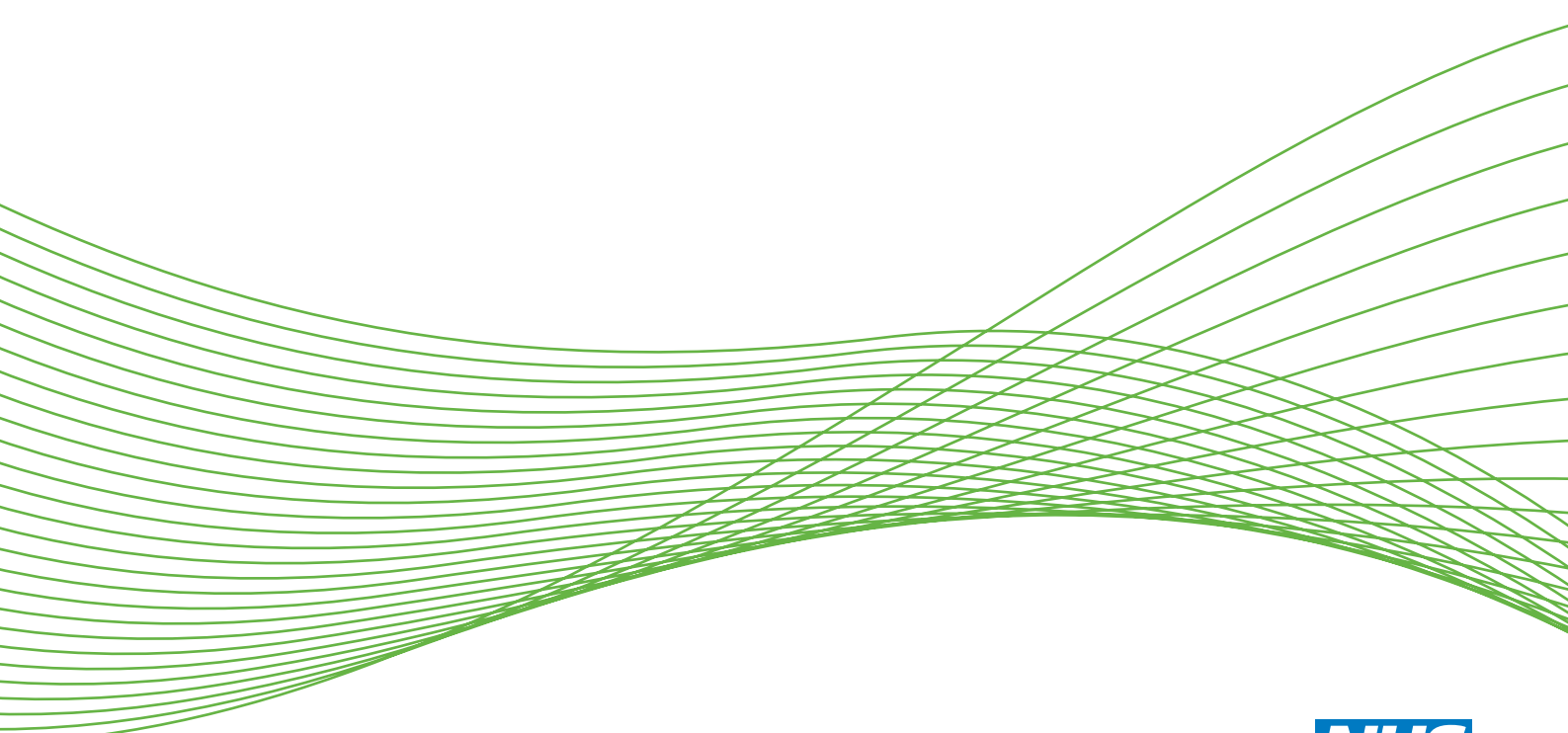


A realist analysis of hospital patient safety in Wales: applied learning for alternative contexts from a multisite case study

Andrea Herepath, Martin Kitchener and Justin Waring



***National Institute for
Health Research***

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research, or similar, and contains language that may offend some readers.

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Abstract

A realist analysis of hospital patient safety in Wales: applied learning for alternative contexts from a multisite case study

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Background: Hospital patient safety is a major social problem. In the UK, policy responses focus on the introduction of improvement programmes that seek to implement evidence-based clinical practices using the Model for Improvement, Plan-Do-Study-Act cycle. Empirical evidence that the outcomes of such programmes vary across hospitals demonstrates that the context of their implementation matters. However, the relationships between features of context and the implementation of safety programmes are both undertheorised and poorly understood in empirical terms.

Objectives: This study is designed to address gaps in conceptual, methodological and empirical knowledge about the influence of context on the local implementation of patient safety programmes.

Design: We used concepts from critical realism and institutional analysis to conduct a qualitative comparative-intensive case study involving 21 hospitals across all seven Welsh health boards. We focused on the local implementation of three focal interventions from the 1000 Lives+ patient safety programme: Improving Leadership for Quality Improvement, Reducing Surgical Complications and Reducing Health-care Associated Infection. Our main sources of data were 160 semistructured interviews, observation and 1700 health policy and organisational documents. These data were analysed using the realist approaches of abstraction, abduction and retroduction.

Setting: Welsh Government and NHS Wales.

Participants: Interviews were conducted with 160 participants including government policy leads, health managers and professionals, partner agencies with strategic oversight of patient safety, advocacy groups and academics with expertise in patient safety.

Main outcome measures: Identification of the contextual factors pertinent to the local implementation of the 1000 Lives+ patient safety programme in Welsh NHS hospitals.

Results: An innovative conceptual framework harnessing realist social theory and institutional theory was produced to address challenges identified within previous applications of realist inquiry in patient safety research. This involved the development and use of an explanatory intervention–context–mechanism–agency–outcome (I-CMAO) configuration to illustrate the processes behind implementation of a change programme. Our findings, illustrated by multiple nested I-CMAO configurations, show how local implementation of patient safety interventions are impacted and modified by particular aspects of context: specifically, isomorphism, by which an intervention becomes adapted to the environment in which it is implemented; institutional logics, the beliefs and values underpinning the intervention and its source, and their perceived legitimacy among different groups of health-care professionals; and the relational structure and power dynamics of the

functional group, that is, those tasked with implementing the initiative. This dynamic interplay shapes and guides actions leading to the normalisation or the rejection of the patient safety programme.

Conclusions: Heightened awareness of the influence of context on the local implementation of patient safety programmes is required to inform the design of such interventions and to ensure their effective implementation and operationalisation in the day-to-day practice of health-care teams. Future work is required to elaborate our conceptual model and findings in similar settings where different interventions are introduced, and in different settings where similar innovations are implemented.

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Glossary

Abduction Abduction is a hypothesis or inference that explains an observation. It differs from deduction or induction because it infers a prior condition that gives rise to what is observed, rather than making assumptions about what will be true as a consequence of the observation. Abduction is a 'logic of discovery' used in realist research to set out an explanatory account of a mechanism acting in a given context.

Abstraction In realist research, abstraction is a step in the analytical process that is used to identify and isolate in thought discrete aspects of an object. The point of abstraction is, therefore, to select one or more aspects, components or attributes and their relationships in order to understand how they impact social reality.

Actor An individual who performs specific acts (see *Agent*).

Agency The purposive action of individuals (and organisations) that is the foundation of changing practice.

Agent; agentic An agent is similar to an actor, but is one who acts within a social structure, although there is debate about the degree to which the structure may or may not affect the action. In agentic transactions, people are seen as producers as well as products of social systems.

Agentic emergent properties See *Emergent properties*.

The Campbell Collaboration The Campbell Collaboration is an international research network that produces systematic reviews of the effects of social interventions (see *Systematic review*).

Causality; causal configuration See *Mechanism*.

Cochrane Cochrane is an international research network that produces systematic reviews of the effects of health-care interventions (mainly randomised controlled trials) to assist the decision-making of policy-makers, health-care professionals and others (see *Systematic review*).

Coercive force In terms of organisational change, a coercive force is one that imposes a change (e.g. by regulation).

Cognitive Cognitive processes are the mental processes of perception, memory, judgement and reasoning. They may be used consciously or happen unconsciously. Cognitive processes use existing knowledge and generate new knowledge.

Comparative case study A research design that facilitates the longitudinal intensive analysis and comparison of different 'cases', typically an organisation or a discrete function within an organisation.

Constraints In Archerian critical realism, constraints are causal powers that are internal to structural and cultural emergent properties. For anything to exert the power of a constraint it has to obstruct the achievement of a specific enterprise.

Context–mechanism–outcome configuration A configuration, used in realist inquiry, to explain what aspects of an intervention work, for whom, why and in what circumstances.

Coupling–decoupling With regard to patient safety interventions, coupling refers to the deliberate connection to – and decoupling to the deliberate disconnection from – organisational structures and associated practices that enhance the legitimacy and effectiveness of such interventions.

Critical realism Critical realism is a complex body of ideas: a movement in philosophy, the human sciences and similar practices that describes an interface between the natural and social world. It is most closely associated with the work of Roy Bhaskar, Margaret Archer and Andrew Sayer, among others.

Cultural emergent properties See *Emergent properties*.

Distributed leadership Distributed leadership is leadership which, rather than being performed solely by one person, is shared between several people. It refers to purposive, concertive action, rather than aggregated, individual acts. Important forms of concertive action are collaboration, intuitive understandings that emerge from close working relationships and a variety of structural relations and institutionalised arrangements. Under distributed leadership some functions may be shared by several members of a group, some may be allocated to individual members and a particular function may be performed by different people at different times.

Ear, nose and throat surgery Otolaryngologists (or otorhinolaryngologists) are commonly referred to as ENT (ear, nose and throat) surgeons and deal with the diagnosis, evaluation and management of diseases of the head and neck and, principally, the ears, nose and throat.

Emergents; emergent properties Emergents or emergent properties are new features or transformations that differ qualitatively from the elements from which they came and, therefore, cannot be returned to their previous forms (e.g. the NHS, once formed, could not be returned to the private institutions which predated it). Agential emergent properties are transformations that come about as a result of deliberate action at the level of the individual, group or organisation (e.g. the NHS was created by Aneurin Bevan and the Labour government of the day). Cultural emergent properties are transformations that are influenced by the cultural situation (the prevailing climate shaped by people's collective beliefs, values or ideologies) in which they occur (e.g. the NHS was influenced by both egalitarian principles and a belief that free health care would profit the nation by improving the health of the workforce). Structural emergent properties are transformations that are influenced by the circumstances in which they occur, be they physical or social (e.g. the structure of the NHS was influenced by existing health-care structures and the perceived needs of the post-war population).

Enablements In Archerian critical realism enablements are causal powers that are internal to structural and cultural emergent properties. For anything to exert the power of an enablement it has to aid the achievement of a specific enterprise.

Epistemology The nature and scope of knowledge – what we think can be known about the world. Additionally, the study of knowledge, and justified belief, centred on the creation and dissemination of knowledge in particular areas of inquiry.

Escherichia coli *Escherichia coli* are a group of bacteria that are an important part of the normal intestinal flora of humans. Most strains of *E. coli* are harmless. However, some strains of *E. coli* can cause illness, typically diarrhoea or urinary tract, respiratory or blood infections.

Extended-spectrum beta-lactamase Some strains of *E. coli* and *Klebsiella pneumoniae* produce an enzyme called extended-spectrum beta-lactamase. This enzyme can break down antibiotics and make them ineffective. Infections caused by extended-spectrum beta-lactamase-producing strains of these bacteria are, therefore, difficult to treat.

First-order emergents (see *Emergents*) First-order emergents are the results of social interaction. In Archerian critical realism, first-order emergents manifest as the agent's involuntaristic placement within the broader social context and role array; their vested interests; the opportunity costs associated with different courses of action; and their perceived interpretive freedom and scope for strategic directional guidance.

Functional team The group of people who carry out the tasks involved in running a ward or department.

Generative mechanism See *Mechanism*.

Health-care-associated infection Health-care-associated infection refers to infections that occur as a result of contact with the health-care system.

Heterarchy A non-hierarchical system of organisation characterised by horizontal positioning of power and authority, with individuals sharing the same status.

Hierarchy A system of organisation characterised by vertical ranking relative to status or authority.

Higher-order societal logics See *Institutions* and *Institutional logics*.

Hospital-acquired infection Hospital-acquired infection – also known as nosocomial infection – refers to an infection that develops in a patient ≥ 48 hours after admission to a hospital. Infections that occur within the first 48 hours are referred to as community-acquired.

Hospital standardised mortality ratio Hospital standardised mortality ratio is the ratio of the actual number of acute in-hospital deaths to the expected number of in-hospital deaths.

Institutional logics Institutional logics focus on how broader belief systems shape organisational interests and individual preferences, define actors' expectations about each other's behaviour and organise their enduring relations with each other. In institutional theory, higher-order societal logics refer to the central institutions of contemporary societies – for example the family, the capitalist market, organised religion, the state and democracy – which inform the core organising principles of these different sectors of society. Institutional logics also operate at the level of professions.

Institutional pillars: regulative, normative and cultural-cognitive Institutions are conceptualised as composed of three pillars: the regulative pillar, which stresses rule setting, monitoring and sanctioning activities, both formal and informal; the normative pillar, which sets out what is considered to be appropriate behaviour given the demands of the situated context; and the cultural-cognitive pillar, which emphasises the centrality of common schemas that guide behaviour.

Institutional theory Institutional theory is one of the dominant perspectives within organisation and management theory.

Institutional work The purposive action of individuals and organisations aimed at creating, maintaining, enhancing and disrupting institutions.

