reports* for policymakers and practical guides targeted on senior managers and practitioners. These reports will be published and distributed through the project website, and main relevant representative organizations such as the NHS Confederation.

Our dissemination of empirical findings at the main patient safety and health research conferences, and in the highest ranked journals, will ensure impact among relevant academic communities. Annual academic conferences at which our work will be presented include: NPSA Safety Research Conference, IHI Forum, and SDO Annual meeting. Our innovative contributions to theoretical understandings of the 'why, what and how?' of patient safety will contribute greatly to several academic literatures across the social sciences, including health services, general management, public administration, and sociology. This impact will be evidenced by the publication of our theoretical and empirical findings, and their subsequent incorporation within the work of other leading researchers, in journals including *Health Services Research* and *Milbank*. The research will also create impact through its incorporation within the teaching programmes of leading universities, and the work of bodies including the Sunningdale Institute, National School of Government, and Institute of Healthcare Management.

Our pioneering development of a realist analysis framework will have significant impact upon practitioners and academics with a concern for research methods in social sciences and the evaluation of patient safety. Indications of this impact will include publications in methods journals such as *Organizational Research Methods and Evaluation*, subsequent applications within future research studies, and research capacity work through engagement with initiatives such as those organized by the NIHR, ESRC, and the British Academy of Management.

Finally, our work will be globally relevant to academic, policy and practitioner debates on patient safety in all nations seeking improvement. As recently noted by leading authorities such as Berwick (2007), Waring et al (2010) and Shortell et al. (2007), theoretical understanding and empirical evidence on the organizational factors associated with patient safety is limited in both quantity and quality, and there is very significant demand for new evidence on this topic. Our research will provide the first comprehensive, and theoretically and empirically rigorous, analysis of what organizational factors, where and why, and therefore has clear potential for global impact on research and policy.

6. Plan of Investigation:

Study Activity/Month:	**1-3**	**4-6**	**7-9**	**10-12**	**13-15**	**16-18**	**19-21**	**22-24**	**25-27**
Advisory board meetings	■				■			■	
Literature review	■	■	■	■					
Instrument development	■	■	■						
Initial site visits	■								
Interviews (Stage 1)		■	■						
Interviews (Stage 2)				■	■	■			
Meeting observation		■	■	■	■	■			
Performance data collection		■	■	■	■	■			
Data analysis			■	■	■	■	■	■	■
Report writing				■			■	■	■
Dissemination writing									■
Site feedback workshop				■				■	■
Feedback seminars									■
Policy forum seminars									■

7. Project Management:

Strategic Oversight. Prior to the start of the study, a project advisory board will be established to include: an independent academic expert on patient safety programmes (Prof. Charles Vincent, Imperial), an independent academic expert on healthcare management (Prof.

Graeme Currie, Warwick Business School), a patient representative (one of the Welsh NPSA safety champions), a LHB chief executive (Dr Andrew Goodhall, Aneurin Bevan LHB), the Caldicott Guardian of patient safety data in Wales (Public Health Wales CEO Bob Hudson), and a co-director of the *1,000 lives* campaign (Janet Davies, Welsh Assembly Government). The board will convene twice a year to ensure the independence of the work, provide access the improvement data, and review and advise on the study design and progress (including interview instrument and fieldwork schedule).

Operational Management. The project will be managed by the PI (Kitchener) in consultation with the Co-PIs (Waring, Herepath, and Gray). The PI and the researcher (Herepath) are members of the high-performing Public Management Research Group at Cardiff Business School. The group is a major locus for government agency-funded work on public services including healthcare, which benefits from strong institutional support within a research-intensive environment. In the 2008 RAE the Business School was ranked 4th on the GPA and 2nd on Research Power (out of 90 Schools of Business and Management). The written feedback from the Business and Management RAE panel singled out the Public Management Research Group as *world leading in all three RAE categories* (outputs, environment and esteem).

As experienced researchers, we will manage the project via a matrix structure (Table 6).
Table 6: Matrix management structure and responsibility for intellectual contributions

Applicant and % time commitment	**Management Responsibility**	**Intellectual Contribution**
Martin Kitchener (20%)	Overseeing the project, research design, liaising with NIHR, staffing, budget, advisory board, team meetings, engagement and publications strategy including project website, reporting, elite interviews. Supervision and mentoring of researcher.	Leading the theorization & investigation of organizational factors associated with patient safety, realist methods, & the theoretical integration of all aspects of the project
Justin Waring (5%)	Design of project, one visit to each case site for fieldwork, consultant on analysis, contribution to production of academic outputs	Leading integration of patient safety (social science) research into theoretical & empirical work
Jonathon Gray (5%)	Liaison with research into other patient safety initiatives, co-ordination of outcome data analysis	Leading the theorization and investigation of patient safety programmes outcomes
Andrea Herepath (100%)	Arranging, collecting, analysing and reporting data, including case studies and performance data	Development of realist analysis techniques and conceptualization of specific context

This matrix arrangement will maximize synergies between the managerial and intellectual contributions of each team member.