Institutions Institutions are the taken-for-granted social prescriptions that guide the behaviour of actors in different societal, organisational and professional contexts.

Intervention–context–mechanism–agency–outcome configuration A configuration used in realist analysis to explain what aspects of an intervention work, for whom, why and in what circumstances.

Intransitive dimension (see *Ontology*) The intransitive dimension is synonymous with ontology and refers to the objects in the domain of the real of any human inquiry, theoretical or practical.

Isomorphic institutionalism Increased similarity between institutions over time.

Klebsiella species *Klebsiella* species are a group of bacteria that are an important part of the normal intestinal flora of man. Usually, healthy people do not get *Klebsiella* infections. However, in health-care settings, patients who are receiving long courses of certain antibiotics and those whose care requires invasive medical devices such as ventilators (breathing machines) or intravenous (vein) catheters are at risk of *Klebsiella* infections.

Legitimacy façade In respect to patient safety interventions, a legitimacy façade is the outward appearance of adhering to guidelines while, in reality, deviation from such guidelines is seen in day-to-day practice.

Mechanism The power to bring about change: the characteristic way(s) of acting possessed by things by virtue of their intrinsic structures. In realist enquiry, mechanisms refer to the engines of explanation embodied in an agent's reasoning and their selective attention to the disparate resources offered through a social programme. Mechanisms are also part of a causal configuration emergent from a cluster of contextual factors and organisational components.

Mediation of structure by agency In Archerian critical realism, the mediation of structure by agency refers to the conditioning influence of context on the actions of individuals.

Metamechanism A metamechanism is a complex 'bundle' of mechanisms.

Metaphysics The branch of philosophy that deals with the first principles of things, including abstract concepts such as being, knowing, identity, time and space.

Methodology Methodology is the systematic, theoretical analysis of the methods used in research.

Meticillin-resistant *Staphylococcus aureus* *Staphylococcus aureus* is a type of bacteria commonly found on human skin. Most of the time, *S. aureus* does not cause any harm. Meticillin-resistant *S. aureus* is a bacterium that is resistant to many antibiotics. In the community most meticillin-resistant *S. aureus* infections are skin infections. However, in health-care settings, such as hospitals and nursing homes, meticillin-resistant *S. aureus* may cause life-threatening bloodstream infections, pneumonia, endocarditis (infection of the heart valves), osteomyelitis (bone infection) and surgical site infections.

Mimetic force In terms of organisational change, a mimetic force is one which copies a change perceived to be successful elsewhere.

Morphogenesis The process of social transformation.

Morphogenetic-morphostatic cycle The morphogenetic-morphostatic cycle is a method of analysing the complex interplay of structure, culture and agency across three temporal phases: structural conditioning, sociocultural interaction and structural reproduction or elaboration.

Morphostasis The process of social reproduction.

'Never events' Serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented. They include incidents such as wrong site surgery and a retained instrument after operation.

Normative force In terms of organisational change, a normative force is one in which change is aligned with what is perceived to be an existing norm, or standard.

Nosocomial infection See *Hospital-acquired infection*.

Ontology The branch of metaphysics that deals with the nature of being or the way we think the world is.

Peripheral venous cannula A peripheral venous cannula is a very thin tube inserted into a small peripheral vein for therapeutic purposes such as the administration of medications, fluids or blood products.

Point prevalence survey A point prevalence survey is a count of the number of patients with a particular condition or treatment (in this report either a health-care-associated infection or an antimicrobial agent) at a particular time (a specified day), as a proportion of the total number of patients who are hospitalised at that particular time. A point prevalence survey counts the condition or treatment only if it is present on the specified day of the survey, and does not count it if it is present at other times during the patient stay in the hospital.

Reflexive agency In Archerian critical realism, reflexive agency originates within the internal conversation of the individual's domain of mental privacy.

Reflexive theorisation Reflexive theorisation, the final stage of the mediation of structure by agency, occurs through three stages: discernment, the preliminary review stage of an issue of concern, where reflective retrospective and prospective thought informs practical action; deliberation, involving the ranking of such concerns against others; and dedication, entailing their prioritisation and alignment to foster a fallible yet corrigible commitment to a chosen path.

Relational structure Relational structure refers to social relations, or the ties that bind social actors, specifically the pattern of causal interconnections and interdependencies among agents occupying defined roles, and their subsequent actions. Relational structure is, therefore, the nexus of connections among actors causally affecting their actions and, in turn, causally affected by them.

Reproduction In realist research, reproduction refers to a lack of change, persistence of the status quo ante.

Retroduction In realist research, retroduction is a step in the analytical process that is used to refine understanding of a distinctive process or mechanism when the basic conditions for its existence have been elaborated.

Risk-adjusted mortality index Risk-adjusted mortality index is a statistical tool by which an estimate is made of probability of death for all admitted patients. Taking into account factors such as age, sex, diagnoses, procedure, clinical grouping and admission type, it allows a calculation of risk of death. From this prediction it calculates the number in a population expected to die. In publishing such data, comparisons are made between the numbers of patients who actually die and those predicted. Where the numbers are the same, the risk-adjusted mortality index will be reported as 100.

Second-order emergents Second-order emergents are the results of necessary and internal relations among first-order emergents. In Archerian critical realism, the second stage of the mediation of structure to agency addresses how an individual or group, confronted by contextual conditioning, exercise their subjective and reflexive mental powers to formulate their strategic goals, individually or collectively. This array of influences gives rise to four potential second-order emergents – 'necessary complementarities, necessary incompatibilities, contingent complementarities and contingent incompatibilities' – which foster the accompanying situational logics of protection, correction/compromise, opportunism and elimination. The situational logic ultimately brought to pass through strategic negotiation – be that via power-induced compliance, reciprocal exchange or the harmonisation of desires – represents the mechanism of morphogenesis or morphostasis.

Situated context Situated context refers to one of the many contexts in which groups and individuals live and work, and which influence their actions in a particular environment.

Situational logic: contingent complementarities A prevailing situational logic of contingent compatibilities entails a situational logic of pure opportunism that generates fundamental change.

Situational logic: contingent incompatibilities A prevailing situational logic of contingent incompatibilities gives rise to the tensions in the strategic arena and fosters morphogenesis. Here, opposing factions become party to the situational logic of elimination, where the greatest gain coincides with inflicting maximum injuries on the other side.

Situational logic: necessary complementarities A prevailing situational logic of necessary complementarities depicts a strategic arena in which transformation threatens the loss of vested interest all round. Necessary complementarities, therefore, generate a situational logic of protection that is conducive to morphostasis.

Situational logic: necessary incompatibilities A prevailing situational logic of necessary incompatibilities depicts a strategic arena that is marked by incompatibilities between institutions, which are nonetheless internally and necessarily related. Accordingly, a situational logic of compromise arises because necessary incompatibilities means that the promotion of vested interests has to be a cautious balancing act – a weighing of gains against losses – where to accrue bonuses is also to invite or incur penalties. The fragility of this structural conditioning, therefore, offers a subtle potential for change.

Situational logic of protection See *Situational logic: necessary complementarities*.

Structural emergent properties See *Emergent properties*.

Systematic review A systematic review is a literature review that aims to identify, critically appraise, select and synthesise published research studies that address a particular research issue. A systematic review typically includes a description of the findings of the collection of research studies. The systematic review may also include a quantitative pooling of data called a meta-analysis.

Third-order emergents In Archerian critical realism, third-order emergents arise from the effects of first- and second-order influences on the outcomes of the intervention. This concept, therefore, captures structural and ideational differentiation, together with the regrouping inherent to the power play of a diverse array of agents.

Transitive dimension The transitive dimension is synonymous with epistemology and refers to human understanding of the objects in the domain of the real.

Venous thromboembolism Venous thromboembolism is a condition that includes both deep-vein thrombosis and pulmonary embolism. Deep-vein thrombosis is the formation of a blood clot in a deep vein, usually in the leg or pelvic veins. Pulmonary embolism is a sudden blockage in a lung artery, usually caused by a blood clot that travels to the lung from a vein in the leg.

List of abbreviations

CAUTI	catheter-associated urinary tract infection	MRSA	meticillin-resistant <i>Staphylococcus aureus</i>
CHC	Community Health Council	NISCHR	National Institute for Social Care and Health Research
CMO	context–mechanism–outcome	PSOW	Public Services Ombudsman for Wales
HIW	Healthcare Inspectorate Wales	PVC	peripheral venous cannula
HOWIS	Health of Wales Information Service	RAMI	risk-adjusted mortality index
HSMR	Hospital Standardised Mortality Ratio	RHAI	Reducing Health-care-Associated Infection
I-CMAO	intervention–context–mechanism–agency–outcome	RSC	Reducing Surgical Complications
IHI	Institute for Healthcare Improvement	WHAIP	Welsh Healthcare Associated Infection Programme
ILQI	Improving Leadership for Quality Improvement	WHO	World Health Organization
IPAC	infection prevention and control	WHOSSC	World Health Organization Surgical Safety Checklist
MI-PDSA	Model for Improvement, Plan-Do-Study-Act		

Plain English summary

The safety of patients in British hospitals is a major social problem because 1 in 10 is harmed during his or her care. UK policy responses focus on new improvement programmes to implement multiple 'evidence-based' interventions, such as checklists of what should be done during surgery. Such interventions are tested on a small scale (e.g. in one operating theatre) before being rolled out more widely.

Although it is known that the success of the programmes varies among hospitals, it is not known why. This is the first study to examine how the 'contextual' features of a hospital (e.g. its size) and its environment (e.g. political values) combine to influence patient safety programmes. Our study had two main parts. First, we developed a new model for analysing the implementation of improvement programmes that directs attention to multiple layers of context. Second, we used our model to conduct seven in-depth case studies of the 1000 Lives+ patient safety programme across Wales. The main source of our information was 160 interviews, supplemented by our archive of nearly 2000 documents, and the observation of practice.

Our findings show how, for specified programme interventions (e.g. surgical checklists), hospital and environmental features combine to derive varied outcomes seen as either more or less successful by stakeholders such as public, professionals, researchers and policy-makers. Our model and findings provide a valuable basis from which stakeholders can (a) better understand existing improvement programmes and (b) design more effective ones in the future.

Scientific summary

Background

Hospital patient safety is a major social problem that is central to global debates about the quality, affordability and sustainability of health care. It is widely appreciated that patient safety is shaped by government policy and demands a nuanced balance of health-care system design and resources to create high-reliability organisations. Yet other factors intervene. Organisational performance management processes and governance systems, together with the beliefs and values of health-care professionals, mould the local cultures of care. Patient safety, therefore, demands leadership at all levels in the NHS. However, health-care professional leadership – especially medical – remains paramount, and may function as catalyst for, or barrier to, patient safety improvement.

In the UK, it is estimated that 1 in 10 hospital patients is harmed during his or her care, and 1 in 300 dies as a result of adverse events such as hospital-acquired infection. Along with these human costs, safety incidents are a drain on NHS resources, costing an estimated £3.5B a year in additional bed-days and negligence claims. This toll of avoidable harm manifests in various forms. Untoward errors, which occur during drug prescribing, supply and administration, represent a significant and persistent burden. So, too, do those that arise as a consequence of surgery. A more veiled cause is incorrect diagnosis, compounded by variation in the delivery of evidence-based medical care.

In the UK, policy responses focus on the introduction of patient safety programmes that seek improvements in service reliability through the implementation of evidence-based clinical practices using the Model for Improvement, Plan-Do-Study-Act cycle. Empirical evidence that the outcomes of such programmes vary across hospitals demonstrates that the context of their implementation matters. However, the relationships between features of context and the outcomes of safety programmes are both undertheorised and poorly understood in empirical terms.

Objectives

This study is the first to employ insights from institutional theory within a realist analysis framework to study the implementation of patient safety programmes. It is designed to address gaps in methodological, conceptual and empirical knowledge about the influence of context on the local implementation of patient safety programmes. Our aim is to ascertain which contextual factors matter – how, why and for whom – in order that processes and outcomes of future patient safety improvement may be improved. The study has five main objectives:

1. to identify and analyse the organisational factors (e.g. structure, culture and managerial priorities) pertinent to the health outcomes of hospital patient safety interventions
2. to identify and analyse the contextual mechanisms, centred on health-care professionals' belief systems, which interact with organisational factors to generate the health outcomes of hospital patient safety interventions
3. to develop and test hypotheses concerning relationships between organisational factors, mechanisms and the health outcomes of hospital patient safety interventions
4. to produce a theoretically grounded and evidence-based model of which organisational 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.

Methods

The research design comprised a critical realist and institutional analysis of a qualitative comparative-intensive case study located within the Welsh Government and NHS Wales. Encompassing seven health boards and 21 hospitals, the study focused on the local implementation of three focal interventions selected from the 1000 Lives+ national patient safety programme: (i) Improving Leadership for Quality Improvement; (ii) Reducing Surgical Complications; and (iii) Reducing Health-care-Associated Infection. Case site selection criteria centred on a two-stage sampling strategy. In phase 1, four clear and readily operable criteria – corporate parent, complexity, function and geographical coverage – were employed to define the purposive sample of case site hospitals within each health board (see *Appendix 1* in main report). Through this approach, three within-case comparators were selected from each health board: (1) a major hospital, (2) a district general hospital and (3) a small community hospital.

Primary data collection included 160 semistructured interviews, undertaken with Welsh Government policy leads; executive directors, senior managers and professionals in NHS Wales' health boards; public sector partner agencies with strategic oversight of patient safety; advocacy groups; and academics with expertise in patient safety. These data were complemented by overt observation of practice and the collection of relevant organisational documents and outcome data (e.g. risk-adjusted mortality index; 'never events') within each health board.

Secondary data collection focused on an analysis of UK and devolved Welsh health-care policy spanning the period from 1997 to 2014. The UK coalition government's White and Green Papers, together with other key legislative proposals, were accessed from the Department of Health's website, while those of the former UK New Labour government were sourced via the National Archives. Relevant Welsh Government documents, together with those from the National Assembly for Wales, were accessed from site-specific policy archives. In addition, Welsh health circulars and Ministerial letters spanning the period 1997–2012 were accessed via the Health of Wales Information Service intranet. A repository in excess of 1700 documents was, therefore, established and archived in an electronic database to facilitate the exploration of the context and structural conditioning of the focal Welsh health-care system. These data were complemented by an analysis of public inquiries into recent failings in health-care provision, together with a comprehensive analysis of patient safety research.

Data analysis centred on interviewees' perceptions of their working environments, the power play inherent to the strategic negotiation of change during the local implementation of each focal intervention and their experience of the ensuing outcomes. Outcome data were substantiated by relevant organisational documents within each health board. The latter stages of analysis involved abstraction and retroduction, processes which identify and examine various components of the focal intervention to aid understanding of the ways in which they combined and interacted in each particular situation. In this way, the mechanisms operating within the various environments were identified through a combination of theory and experimental observation.

Results

Methodological development of realist analysis in patient safety

As one of the first studies of patient safety to apply realist philosophy of social science across inception, design, fieldwork, analysis and writing, this study has generated a number of features that may inform the field of patient safety research. Unlike the majority of health services research studies, this study has taken seriously, and explicated, realist ontology (theories of being) and epistemology (theories of knowledge). These foundations of our research conditioned its design, conduct and reporting. Moreover, our consideration of ontological depth helped to shape our conceptualisation of contextual strata and the identification and explanation of the underlying mechanisms that shape structure, agency, social relations and ensuing practices.

In terms of analysis, this one of the first studies of health services research to use the realist methods of abstraction, abduction and retroduction to devise an explanatory structure through a combination of theory and experimental observation. While acknowledging the many challenges posed by the critical realist approach, and that the conclusions of our analysis are both provisional and fallible, this study demonstrates its value in helping to reconstruct the basic conditions, structures and mechanisms relating to the focal objects of our research.

Conceptual development of intervention–context–mechanism–agency–outcome configurations in the realist analysis of patient safety interventions

We have developed an innovative framework that harnesses realist social theory and institutional theory to address challenges we identify within existing applications of realist inquiry in patient safety research. Four refinements are advanced to help explain which contextual factors matter, how they matter and why they matter.

First, so that we may understand precisely ‘what’ is working, for whom, how and in what circumstances, we include intervention as a separate analytical category in our realist analysis. Second, we forward a view of ‘situated context’ as stratified, conditioned, relational and temporally dynamic. This involves identifying the dominant structural and cultural emergent properties in play, and separating context from its mediation. Third, we link both mediation and reflexive theorisation to mechanism, thus distinguishing the conceptual elements of mechanism from its ensuing outcomes. Within outcomes we include the agential emergent properties, expressed through the unfolding strategic negotiation of change and the mode of institutional work enacted, which deliver sustainable outcomes, be they elaborative or reproductive. Finally, in our realist framework, outcome is not perceived as a simple, single aspect of change, such as a defined health outcome. Rather, we concentrate on structural and ideational differentiation, reproduction and change. This fine-grained realist analysis, therefore, illuminates the fundamental effects of beliefs and values – institutional logics – on the propensity to act, revealing the contested nature of institutional change, health-care practice evolution, and, thus, social elaboration.

The products of our framework are demonstrated through the development of explanatory intervention–context–mechanism–agency–outcome (I-CMAO) configurations, where I is a specified component of a patient safety intervention; C is the situated context; M is the mechanism of explanation expressed in peoples’ reflexive theorisation and reasoning; A is agency, the ensuing actions undertaken to broker change; and O is outcome, classed in this study as a structural and cultural elaboration or reproduction that manifests over time.

The focal patient safety interventions examined in this study were framed in relation to bureaucratisation and normalisation, thereby generating multiple nested I-CMAO configurations. These illustrate that local implementation is modulated by context, specifically isomorphism, by which an intervention becomes adapted to the environment in which it is implemented; the manifestation of complementary, co-existent or countervailing institutional logics, and their perceived legitimacy among different groups of health-care professionals; and the relational structure and power dynamics of the functional group, that is those tasked with implementing the initiative. This dynamic interplay shapes and guides actions leading to the normalisation or the rejection of the patient safety programme.

Empirical contribution of realist analysis to patient safety research

For each of the three focal interventions of 1000 Lives+ programme analysed, this study offers a nuanced explanation of how local conditions differentially combine with mechanisms to derive various qualitatively different outcomes. Reflecting social reality, these causal configurations are complex and nested. Accordingly, we augment our textual description with an innovative series of explanatory graphics.

This approach to the presentation of our findings allows us to clearly specify how particular configurations of factors, across multiple layers of context, generate the outcomes of patient safety interventions, as outlined below.

- At the level of the ward or department and those that work in it (the functional team), context is perceived to be distinctively different from that of the wider organisation. Indeed, it resonates with that of a bounded health-care managerial or clinical micro-work system. We argue that this finding challenges the use of the health-care organisation as a unit of analysis for patient safety programmes.
- Across the stratified contextual strata of the Welsh health-care institutional field, each individual – whatever their position or professional status – has to negotiate, both personally and as part of a functional team – the influences of the institutional logics evident in their environments. Furthermore, our findings indicate that the precise balance of such logics impacts patient safety. The paradigmatic logic of bureaucratic command and control, which fosters mandated engagement with 1000 Lives+ via coercive institutional isomorphism is dominant at the level of the infrastructural system. However, professional logic is ascendant at sub-board organisational levels across each health board. This gives rise to conflict between logics that challenges the moral and pragmatic legitimacy of the 1000 Lives+ programme. Importantly, it is not the central issue of patient care that promotes such contestation, but the means through which it is imposed. Mandated engagement is perceived in a pejorative light as a means of management control that erodes professional autonomy, a core component of professional logic.
- The local implementation of the 1000 Lives+ programme is widely coupled to desired programme goals. However, when key actors' institutional logics are in opposition, the operationalisation of 1000 Lives+ is distorted and disruptive behaviours that hinder the remoulding of underlying belief systems, thereby diminishing the legitimacy and moral foundation of the 1000 Lives+ programme.
- High-status professional individuals, typically board-level managers and consultant medical or surgical health-care practitioners, play a pivotal role in reconfiguring other actors' belief systems to support the local implementation of 1000 Lives+. Our findings, therefore, echo those that recognise the role of managerial, medical and nurse leadership in patient safety, especially in facilitating change across different staff teams. However, there was a need to empower and emancipate a wider array of health-care staff to lead patient safety.

These findings provide a valuable resource for policy-makers, managers and practitioners, locally, nationally and internationally. They can aid stakeholders to develop improvement interventions that are more likely to 'work' for specified stakeholders in their local contingent circumstances, thereby leading to the design of more differentiated and context-sensitive patient safety interventions.

Conclusions

Heightened awareness of the influence of situated context on the local implementation of patient safety programmes is required to inform the design of such interventions, and to ensure their effective implementation and operationalisation in the day-to-day practice of health-care teams.

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Chapter 1 Introduction

Overview

This chapter introduces our study and is presented in three main parts. We begin by discussing the development of patient safety as the field of research that is concerned with one of the most significant social problems of our time: avoidable harm, waste and variation in health-care. Using the available literature, we outline the nature of this problem and present five factors which are thought to represent its foundations: (1) deficits in cultures of care, (2) leadership inadequacies, (3) ineffective team working, (4) problematic governance systems and (5) limited patient and public engagement. We then introduce the current agenda for patient safety improvement across the devolved NHS in the UK.

Second, we discuss the role of patient safety improvement programmes. We consider the design, implementation and evaluation of these complex social interventions and highlight the current lack of systematic analysis of relations between contextual (organisational and environmental) factors and the outcomes of patient safety interventions.

We then introduce the focal case of our study, the 1000 Lives+ national patient safety programme in Wales, and the three interventions selected for our detailed analysis: Improving Leadership for Quality Improvement (ILQI), Reducing Surgical Complications (RSC) and Reducing Health-care-Associated Infection (RHA). We conclude this chapter by outlining the aim and objectives of our study, the structure of this report and the report's intended audience.

Patient safety: a major social problem of our time

Since the publication in 2000 of *To Err is Human: Building a Safer Health System*,¹ patient safety has become recognised as a major social problem of our time. It now sits at the centre of global debates about the quality, affordability and sustainability of health care.²⁻⁶ Since 2000, understandings of the prevention, detection and mitigation of harm have improved.^{4,7-13} Crucially, from an earlier concentration on individual factors, it is now recognised that the consistent delivery of high-quality, safe and effective health care is complex and multidimensional.

Considered at higher system levels of analysis, it has been shown that patient safety is shaped by government policy¹⁴⁻²¹ and demands a nuanced balance of health-care system design^{22,23} and resources to create high-reliability organisations.^{24,25} At the organisational level of analysis, it has been demonstrated that patient safety is moulded by culture, capacity, processes and governance systems,²⁶⁻²⁸ and that each is enhanced by distributed (shared, see *Glossary*) leadership.²⁸⁻³⁶ At the level of health-care practice, it is known that patient safety is informed by the beliefs and values of health-care professionals,³⁷⁻⁴¹ and is ultimately underpinned by their personal commitment to care.^{42,43}

The extent and burden of the problem

Despite growing awareness of the challenges posed by patient safety,⁴⁴⁻⁴⁶ and concerted improvements efforts within some health-care systems,^{47,48} considerable hospital patient safety problems persist. Global estimates of the burden of harm vary. However, they are normally reported to be around 10% of all inpatient admissions with a range of 3.8–16.6%,⁴⁹ though such results are influenced by the means of measurement employed.⁵⁰⁻⁵³ In the UK, it is estimated that 1 in 10 NHS hospital patients is harmed during his or her care, and 1 in 300 dies as a result of adverse events such as acquired infection.^{54,55} Along with these human costs, safety incidents are a drain on NHS resources, costing an estimated £3.5B per year in additional bed-days and negligence claims.⁵⁶

Avoidable harm takes various forms. Errors occurring during drug prescribing, supply and administration represent a significant and persistent burden.⁵⁷⁻⁶² So, too, do those that arise as a consequence of surgery.^{63,64} A more hidden cause is, quite simply, incorrect diagnosis.⁶⁵⁻⁶⁹ In addition, there is variation in the delivery of medical and nursing care.^{70,71} Failure in the safety of care is a particular issue for high-risk patient groups,^{72,73} but all patients may be at risk of harm, for instance, from communication deficits at handover;⁷⁴⁻⁷⁷ from low staffing,⁷⁸ especially at weekends; or because the delivery of care coincides with the influx of a new cohort of junior doctors in training.^{79,80}

Foundations of the problem

Rising concerns about patient safety have led, in recent years, to a number of public enquiries into highly publicised failures of the health-care system, such as patient safety failings at the Mid Staffordshire NHS Foundation Trust,⁸¹ events at the Bristol Royal Infirmary⁸² and the Royal Liverpool Children's Hospital,⁸³ and the actions of Dr Harold Shipman.⁸⁴ The major reports published following these enquiries have helped to identify reasons for the failures⁸⁵ and have sought ways of improving the safety of patients.⁸⁶ Taken as a whole, the findings of successive UK inquiries have emphasised five issues that can be seen as foundations of the problem of patient safety: (1) deficits in cultures of care, (2) leadership inadequacies, (3) ineffective team working, (4) problematic regulatory oversight and governance systems and (5) limited patient and public engagement. We summarise these issues, and the recommendations made to address and eliminate them, in *Table 1*, as a way of introducing what was known (by us), prior to our study, about the context of patient safety.