Data Management: Anonymity, Storage, and Disposal
Professor Kitchener (Principal Investigator) will act as custodian, and is responsible for the accuracy, completeness, security and destruction of all research evidence within Cardiff Business School, Cardiff University.

Anonymity will be assured by each site, participant, transcription, and researcher being given an identity code: Dr Herepath will undertake the anonymisation of all data. One source of person-identifiable information—the anonymisation record stating the participant's name, role, employing organisation, and corresponding identification code—will be held as a paper record, and stored in a locked filing cabinet in Cardiff Business School. This information will only be accessible to Professor Kitchener and Dr Herepath. No further person-identifiable information will be stored in the form of a paper document.

An electronic version of the anonymisation record will be stored on the proposed study's dedicated shared drive within Cardiff University. Access to this drive will be restricted to Professor Kitchener and Dr Herepath. No further person-identifiable information will be stored in the form of an electronic record. All anonymised electronic raw data files will be password protected, and accessible only by Kitchener, Waring, and Herepath. Collated, anonymised, and analysed data will also be password protected and available to all of the research team members.

(i) Electronic transfer by magnetic or optical media, email or computer networks—Potential research participants, who have been initially contacted by e-mail to seek their engagement in the proposed study, will received an information leaflet describing: (i) the aims of the project; (ii) interview arrangements, including the scope of the hospital patient safety topics to be discussed; and (iii) information covering issues of consent, confidentiality, and secure data storage. If no response is received, a follow-up email will be sent after one working week. Such communication will, therefore, identify the individual potential research participant. Once the individual has given their consent to participate in the propose study, they will be given an identity code. From this point onwards, all electronic transfer of data (via email or computer networks) will be anonymised through the use of this code, and encrypted during data transfer.

(ii) Sharing of personal data with other organisations—The electronic transfer of data within the UK (via email or computer networks) between Kitchener, Waring, and Herepath will consist of anonymised and encrypted data. This data will be shared with the explicit proviso that the recipients cannot: (i) disclose the data to third parties; or (ii) link the data with other data, which may render the information more identifiable. Please note: analysed data (collated, aggregated and anonymised) will also be encrypted during data transfer to Gray (New Zealand).

(iii) Publication of direct quotations from respondents—Such data will be anonymised at the individual and organisational level.

(iv) Storage of personal data on manual files (includes paper or film) and University computers—All hard copy archive and anonymised data will be stored in a locked filing cabinet in Cardiff Business School, and accessible only by Kitchener and Herepath. All electronic raw data files will be password protected, and accessible only by Kitchener, Waring, and Herepath. The following information will be archived within the study's master file:
(i) records of participant consent;
(ii) records of procedures followed and results obtained, including interim results (e.g. protocol documents, risk assessments) and detailed analysis;
(iii) data generated in the course of research (e.g. transcripts, diaries, audio tapes, emails etc.);
(iv) records relating to the administration and financial management of the project (e.g. grant applications, purchase and sales invoices, orders, delivery notes, petty cash vouchers and supporting accounting records). Specialised archive boxes will be used for the long-term storage of all essential documentation. A record of the content and whereabouts of all of the research study's related archived boxes will be kept by Professor Kitchener, so that access can be gained readily if necessary (e.g. after research personnel have moved on).

All data will be disposed of securely:
(i) printed material will be shredded either within the school or by using the University's confidential waste service;
(ii) tapes and discs will be destroyed using the confidential waste service;

(iii) computers will be completely cleared of data before disposal or use for other purposes. The destruction of all paperwork, after the expiry of the time limit, will be recorded and signed by Professor Kitchener. This record will be retained centrally within Cardiff Business School for 7 years.

8. Service users/public involvement:

At the heart of NHS hospital safety programmes is the intention to improve the patient experience. The safety campaigns such as *1000 Lives +* are built around the patient/user of healthcare services. Identifying the effective management of patient safety programmes that is sensitive to different hospital contexts will facilitate the spread of effective safety programmes, and improved quality of care. Patients are asking for roles in supporting such work as we propose. Therefore, we will interview the Patient Champions for Wales (NPSA England and Wales, 2008). One will be invited to join the project board. The Safety Champions were coordinated through Action Against Medical Accidents (AvMA), and we will engage with the AvMA as stakeholders in this work.

In addition, through working in close liaison with the NISCHR CRC Involving People programme, a further two lay representatives will be engaged. These will contribute to Steering Group meetings, and the study's planned workshop and feedback sessions. All costs associated with this support are to be provided by NISCHR CRC Involving People programme.

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