TABLE 1 Patient safety: the foundations of the problem

Deficits in culture(s) of care

Recommended improvements

- We will make demonstrable progress towards reducing avoidable deaths in our hospitals, rather than debating what mortality statistics can and cannot tell us about the quality of care hospitals are providing
- No hospital, however big, small or remote, will be an island unto itself. Professional, academic and managerial isolation will be a thing of the past
- The NHS should continually and forever reduce patient harm by embracing wholeheartedly an ethic of learning.
- Mastery of quality and patient safety sciences and practices should be part of initial preparation and lifelong education of all health-care professionals, including managers and executives
- The NHS should become a learning organisation. Its leaders should create and support the capability for learning, and therefore change, at scale, within the NHS. It should be committed to:
 - placing the quality of patient care, especially patient safety, above all other aims
 - engaging, empowering, and hearing patients and carers throughout the entire system and at all times
 - fostering whole-heartedly the growth and development of all staff, including their ability and support to improve the processes in which they work
 - embracing transparency unequivocally and everywhere, in the service of accountability, trust and the growth of knowledge

Leadership inadequacies

Recommended improvements

- The boards and leadership of provider and commissioning organisations will be confidently and competently using data and other intelligence for the forensic pursuit of quality improvement. They, along with patients and the public, will have rapid access to accurate, insightful and easy-to-use data about quality at service-line level
- Junior doctors in specialist training will not be seen just as the clinical leaders of tomorrow, but as the clinical leaders of today. The NHS will join the best organisations in the world by harnessing the energy and creativity of its 50,000 young doctors
- All leaders concerned with NHS health care – political, regulatory, governance, executive, clinical and advocacy – should place quality of care in general, and patient safety in particular, at the top of their priorities for investment, inquiry, improvement, regular reporting, encouragement and support

TABLE 1 Patient safety: the foundations of the problem (*continued*)**Ineffective team working**

Recommended improvements

- Nurse staffing levels and skill mix will appropriately reflect the caseload and the severity of illness of the patients they are caring for and be transparently reported by trust boards
- All NHS organisations will understand the positive impact that happy and engaged staff have on patient outcomes, including mortality rates, and will be making this a key part of their quality improvement strategy
- Government, Health Education England and NHS England should assure that sufficient staff are available to meet the NHS's needs now and in the future. Health-care organisations should ensure that staff are present in appropriate numbers to provide safe care at all times and that they are well supported

Problematic regulatory oversight and governance systems

Recommended improvements

- Patients and clinicians will have confidence in the quality assessments made by the Care Quality Commission, not least because they will have been active participants in inspections
- Transparency should be complete, timely and unequivocal. All non-personal data on quality and safety, whether assembled by government, organisations or professional societies, should be shared in a timely fashion with all parties who want it, including, in accessible form, with the public
- Supervisory and regulatory systems should be simple and clear. They should avoid diffusion of responsibility. They should be respectful of the goodwill and sound intention of the vast majority of staff. All incentives should point in the same direction
- We support responsive regulation of organisations, with a hierarchy of responses. Recourse to criminal sanctions should be extremely rare, and should function primarily as a deterrent to wilful or reckless neglect or mistreatment

Limited patient and public engagement

Recommended improvements

- Patients, carers and members of the public will increasingly feel like they are being treated as vital and equal partners in the design and assessment of their local NHS. They should also be confident that their feedback is being listened to and see how this is impacting on their own care and the care of others
- Patients and their carers should be present, powerful and involved at all levels of health-care organisations from wards to the boards of trusts
- All organisations should seek out the patient and carer voice as an essential asset in monitoring the safety and quality of care

Culture(s) of care

Inquiries into the events at the Mid Staffordshire NHS Foundation Trust draw attention to 'the culture of care in the NHS'.^{5,87-89} Unfortunately, as noted by Professor Jon Glasby,⁸¹ 'The trouble with culture is everyone blames it when things go wrong but no-one really knows what it is or how to change it'. This issue is compounded when viewing (as we do) health-care organisations as comprising multiple cultures/cultural frames, rather than as a single culture of care. These points notwithstanding, research indicates that five aspects of culture are of particular salience to patient safety: (1) the need for a culture of compassion in care;⁸¹ (2) the problematic intra- and interprofessional hierarchies, which privilege a perceived elite at the expense of the broader health-care team;^{41,90-92} (3) the culture of blame that retards the promotion of adverse incident reporting and disclosure of harm to patients;^{42,93-95} (4) the culture of bullying⁹⁶⁻⁹⁸ that, regrettably, appears to be widespread across the NHS;⁹⁹⁻¹⁰⁴ and (5) the culture of unrelenting pressure to attain government targets, which creates a range of unintended and dysfunctional consequences.¹⁰⁵⁻¹¹¹

Leadership

It is well recognised that patient safety improvement requires 'sustained investment in developing leadership skills at all levels in the NHS' and its aligned regulatory organisations.⁸² Failures in strategic leadership may arise across the public sector,¹¹² with such failures attributed to, for instance, the detrimental impact of external pressures,¹¹³⁻¹¹⁵ structural change¹⁶ and the challenges posed by the global financial downturn.¹¹⁶

Nevertheless, such contextual constraints do not obviate the need for distributed leadership in health care from board to ward.^{30,36,117} The detrimental impact on patient safety of a weak board and senior management team, marred by professional disengagement, poor governance and a lack of focus on the standards of care, has been illustrated in the Francis Inquiry.⁸¹ However, at the point of care, professional leadership, especially medical, remains paramount^{118–121} and may function as catalyst for, or barrier to, patient safety improvement.^{28,90,122–125}

Team work

Research shows that, given the complexity and multidisciplinary nature of modern health care, effective team working is an important element in patient safety,^{33,126,127} necessitating good communication and co-ordination,^{119,128} particularly in high-pressure environments such as the operating theatre.^{74,75,129–133} It also requires a degree of consistency in the meanings, beliefs and values that frame different health-care professionals' commitment to care.³⁹ Yet effective team working remains vulnerable to the adverse effects of hierarchy,¹³⁴ poor staffing,⁸¹ enmity and conflict³⁰ and the human factors that give rise to team fragility.¹³⁵ Greater understanding of such human factors, specifically with regard to (i) human error, (ii) the role of health-care worker performance and (iii) the design of health-care technology, is increasingly recognised as core to patient safety.^{136–138} But to be successful, this, too, necessitates careful consideration of the local context and the informal culture of clinical practice.¹³⁹

Regulatory oversight and governance systems

Public inquiries into failures in patient safety have consistently sought to enhance regulatory oversight^{81,82} and heighten both professional and organisational systems of governance.^{83,84,140} It has been argued that these pressures have eroded professional self-regulation,¹⁴¹ replacing this traditional mode of control with an increasingly legalised regulatory system.¹⁴² As a consequence, organisational, professional and work group boundaries have shifted.¹⁴³ This has the potential to foster defensive activity,¹⁴⁴ which, as evidenced in the Francis Inquiry,⁸¹ may prove detrimental to the safe provision of health care.

Patient and public engagement

A final foundation of the problem of patient safety that emerges from recent inquiries is the weak representation of patients, their families and carers at all levels of the health-care system. Lauded as a more bottom-up approach to service planning and provision,¹⁴⁵ a robust patient-centred focus is increasingly considered a core dimension of health-care quality.¹⁴⁶ This involves providing opportunity for patient, and broader lay, involvement in professional oversight bodies⁸⁴ and health-care organisations' formal governance structures,^{147–150} as well as active patient engagement in decisions about their care and the ensuing evaluation of their experience.^{151–156}

The patient safety agenda

In 2013, the Francis Inquiry⁸¹ was accompanied by two major reports into hospital patient safety. The first was a review into the quality of care and treatment provided by 14 hospital trusts in England, led by Sir Bruce Keogh, National Medical Director for the NHS in England.¹⁵⁷ While this review acknowledged (as other commentators did^{158–160}) the difficulties in adopting mortality measures as an indicator of hospital performance, it also set out core features of high-quality care for patients. The second, a report by the National Advisory Group on the Safety of Patients in England, led by Don Berwick, President Emeritus of the Institute for Healthcare Improvement (IHI),¹⁶¹ also endorsed these goals. Each addresses the foundations of the social problem of patient safety that are outlined in *Table 1*.

The improvement agenda proposed by these two recent reports is exacting. It demands changes in policies, the education of health-care professionals and wider NHS workforce and further research into the quality and safety of health care.⁵

Patient safety improvement programmes

Recent reports and inquiries indicate that the global debate has progressed from the recognition and acknowledgement of the foundations of the problem of patient safety to the quest for systemic solutions to the challenges it poses.^{88,162–167} In England, a special health authority of the NHS, the National Patient Safety Agency, was established in 2001 with the remit of monitoring patient safety. It identified the need to introduce patient safety improvement programmes to help foster local capacity and progress from a 'blame' culture to one that was perceived to be 'just' and capable of facilitating the open reporting of errors and near-misses.¹⁶⁸ Informed by the work of the US-based IHI,¹⁶² and advances in safety within other industries,^{22,169,170} NHS hospital patient safety programmes have typically sought to achieve improvements by implementing evidence-based clinical practices and enhancing performance monitoring systems.^{171–173} Although the National Patient Safety Agency was dissolved in 2012, these policy goals continue to be pursued, in England, through the NHS Commissioning Board and the Safer Patients initiative sponsored by the Health Foundation, a charitable trust, and in Wales through the 1000 Lives campaign and its successor, the 1000 Lives+ national programme, the focus of this study.

1000 Lives+ national programme in NHS Wales

Patient safety interventions range from isolated interventions within a discrete health-care setting, such as the estimation of intraoperative blood loss¹⁷⁴ or the validation of specific measures of harm,¹⁷⁵ through to national programmes of the type we are investigating in this study.¹⁷⁶

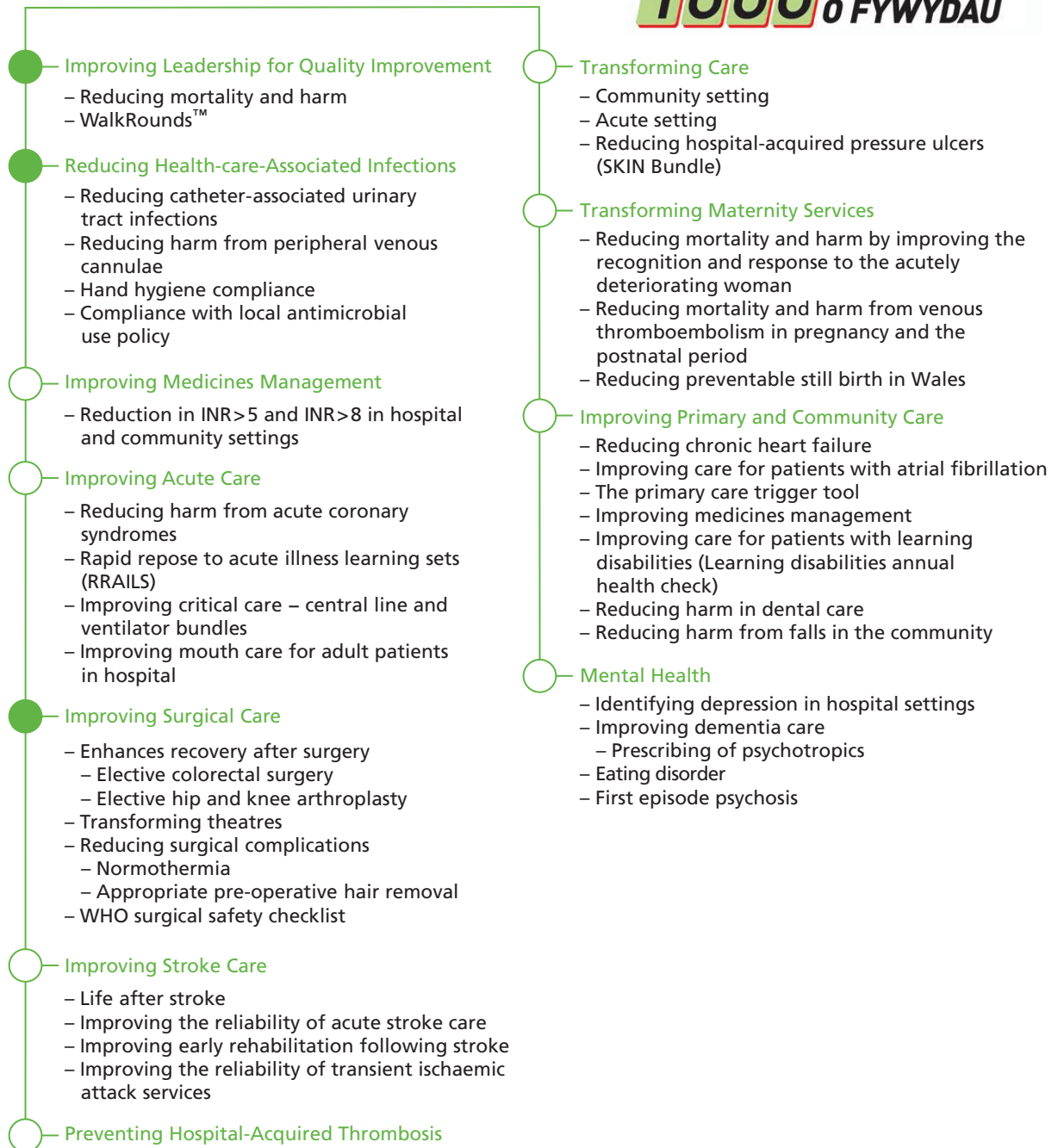
In April 2008, the Welsh 1000 Lives+ campaign was launched by a collaborative involving the Welsh Assembly Government's Clinical Governance Support and Development Unit, the Wales Centre for Health, the National Leadership and Innovation Agency for Healthcare, the National Public Health Service and the National Patient Safety Agency. It had two distinct goals: (1) to reduce by 1000 the number of deaths caused by suboptimal care and (2) to reduce by 50,000 the number of adverse incidents. All health-care organisations in NHS Wales volunteered to participate in the programme. In 2010, the campaign was superseded by the 1000 Lives+ national programme. This continued the ethos of high-quality person-centred care and offered a broader range of patient safety interventions, and aligned resources, for NHS Wales' health boards to implement. This ambitious and complex intervention built on the momentum of its predecessor and now forms a core component of the Welsh Government's delivery framework for the NHS in Wales. As illustrated in *Figure 1*, 1000 Lives+ comprises a complex array of 11 core programme improvement areas.

In this study, our attention is concentrated on three focal interventions: (1) ILQI, (2) RSC and (3) RHA1.

The 1000 Lives+ programme and its predecessor are adaptations of the IHI's 100,000 Lives campaign.^{162,177} Both are informed by the Model for Improvement (MI), developed by Langley *et al.*,¹⁷⁸ depicted in *Figure 2*. This model^{179,180} first directs attention to three questions: what are we trying to accomplish?; how will we know that a change is an improvement?; and what changes can we make that will result in improvement? It then prescribes the implementation of solutions through a Model for Improvement, Plan-Do-Study-Act (MI-PDSA) cycle.

Centred on Deming's system of profound knowledge,¹⁷⁸ the MI-PDSA approach is an acknowledged cornerstone of the science of improvement,^{44,181} and is informed by a diverse array of theoretical perspectives.

The MI-PDSA cycle has been promoted by the IHI as *the* means to foster the transformation of patient safety.¹⁷² The strength and success of this promotion is reflected in the way that the MI-PDSA approach has been applied across a range of contexts, and to a variety of issues. Many of these themes are of direct relevance to this study, including (i) the role of local champions in leading change;^{182–184} (ii) the education of health-care professionals in evidence-based practice change;^{185–188} (iii) the implementation of the World Health Organization Surgical Safety Checklist (WHOSSC);^{169,189–191} (iv) the development and implementation of anti-infective prescribing policies,^{192–194} including those for correct hand hygiene;¹⁹⁵ and (v) the large-scale transformation of health-care services through a heightened emphasis on patient safety.^{5,196}



<http://www.1000livesplus.wales.nhs.uk/programme-areas>

FIGURE 1 1000 Lives+ national patient safety programme areas.

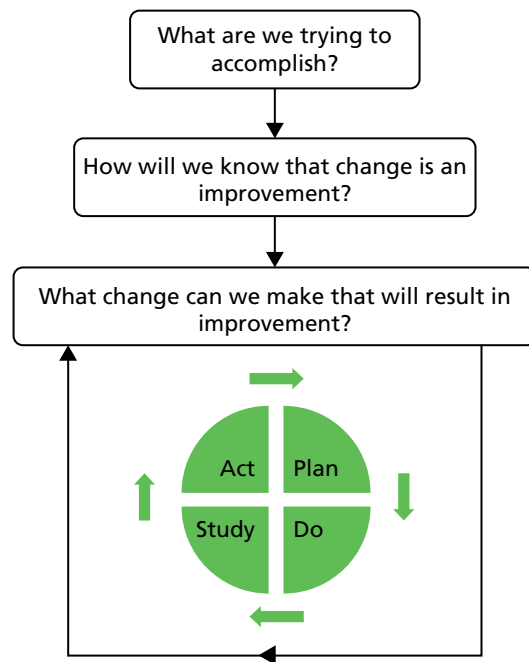


FIGURE 2 Model for improvement.

Design, implementation and evaluation

The 1000 Lives+ national programme incorporated a range of IHI-inspired patient safety interventions that have been utilised worldwide.⁵ These include (i) the use of checklists; (ii) care bundles (checklists and associated directive guidelines) for high-risk drugs¹⁹⁷ and invasive practices;^{192,198,199} (iii) multicomponent interventions, such as those advocated for the prevention and management of pressure ulcers, falls and hospital-acquired infections;^{200–203} and (iv) various other forms of intervention, including staff training,^{118,204–206} adverse event simulation,^{207,208} computer-assisted care management,^{62,209} national and/or local alert systems and trigger tools.^{28,53,210,211}

Hospital patient safety: a realist analysis

Context matters

Despite having a basic improvement approach in common, the differences in scale and scope of the patient safety programmes impact on both the complexity of their implementation and the evaluation of their outcomes^{5,168,212–215} and the reported outcomes of these interventions are marked by considerable variation. However, although public inquiries and research evidence now concur that patient safety is, in part, a matter of context,¹⁶⁸ there has been very limited systematic and independent analysis of the relationship between organisational factors which shape the local context of health care and the outcomes of patient safety interventions.^{124,216–223}

Prior to this study, relationships between the recently advocated ‘four high-priority’ features of organisational context:^{5,223} (1) external factors such as regulatory requirements; (2) organisational structural characteristics; (3) leadership, team work and patient safety culture; and (4) management priorities – and the outcomes of safety programmes were both undertheorised and poorly understood in empirical terms.²²⁴ As a result, the context of patient safety remained amorphous²²⁵ and ill defined.²²⁶ In contrast, this study is designed to address the conceptual and empirical knowledge gaps involving the context of patient safety.

Aim and objectives

This study employs insights from institutional theory²²⁷ within a realist analysis framework^{228–235} to examine the impact of context on the implementation of the 1000 Lives+ national programme across the Welsh NHS. We present and explain our conceptual framework in *Chapter 2*.

Our approach arises from an appreciation that the influence of organisational features on hospital patient safety programmes cannot be readily understood from traditional evaluation methods.^{236,274} Building on findings from previous studies of the design²³⁷ implementation,^{21,220,238,239} and outcomes^{146,240} of patient safety improvement programmes, we examine the implementation of three focal interventions in a multisite comparative-intensive case study of hospitals in NHS Wales. We seek to reveal the complex interplay of context and concerns,^{234,235} captured through the organisational factors and competing institutional logics – belief systems – which guide acceptance of, or resistance to, the local adoption and adaptation of patient safety programmes.^{3,240}

This realist analysis of patient safety aims to ascertain which contextual factors matter, and how, why and for whom they matter, in the hope that processes and outcomes of future improvement programmes may be improved. Hence the unit of analysis in this study is the process of local implementation of the 1000 Lives+ programme, centred on the three focal interventions (rather than an evaluation of the 1000 Lives+ programme per se). The study has five main objectives:

1. to identify and analyse the organisational factors (e.g. structure, culture and managerial priorities) pertinent to the health outcomes of hospital patient safety interventions
2. to identify and analyse the contextual mechanisms (logics or belief systems) that interact with organisational factors to generate the health outcomes of hospital patient safety interventions
3. to develop and test hypotheses concerning relationships between organisational factors, mechanisms and the health outcomes of hospital patient safety interventions
4. to produce a theoretically grounded and evidence-based model of which organisational 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.

The achievement of these objectives should allow us to suggest how a particular configuration of organisational factors may influence the mechanisms that lead to more or less successful health outcomes of the three focal safety interventions considered. It is hoped that these findings will inform policy-makers, managers and practitioners, locally, nationally and internationally; will empower stakeholders to develop improvement interventions that are more likely to work in their local contingent circumstances; and may serve as a diagnostic tool to be used as a precursor to the design of more differentiated and context-sensitive interventions in future.

Report structure

The remainder of this report is presented in eight further chapters. Recognising the complexity of the subject matter and the novelty of our conceptual framework, we have produced an innovative set of explanatory schematics to accompany each chapter, in addition to our use of standard data tables and figures. Below, we outline the structure of this report and the way in which we combine text, explanatory schematics and other forms of data presentation to ensure the clarity of our reporting.

Chapter 2 presents the conceptual framework developed in this study – realist analysis – and defines our elaboration of established approaches to realist inquiry, centred on Archerian critical realism and augmented by sociological institutionalism and neo-institutional theory (see *Figures 3–6*).

Chapter 3 presents the research design – comparative case study – and multimethod approach to data collection and analysis (including our alignment to realist analysis) (see *Figure 7* and *Tables 2–5*).

Chapters 4 and 5 present our analysis of the implementation and institutionalisation of the 1000 Lives+ programme in NHS Wales. Together, they form the foundation for our realist analysis of the three focal interventions selected from the programme. *Chapter 4* presents our analysis of the bureaucratisation of 1000 Lives+ programme across NHS Wales, defining our preliminary understanding of the local implementation of the 1000 Lives+ programme (see *Figures 8–11* and *Tables 6–9*). *Chapter 5* explores interpersonal and individual engagement with 1000 Lives+ to offer an account of the normalisation of the programme at the level of the functional team within each health board (see *Figures 12–15* and *Table 10*).

Chapters 6–8 present our realist analysis of the three focal interventions – ILQI, RSC and RHA1 – and our understanding of the complex and dynamic relationships between organisational factors, generative mechanisms and the outcomes of hospital patient safety interventions: *Chapter 6, Improving Leadership for Quality Improvement* (see *Figures 16* and *17*, and *Tables 11–21*); *Chapter 7, Reducing Surgical Complications* (see *Figures 18–20* and *Tables 22–27*); and *Chapter 8, Reducing Health-care Associated Infection* (see *Figures 21* and *22*, and *Tables 28–33*).

Chapter 9 presents the discussion and conclusion of our study, wherein we debate which contextual factors appear to impact on the implementation of patient safety improvement programmes, promoting or retarding their local success. In addition, we discuss the generalisability of our findings, the limitations of our study and potential for future work in this important area.

Intended audience

Throughout this report we have been concerned to ensure that our findings are accessible to the public, professionals, researchers and policy-makers wishing to (a) better understand existing improvement programmes and (b) design more effective ones in the future. We hope that our innovative use of neat description and summary graphics will assist in this objective, and the summaries presented in *Chapters 1* and *9* are written for this extended audience in particular. In addition, we hope that much of the detailed narrative in the report will be of relevance to social scientists and others with an academic interest in the realist analysis of complex organisational phenomena.

Chapter 2 Conceptual framework

Overview

This chapter presents the realist analysis framework that was developed and then used in this study. It is presented in three main parts.

We begin by introducing the foundational realist philosophy of social science together with the approach to realist inquiry that underpins our framework. We then define the manner through which intervention, context, mechanism and outcome have traditionally been conceptualised and identify four challenges that have emerged.

The second section of this chapter, guided by Pawson's²⁴¹ belief that methods gain their spurs by thoughtful adaptation rather than mindless replication, introduces the conceptual resources from sociological institutionalism and Archerian critical realism that we have employed to address the challenges of applying realist inquiry.

In the final section, we draw from those resources and set out our innovative approach to the interplay of intervention, context and mechanisms in realist analysis. Briefly, our elaborations to realist inquiry are as follows. First, we include intervention as a separate analytical category in our realist analysis so that we may understand precisely 'what' is working, for whom, how and in what circumstances. Second, we forward a view of situated context as being stratified, conditioned, relational and temporally dynamic. Next, we distinguish the conceptual elements of mechanism from its ensuing outcomes and demonstrate the fundamental role of beliefs and values, institutional logics, on the propensity to act. Finally, in our realist analysis framework, outcome is not perceived as a simple, single aspect of change, such as a defined health outcome. Rather, we consider patterns of structural, political and ideational elaboration and maintenance.

Foundations of realist inquiry

Realist inquiry has emerged at the forefront of theory-informed policy evaluation methodology in health services and in other areas of social scientific enquiry.^{228,241-243} Orthodox strategies for marshalling evidence in health-care research, epitomised by the Campbell and Cochrane Collaborations' systematic reviews, seek to produce answers to the question 'what works?'. In contrast, realist inquiry seeks to better bridge the gap between research, policy and practice²⁴⁴⁻²⁴⁶ by addressing the question 'what works for whom, why and in what circumstances?'.^{242,247} Within realist scholarship, two main approaches have gained prominence. Realist evaluation is the mode of inquiry for primary research, in which new data are collected from original sources. Its companion, realist review or synthesis, is the secondary research equivalent and involves analysis and interpretation of existing data. Both realist modes place emphasis on explanation of the interplay of contextual circumstances and mechanisms that foster the success or failure of an intervention. The principal aim is to refine understanding of how and why the intervention operates through the development of a more nuanced explication of what is termed programme theory, that is, the implicit or explicit hypotheses about anticipated outcomes on which a series of interventions (such as 1000 Lives+) are based.²⁴⁷

Realist inquiry is rooted in the realist tradition in the philosophy of science. At base, realism steers a path between empiricist/positivist and constructivist accounts of scientific explanation²⁴³ and is regarded as the principal post-positivistic perspective.²⁴²

The scholarship of Pawson and other realists is underpinned by a generative theory of causation. Hence the aim of realist research, such as ours, is not to identify variables that associate with one another as advocated by positivism. Instead, the research goal is to surface and explain how the association itself came about.²⁴⁸ In this mode of inquiry, analysis is directed towards the identification and explanation of the underlying generative mechanisms which shape structure, agency, social relations and ensuing practices that are reproduced and/or transformed.^{249,250} The realist approach to reviewing the evidence from complex interventions such as patient safety improvement programmes, therefore, assumes that deterministic theories cannot always explain or predict outcomes in every context.²⁵¹

The aim of realist inquiry is to further inform our understanding of the nuanced interplay between context, mechanism and outcome for particular interventions.^{252–254} Its hallmark is, therefore, a quest to progress from a presumptive definition through to an evidence-informed refinement of a causal explanation.^{247,255,256} Crucially, the conclusions of realist studies are recognised to be both provisional and fallible.²⁵⁷

Realist inquiry

In realist inquiry, testable propositions of how an intervention is perceived to work are depicted through context–mechanism–outcome configurations (hereafter, CMO configurations).²²⁸ In essence, a CMO configuration is a hypothesis that the programme outcome (O) emerges because of the action of some underlying mechanisms (M), which come into operation only in particular contexts (C).²⁵⁶ Each CMO configuration, therefore, explicates and progressively refines the scope of the original programme theory.^{258–260} In this manner, a virtuous circle is completed, fostering deeper understanding of the opportunities and challenges presented by an intervention, to inform future policy and practice.

Realist inquiry has gained increasing acceptance in health-care research, in part owing to its suitability for examining the implementation of complex interventions in heterogeneous, multiprofessional social systems.^{261–266} However, a number of challenges have emerged concerning the operationalisation of each component of the CMO configuration. These challenges are discussed in the following four sections.

Intervention

Following Pawson, we recognise that while interventions designed to foster individual, organisational or system change (e.g. patient safety improvement programmes) are complex and diverse,^{260,267,268} they often depict consistent features. However, each intervention is dependent on collaborative human agency (motivated action) to achieve their effects. Consequently, the implementation chain of an intervention will be shaped by inconsistencies, as individuals and collectives, each differently enabled or constrained by the social system, engage with, adopt and adapt or ultimately reject the resources and reasoning provided by the programme.²⁵¹ The operationalisation of an intervention is, therefore, contextually dependent, influenced by the social system into which it is introduced and apt to mutate in situ.^{251,269}

There have been a number of realist approaches to analysing interventions in health-care organisations. For instance, an early application of realist inquiry into intervention in health care was research undertaken by Greenhalgh *et al.* into a major reorganisation of four inner-London health-care organisations^{176,261,270} They present an inclusive analysis of the interwoven components of an intervention, together with a postulated theory for each facet.^{176,261,270,271} Similarly holistic approaches are illustrated in Byng *et al.*'s evaluation of a complex health services intervention targeted towards people with long-term mental illness,^{264,272} Manzano-Santaella's realist evaluation of financial incentives in English hospital discharge policy,²⁷³ and other causal explanations of interventions targeted at various stakeholder groups, including (i) patients;^{274–276} (ii) specific groups of health-care and aligned workers,^{277–284} and (iii) the standardisation of evidence-based practice through protocol-based care.^{285–287}

Alongside realist approaches that have been applied to consider 'whole interventions', more selective analyses of the discrete components of an intervention are depicted in studies such as Leone's evaluation of an illicit drug deterrence programme.²⁸⁸ This sanctions-based intervention is considered only with regard to the effects of its mandatory interview component. Similar approaches are demonstrated in other realist

studies of health-care settings, such as (i) Blaise and Kegels' evaluation of the development of the quality management movement in health-care systems in Europe and Africa,²⁶³ (ii) Ogrinc and Batalden's evaluation of teaching about improvement of care in a clinical setting;²⁸⁹ and (iii) Pittam *et al.*'s evaluation of employment advice provided to help people with mental health problems gain work.²⁹⁰

Thus, it may be argued that previous applications of realist inquiry in health care have applied the concept of intervention inconsistently. Moreover, in our view, intervention is regularly underspecified and is too often conflated with context. As will be described later (see *Intervention: a distinct analytical category*), in this study we have tried to address these problems by treating intervention as a separate analytical category.

Context

In realist inquiry, four concentric layers of context are typically defined: (1) the broader infrastructural system, the outermost layer; (2) the institutional setting, encompassing the cultural aspects of a given contextual domain; (3) the interpersonal relationships which constitute the relational structure within which actors are embedded; and (4) the individual capacities of the key actors.²⁴² However, with rare exceptions (e.g. the work of Greenhalgh *et al.*²⁷⁰ and of Byng *et al.*²⁶⁴), realist studies in health care have, typically, been limited to a domain-specific notion of context. For example, focus may be directed towards the broader infrastructural system and associated aspects of the institutional setting as illustrated in Evans and Killoran's realist evaluation of tackling health inequalities through partnership working²⁹¹ or Pommier *et al.*'s analysis of health promotion activities within the French education system.²⁹²

Alternatively, realist inquiries have focused on discrete organisational sites²⁹³ as in Oroviogioicoechea *et al.*'s evaluation of the impact of a computerised hospital information system on nurses' clinical practice,^{294,295} Pittam *et al.*'s evaluation of employment advice for those with mental health issues,^{290,296} and Tolson *et al.*'s study of managed clinical networks in the care of individuals with cancer-related pain.²⁹⁷

More recently, other aspects of context have been considered within realist studies in health care. These typically encompass the notion of organisational culture and influences emerging from wider interorganisational alignment.^{3,298-300} Key contextual features include leadership, both by corporate management and by clinical health-care professionals,^{81,181,301} and governance systems, including performance monitoring, evaluation and feedback, which is increasingly patient informed.^{28,146,302}

Overall, as noted by Shekelle *et al.*,²²³ many previous applications of realist inquiry have failed to agree on what elements of context are most influential and how context should be conceptualised.^{27,303,304} We have tried to avoid this problem by using a multilevel approach to this issue (see *Context: structural conditioning*).

Mechanism

As originally described by Pawson, the mechanisms of a programme describe what it is about programmes and interventions that bring about any effects and are the processes by which subjects interpret and act on the intervention stratagem.^{228,241,242} Thus, it is not programmes that work per se. Rather, it is the underlying reasons or resources that they offer subjects that generate change.³⁰⁵ In this view, mechanisms explain causal relations by describing the powers, propensity or particular ways of acting inherent to a system and are linked to, but not synonymous with, the underlying programme theory.^{306,307}

Further insight into the nature of mechanisms is contributed by the work of Hedström and Ylikoski,³⁰⁸ who contend that a mechanism is a causal process that produces an effect or phenomenon. In addition, they posit that a mechanism has structure and operates in hierarchical sequence. This conceptualisation parallels that of Fleetwood,³⁰⁶ who sees mechanisms as consisting of a cluster of causal factors or components comprising social structures, practices, relations, rules and resources, with each cluster possessing the powers, capacities and potentials to do certain things. It is also important to appreciate that mechanisms produce contextually modulated effects according to their spatiotemporal relations with other objects, and have their own causal powers and liabilities, which may trigger, block or modify their action.^{309,310}

In realist inquiries, mechanisms are typically presented as part of a CMO configuration.^{311,312} Indeed, some studies extend this explanatory analysis to expose the specific roles of different components of the intervention. This is exemplified in Mazzocato *et al.*'s study,³¹³ where candidate mechanisms, attributed to the operationalisation of service improvement methods, are used to define multiple CMO configurations. However, in studies where CMO configurations are not developed, merely disconnected mechanisms or outcomes, as opposed to a causal explanation, may be reported, as in Harris *et al.*'s³¹⁴ realist review of journal clubs and Gunawardena's³¹⁵ review of the effectiveness of geriatric day hospitals.

It is acknowledged in realist inquiry that one CMO configuration may be embedded in another or configured in a series (in which the outcome of one CMO becomes the context for the next in the chain of implementation steps).³⁰⁷ This aspect of realist inquiry remains underdeveloped, as it demands a highly complex formulation of CMO configurations.^{316–318}

In addition, although it is acknowledged that mechanisms encompass the reasoning of its participants, this aspect of realist inquiry is also little explored,²⁵⁶ with few studies reporting participants' thoughts about why they chose to change, or indeed adhere to, their established practice (for two exceptions, see Dieleman *et al.*³¹⁹ and Jackson *et al.*³²⁰). The relative neglect of this aspect of mechanism may not be surprising as, as noted in Vassilev *et al.*'s realist review of the role of social networks in the management of chronic illness,³²¹ unpacking and conceptualising reasoning is fraught with difficulty as justifications for choices can operate within different, and often contradictory, stances.

Outcome

In realist inquiry, an outcome cannot be perceived as a simple, single aspect of change. The multifaceted nature of an intervention, particularly when implemented within different organisations, each shaped by their own contextual constraints and enablements, leads to different patterns of social transformation.^{243,269}

Many applications of realist inquiry in health care attempt to present the health outcomes of interventions. However, as noted by Floyd *et al.*,³²² the specification and measurement of outcomes poses challenges. For example, health outcomes may be obscured, merged with context and mechanism and depicted as factors,³²³ or simply framed in terms of the intervention's effectiveness.³²⁴ Outcomes supported by CMO configurations, and thus setting out a clear explanatory argument, such as Tilley's³²⁵ realist evaluation of a British crime reduction programme, do something to tackle this problem. However, few studies explicitly address more subtle and aligned outcomes arising from the intervention.

To summarise, the above section has suggested that, despite the contributions made by realist inquiries in health care, four issues have consistently challenged researchers who have sought to apply existing models: (1) the tendency to conflate intervention with context; (2) the limited conceptualisation of context and mechanism, thereby inhibiting rigorous analysis of their boundaries; (3) the preoccupation with health outcomes, as opposed to wider organisational and systemic gains or losses; and (4) the limited capacity to frame the dynamic, temporal, interplay of intervention, context, mechanisms and outcomes. We now move on to explain how we sought to address these issues through an elaborated model of realist analysis.

Addressing the challenges of realist inquiry

In our realist analysis framework, we employ resources from sociological institutionalism and Archerian critical realism to help better specify context and mechanism and hence to address the challenges outlined above. In the next two sections we introduce the key concepts that inform the revised CMO model we present in *Realist analysis: an elaborated intervention–context–mechanism–agency–outcome model*.

Sociological institutionalism

Within organisation studies, there has been a 'growing disenchantment' with analytical perspectives that emphasise the influence of managerial rationality within organisational life.³²⁶ Rejecting the tenets of strategic management and classical economic theory, sociological institutionalists examine the significance of institutions, the 'regulative, normative and cognitive [see *Glossary*] structures that provide stability and meaning to social behaviour'.³²⁷

Some of the main contributions to understanding institutional change and inertia in health care have emerged from analyses conducted at the level of organisational fields, defined as communities of organisations that 'partake of a common meaning system and whose participants interact more frequently and fatefully with one another than with actors outside of the field'.³²⁸ In a seminal example, DiMaggio and Powell³²⁹ suggest that within organisational fields, three forces – mimetic (copying those perceived to be successful), coercive (e.g. regulation) and normative (e.g. stemming from professional norms) – combine to produce powerful templates of what constitutes legitimate organisational structure and action, and we use these terms in our analyses of the data from our study.

In common with critical realism, sociological institutionalism depicts a world of virtual depth,³³⁰ stratified and organised through different levels of institutional structures, along with their logics, or commonly held sets of beliefs and values. There are higher, or macro-level, structures; these include societal systems such as the bureaucratic state, capitalist markets, democracy and religion. Then come meso-level structures characterised as organisation sectors or fields; these are composed of those organisations that are involved in a particular issue or policy community. The concept incorporates field-level structures, participating organisations and the people working within and between these organisations. For instance, the field of health-care organisations comprises distinctive actors, diverse institutional logics and distinct governance structures. Finally, there is the micro-level of the individual organisation, together with further intraorganisational levels or groups.

Typically, the multiplicity of logics in a given domain is represented as some combinations of (i) higher-order societal logics,³³¹ (ii) field-level logics³³² and (iii) institutional or 'cultural' logics.³³³ At the societal level, heterogeneous higher-order logics sculpt the social world, conveying the core organising principles of different sectors.³³¹ Institutional logics orchestrate lower-level institutional strata and ensuing practices. They shape organisational interests, individual preferences, define actors' expectations about each other's behaviour and organise their enduring relations with each other.^{330,334}

Previous studies of UK health-care fields have concentrated on the role of, and dynamics among, three logics: professionalism, bureaucracy and market. Professional logic was dominant for much of the twentieth century and gave workers with specialised knowledge (e.g. doctors) cultural and material privileges, including the power to organise and control their own work and that of others.^{335,336} The primary justification for these arrangements was that service delivery is optimised when it is under the control of experts acting with the altruism they are assumed to develop during prolonged training and socialisation. During the latter part of the twentieth century, successive governments promoted combinations of two alternative logics in health care: (1) bureaucratic logic, which holds that service delivery is improved under the administrative control of work using techniques of performance management, and (2) market logic, which holds that improved service delivery arises from conditions of competition among providers and choice among clients.

In our framework, multiple layers of logics constitute and provide the inherent structure to context. However, organisational actors (or agents) may go along with or actively resist these social prescriptions,³³⁷ thus inhibiting or supporting change. The process of institutional change is, therefore, both enabled and constrained by (i) the array of institutions, which compose and condition the substructure of the health-care field, and (ii) agential theorisation, reflexivity and ensuing modes of institutional work.^{338–340} Accordingly, even though institutions provide meaning to social life, such conditioning is non-deterministic.^{229,341}

Realist social theory

To further elaborate realist inquiry, we turn to Margaret Archer's seminal work on critical realism.^{229–235} As in Herepath's study,³⁴² our approach employs Archer's conceptual approach to structure,²²⁹ culture²³⁰ and agency,²³¹ together with her later work on reflexivity.^{232–235} Our reasons for incorporating Archer's realist social theory are threefold.

First, Archer's ontological stance holds structure (context) and agency (mechanism) as separate entities. Consequently, Archer offers help to researchers who struggle over this distinction when analysing the complex interplay of context and mechanism during the development of CMO configurations.

Second, an Archerian approach resonates with sociological institutionalism.^{343,344} Hence by harnessing institutional theory within an Archerian approach, institutions are given their due recognition and temporal role as both symbolic constructions and a set of material practices which guide actors' behaviours.³⁴⁵ This helps to reveal the multiple logics which shape adherence to, or disregard for, the components of an improvement programme and its underlying ethos.

Third, an Archerian approach offers a robust methodological framework composed of three phases,²²⁹ which parallel the context, mechanism and outcome components of a CMO configuration. Therefore, methodologically, the researcher is guided by an aligned approach that helps to distinguish the boundaries between context and mechanism and to reveal possible causal links between them.

Realist analysis: an elaborated intervention–context–mechanism–agency–outcome model

This section explains how our model of realist analysis draws from the resources outlined above to address the challenges of realist inquiry.

Intervention: a distinct analytical category

Our first elaboration to realist inquiry is to include intervention as a separate analytical category in our realist analysis model. This stems from our recognition that although realist studies have adopted similar Pawsonian conceptions of intervention, the absence of intervention as an analytical component has encouraged its underspecification and conflation within context.²⁸⁶

We therefore consider that there is an imperative within realist inquiry to (i) explicitly define the intervention 'I' and (ii) add this to Pawson's original CMO formula to produce intervention–context–mechanism–agency–outcome (I-CMAO) configurations. This allows us to understand precisely 'what' is working in a situated context, for whom, how and in what broader circumstances. This refinement is depicted in *Figures 3 and 4*, and this method of representation forms the basis of all the translational schematics for the realist analysis presented in *Chapters 6–8*.

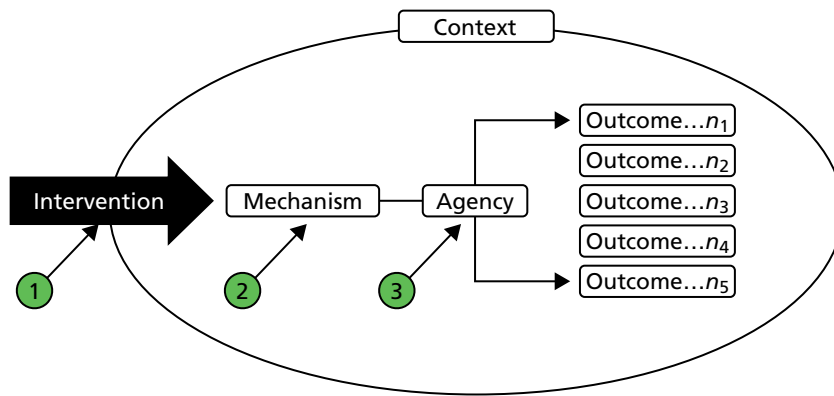


FIGURE 3 Basic I-CMAO schematic.

Figure 3: key point summary

In *Figure 3* we depict a schematic representation of an I-CMAO configuration. Point 1 highlights the introduction of an intervention into a given context. Point 2 highlights the activation of a mechanism. Point 3 highlights the ensuing agency that gives rise to outcomes.

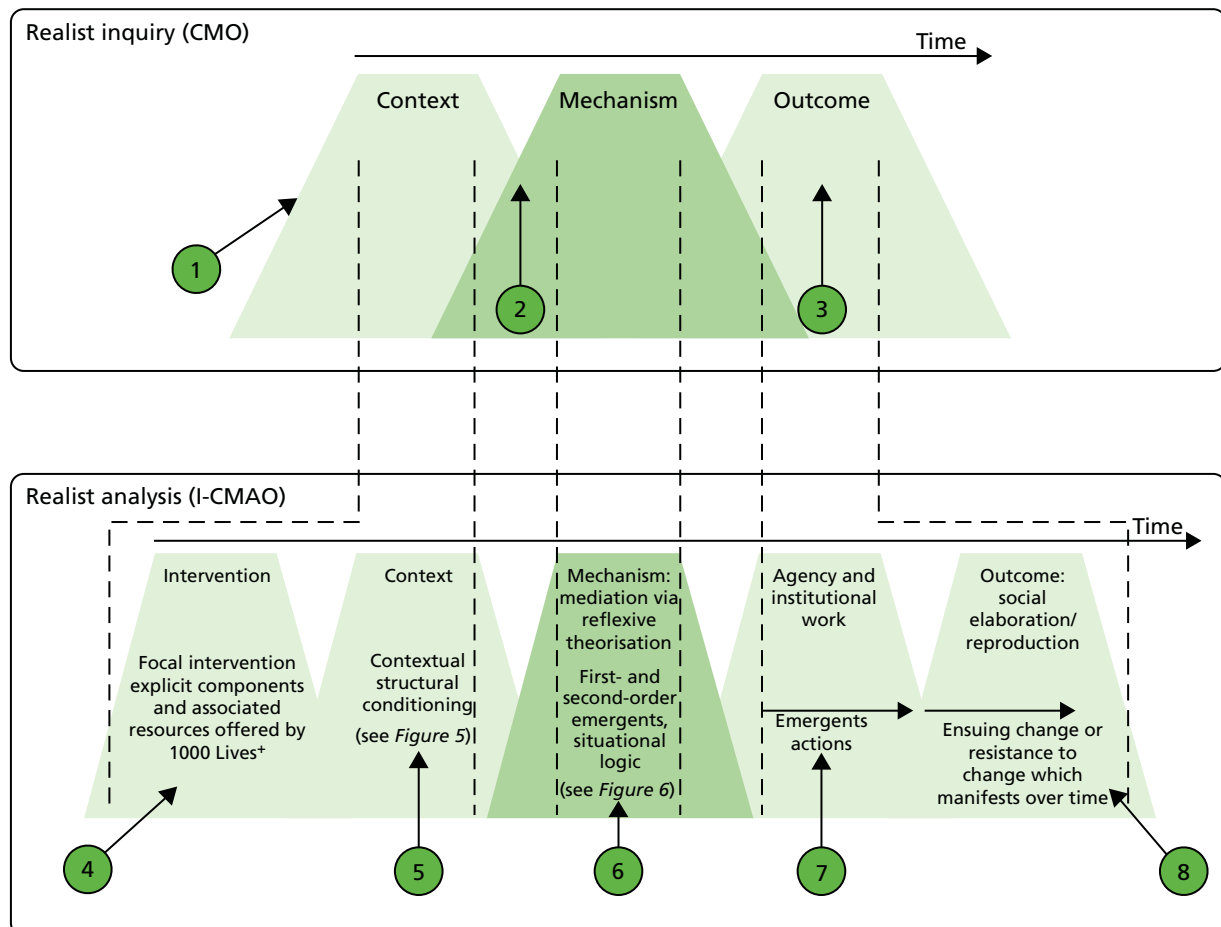


FIGURE 4 Translation from a CMO configuration to an I-CMAO configuration.

Figure 4: key point summary

In the upper graphic of *Figure 4* we depict a schematic representation of a CMO configuration. As asserted in *Realist inquiry*, a CMO configuration is a hypothesis that the programme outcome (O) emerges because of the action of some underlying mechanisms (M), which only come into operation in particular contexts (C).

Point 1 highlights the absence of intervention as a separate aspect of the analysis.

Point 2 highlights the difficulty that may arise in distinguishing context from mechanism in realist inquiry due, in part, to the lack of clarity and consistency with which context is conceptualised and operated.

Point 3 draws attention to outcome in realist inquiry. An outcome cannot be perceived as a simple, single aspect of change; however, few studies explicitly address more subtle and aligned outcomes, which arise consequential to the intervention, impacting social elaboration or reproduction.

To address these issues, in the lower graphic of *Figure 4*, we depict a schematic representation of our I-CMAO configuration and set out our four elaborations.

First, as indicated by point 4, we include intervention as a separate analytical category embedded with the context under consideration.

Second, at point 5 we forward a view of context as stratified, conditioned, relational and temporally dynamic, as expanded in *Figure 5*. In doing so, we seek to define the 'situated context', through the dominant structural and cultural emergent properties in play, their attendant mechanisms and, thus, the impact on lower contextual strata.

Third, at point 6 we apportion mediation and reflexive theorisation to mechanism. In this manner, we distinguish the conceptual elements of mechanism from its ensuing outcome (this is expanded in *Figure 6*).

Point 7 highlights our goal of examining the ensuing process of institutional change, as opposed to that which ultimately manifests as an outcome, thereby recognising that such change unfolds through time, may be contested and may be at different stages of maturation in different situational contexts.

Finally, as depicted in point 8, outcome is not perceived as a simple, single aspect of change. Rather, we seek to reveal structural and ideational differentiation.

Context: structural conditioning

As noted earlier, both realist inquiry and sociological institutionalism not only stress the importance of context²²⁸ but also warn that to enable meaningful explanatory analysis, context cannot be reduced to the spatial, geographical or institutional location into which a social programme is introduced and that a more nuanced understanding of the multiple layers that compose a given context must be established.^{236,244,257}

Guided by the approach to realist inquiry adopted by Pawson,²²⁸ we address the need to develop a more subtle analysis of context by specifying four main levels of contextual hierarchy (infrastructural system, institutional setting, interpersonal relations and individual) with all but the individual level divided into substrata (see *Figure 5*).

At the highest hierarchical level, we see the infrastructural system of the Welsh health-care state as comprising three strata: (1) the higher-order societal logics which mould this contextual arena; (2) the Welsh Government, as a devolved substate nation, and (3) the public sector partner agencies with regulatory oversight of health-care quality and patient safety, which operate in close liaison with, but distinct from, the Welsh Government and NHS Wales. The second highest hierarchical level of context, the institutional setting, is conceptualised through two strata: (4) NHS Wales, as a corporate whole, and (5) its seven constituent health boards as distinct multisite organisations. The third level, interpersonal relationships, which constitute the relational structure within which actors are embedded, is captured across two further strata: (6) a hospital site-based ward or multisite department and (7) the functional team (the group of people who carry out the tasks involved in running a ward or department). Our final stratum (8) describes the capacities of the individual actors.

However, a stratified model of context provides only the basic architecture of our argument, as it lacks the means to consider context as 'situated', meaning dynamic, conditioned, relational and temporally fluid. In essence, we see the dynamism of context as contoured by emergent structural, cultural and agential powers across time. Our recourse to Archerian critical realism, together with the work of Herepath,³⁴² therefore offers a more complex yet nuanced means to develop I-CMAO configurations.

An underlying premise of realist theory and research is that context affects or mediates ensuing agential actions³⁴⁶ and hence the structural constraints and enablements of context are mediated to the agent as first-order emergents. First-order emergents encompass agents' placement within their broader social context and roles, their vested interests, the opportunity costs associated with different courses of action and, thus, their perceived interpretive freedom. Such first-order emergents impact differently on each agent, enabling or frustrating the attainment of their desired goals depending on their social bargaining power, both as individuals and as members of groups. Consequently, our analysis of how context impinges on agents is stratified across three levels: social position, how their roles relate to others and the cultural logics of the institutional domain within which they are situated. In this way we expose the contextual constraints and enablements imposed on the agent.

The second stage by which the constraints and enablements of context are mediated addresses how agents, conditioned by their contexts, think about and influence the formulation of their desired projects, both individually and collectively.²³² These influences give rise to potential second-order emergents (i.e. 'the results of the results' of the first-order emergent properties³⁴⁶), which in their turn affect the ways in which an intervention is implemented.

Accordingly, in our realist analysis, we separate context from its mediation (or the effects of the context on the intervention). As depicted in *Figure 5*, we first specify the explicit stratum concerned, so that hierarchical and heterarchical influences may be more readily appreciated within a situated context. Second, we identify dominant structural and cultural emergent properties within that context to define the structural conditioning in play. Third, we apportion its mediation to mechanism, as expanded in *Mechanism: sociocultural interaction*.

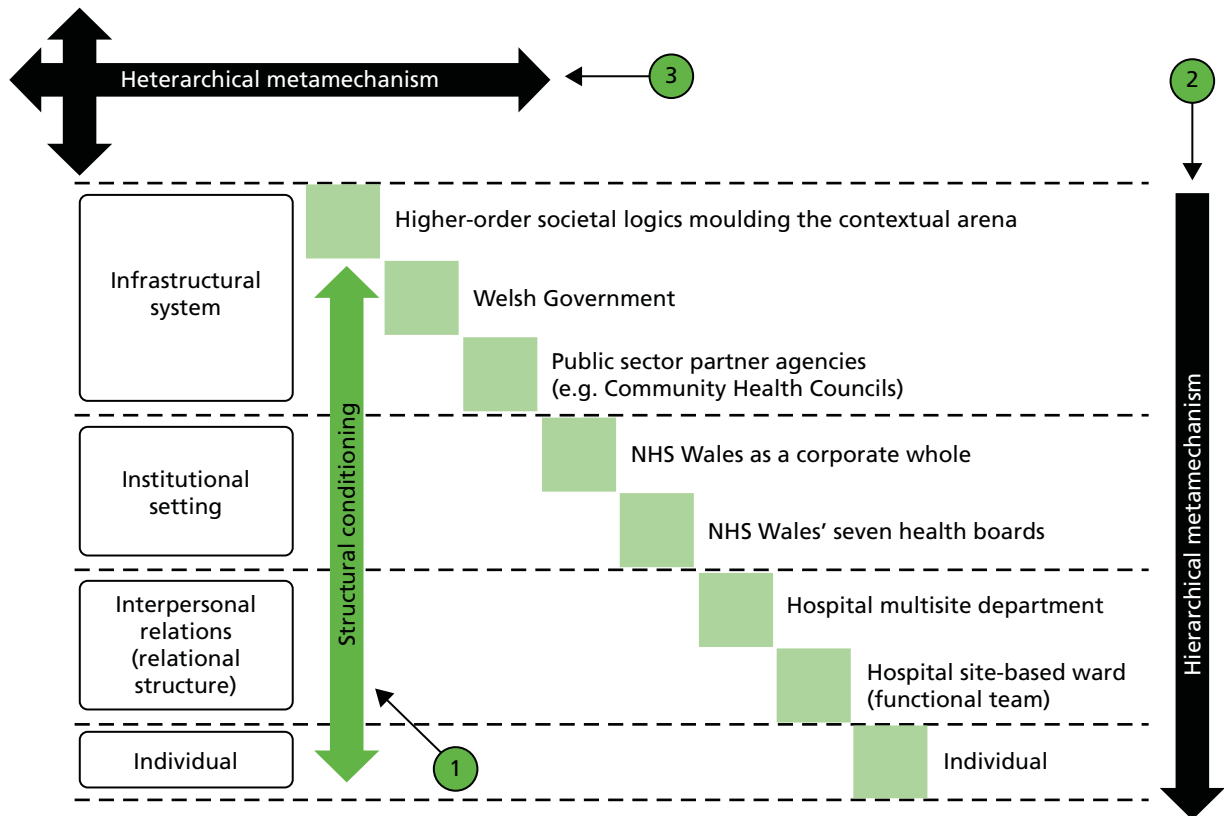


FIGURE 5 Contextual strata: structural conditioning, hierarchical and heterarchical metamechanisms.

Figure 5: key point summary

In Figure 5, we illustrate our view of context as stratified, conditioned, relational and temporally dynamic through the ‘steps’ of the contextual strata. This shows how the outcome of one I-CMAO becomes the context for the next in the chain of implementation steps.

In point 1, we depict the collective weight of structural conditioning impacting across contextual strata. This notion, as expanded in *Context: structural conditioning*, is an underlying premise of realist inquiry and Archerian realist social theory.

In addition, we highlight the notion of a ‘meta mechanism’ that functions as a ‘carrier’ for the 1000 Lives+ national programme across NHS Wales. Point 2, therefore, depicts a hierarchical meta mechanism emergent from the bureaucratisation of the programme across the policy/practice gap in NHS Wales.

Furthermore, point 3 depicts a heterarchical metamechanism inherent to normalisation of the programme at the level of the functional team across linked strata.

Mechanism: sociocultural interaction

In her later work, Archer has refined her conceptualisation of the mediation of contextual influences, which, she contends, is undertaken via two mechanisms: habituation, guiding routine action, and reflexivity, guiding those actions which demand a more creative response.³³⁸ Critically, Archer asserts that such reflexive theorisation occurs through three stages: (1) discernment, the preliminary review stage of an issue of concern, where reflective retrospective and prospective thought informs practical action; (2) deliberation, involving the ranking of such concerns against others; and (3) dedication, entailing their prioritisation and alignment to foster a fallible yet correctable commitment to a chosen path. Reflexive theorisation thus represents the explicit interplay of social context and personal concerns that lies at the heart of Pawson's notion of mechanism.

Following this approach, in our realist analysis we allocate contextual mediation to mechanism, and to this we add reflexive theorisation. Furthermore, as depicted in *Figure 6*, we distinguish the conceptual elements of mechanism from its ensuing outcome, illuminating the fundamental role of beliefs and values – institutional logics – on the propensity to act, and revealing the contested nature of institutional change and practice evolution.

In this study of the 1000 Lives+ programme, we examine the demarcation between context and mechanism, focusing on mediation, reflexive theorisation, ensuing agency via negotiation and the mode of institutional work enacted during two fundamental institutional processes: bureaucratisation and normalisation. These, we contend, operate as sociocultural and organisational meta mechanisms, the underpinning carriers³⁴⁷ of the processes of health-care change desired by 1000 Lives+. In essence, it is through successful embedding within these fundamental meta-mechanisms that the patient safety programme becomes institutionalised.

Bureaucratisation

Given that the logic of the bureaucratic state is predominantly that of command and control, we envisaged bureaucratisation as a vertical, top-down meta mechanism. In this manner, the Welsh Government has enacted state-centric control over NHS Wales. This is exemplified by the gradual bureaucratisation of the 1000 Lives+ national patient safety programme; specifically, the shift from optional engagement to mandatory engagement as defined in the Welsh Government's tier 1 performance targets for NHS Wales. Such bureaucratisation now composes and conditions the substructure of the health-care field, creating a context of politicised force majeure. We therefore examine the consequences of adherence to the 1000 Lives+ programme and describe the mechanisms which foster institutional coupling to, and decoupling from, patient safety governance processes.^{85,348,349}

Drawing on the work of Greenwood *et al.*,²²⁷ as well as terminology used by Lewin and Schein,^{350,351} we frame such institutional change through six stages – disconfirmation, deinstitutionalisation, preinstitutionalisation, theorisation, diffusion and reinstitutionalisation – and use these to develop our understanding of the local implementation of the 1000 Lives+ programme, as set out in *Chapter 4*.

Normalisation

We envisaged normalisation as a heterarchical metamechanism operating (i) horizontally across discrete functional teams, such as policy, health-care management or health-care clinical professionals; and (ii) hierarchically, bottom-up and top-down, across conceptual strata. Hence, to provide deeper insight into the implementation of the 1000 Lives+ programme, we use normalisation process theory, as developed by May *et al.*,³⁵²⁻³⁵⁵ to refine our understanding of how agency embedded this patient safety improvement programme in a local context. The concept of normalisation acknowledges that those involved in the process of institutional change have to undertake institutional work – and thus theorise in a reflexive manner^{338,356} – to reconfigure ensuing practices to meet local conditions.³⁵⁷

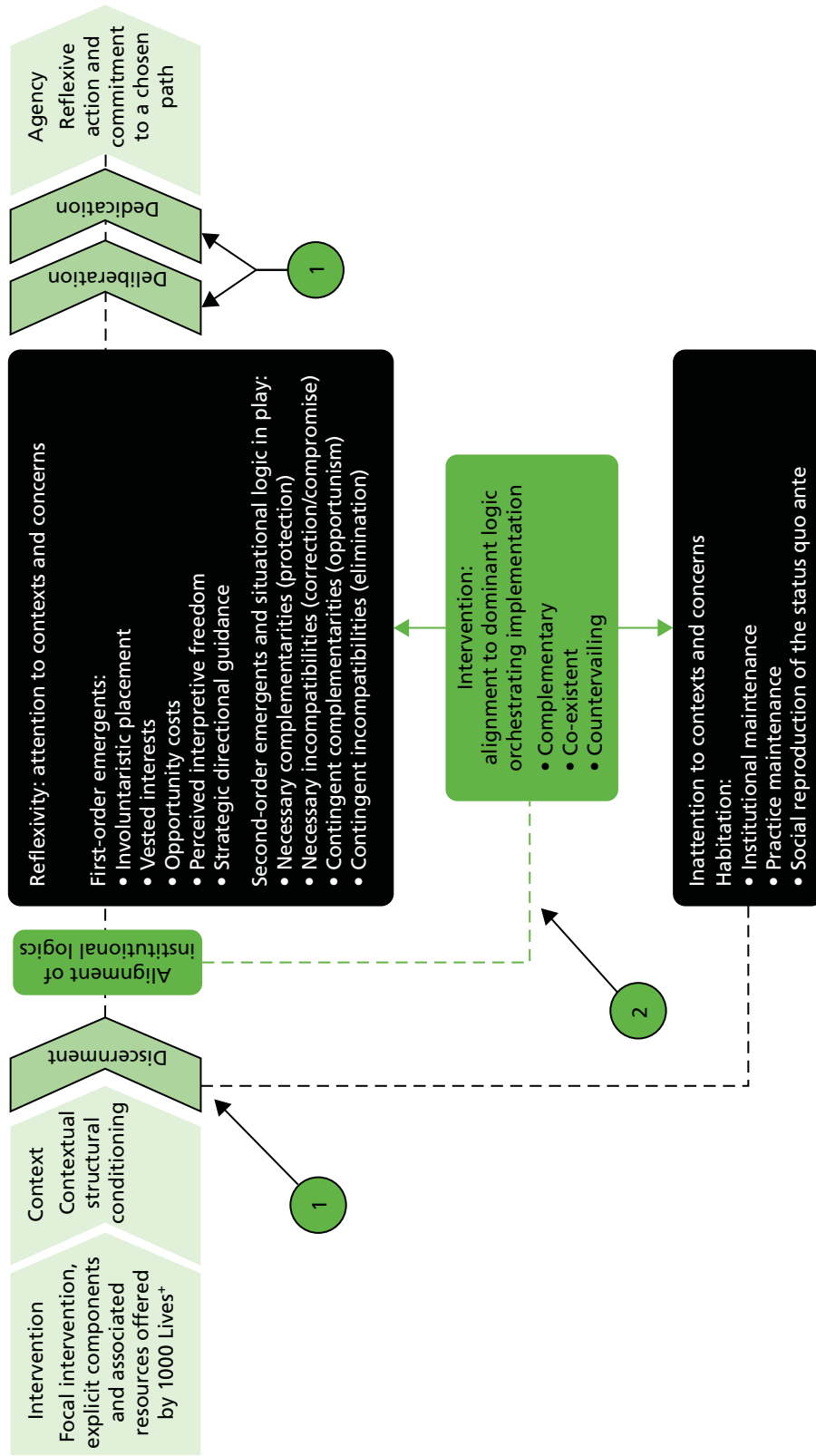


FIGURE 6 Mechanism: mediation via reflexive theorisation vs. habituation.

Figure 6: key point summary

Figure 6 shows a preliminary outline of the key components of a mechanism. As noted in Figure 3, we apportion mediation and reflexive theorisation to mechanism. We thus distinguish the conceptual elements of mechanism from its ensuing outcome: the agential emergent properties, expressed through the unfolding strategic negotiation of change, and the mode of institutional work enacted, to deliver sustainable outcomes, be they elaborative or reproductive.

In point 1, we depict Archer's refinement of her notion of contextual conditioning via the mediation of structure by agency. This, Archer contends, is undertaken via two mechanisms: habituation, guiding routine action, and reflexivity, guiding those actions that demand a more creative response. This manifests through three stages: discernment, the preliminary review stage of an issue of concern, where reflective retrospective and prospective thought informs practical action; deliberation, the ranking of such concerns against others; and dedication, their prioritisation and alignment to foster a 'fallible yet corrigible' commitment to a chosen path. Such reflexive agency thus represents the explicit interplay of social context and personal concerns.

In point 2 we assert that this three-stage process is modulated by the alignment of institutional logics. Complementarity, co-existence or contradistinction via a countervailing stance thus impact first- and second-order emergents to shape the individual's situation logic and the ensuing stance that emerges from their deliberation and dedication to a chosen path.

This mid-range theory presented four possible generative mechanisms – coherence, cognitive participation, collective action and reflexive monitoring – which are viewed to be central to the embedding and integration of institutionally refined practices. As May and Finch³⁵³ point out, such mechanisms are subject to the power play of social actors. Therefore, by focusing on normalisation, our examination of the implementation of the 1000 Lives+ national programme was sensitised to the dynamic interplay of multiple logics.

Agency and ensuing outcomes: structural and cultural elaboration or reproduction

In our realist analysis framework, outcome is not perceived as a simple, single aspect of change such as a defined health outcome. Instead, it is recognised that the multifaceted nature of an intervention, particularly when implemented within different organisations, each shaped by their own contextual constraints and enablers, gives rise to discordant mechanisms which trigger different patterns of social transformation.^{243,269} Moreover, such outcome patterns are contingent on all the tiny process and positioning issues that occur on the way to the goal.²⁴⁴

Our framework is, therefore, concerned with the explication of these unfolding actions over time. Specifically, we seek to examine the means through which the health-care practice change advocated by the 1000 Lives+ programme, and the three focal interventions we consider in depth, are negotiated by the functional teams positioned within the contextual strata depicted in Figure 5. We thus seek to illuminate how health-care practice evolves (or not) over time, by considering the third-order emergents impacting within the contextual arena.

Third-order emergents arise from the effects of first- and second-order influences on the outcomes of the intervention.²²⁹ This concept, therefore, captures structural and ideational differentiation, together with the regrouping inherent to the power play of a diverse array of agents.

Summary

We argue in this chapter that, as an established methodological complement to the critical realism of which Pawson is a key advocate, and as an innovative lens for realist inquiry, an Archerian approach provides both an explanatory framework for examining the interplay between structure (context) and agency (mechanism) and a viable means for developing and refining emergent I-CMAO configurations.

In seeking to demarcate context from mechanism and intervention, our stratified model of context depicts strata as hierarchical and interconnected. This purposely deviates from the notion of context bifurcated into external and internal domains,^{216,358} and echoes the broader realist literature in terms of a sociology divided into levels.^{359,360} Moreover, by revealing the mechanisms that operate within and between these conceptual strata,³¹⁶⁻³¹⁸ as each action-level or arena is, simultaneously, a framework for action and a product of action,³³⁰ we carry forward these generative threads into our realist analysis to define the web of mechanisms operating within the focal context.

Chapter 3 Research design

Overview

This chapter sets out our research design and approach to data collection and analysis. First, acknowledging recent changes to research ethics and access permissions in NHS Wales, we provide a step-by-step account of our actions in the start-up stage to the study. Second, our comparative case study research design is presented, explaining our approach to realist analysis, case site selection and sampling strategy, and to data collection, coding and analysis. Finally, we reflect on the challenges encountered during our research across NHS Wales and discuss their impact on our realist analysis of hospital patient safety.

Research ethics and access permissions in NHS Wales

In February 2011, following notification of the award from the National Institute for Health Research Health Services and Delivery Research programme, an Integrated Research Application System project data set was developed prior to the formal start of the study in October 2011. Over the next 4 months, working in collaboration with the National Institute for Social Care and Health Research (NISCHR) Patient Safety and Healthcare Quality Registered Research Group, hosted by the School of Medicine, Cardiff University, and in close liaison with the Director General, Health and Social Services and NHS Wales Chief Executive, the 'in principle' engagement of all NHS Wales' seven local health boards [Abertawe Bro Morgannwg University Health Board; Aneurin Bevan University Health Board; Betsi Cadwaladr University Health Board; Cardiff and Vale University Health Board; Cwm Taf University Health Board; Hywel Dda University Health Board; and Powys (Teaching) Health Board] was secured. In each health board, study contacts with delegated strategic oversight for patient safety were recruited at medical director or associate medical director level.

Having gained NHS Wales' 'in principle' engagement, sponsorship of the study was secured from Cardiff University and the required documents were submitted to the Main Research Ethics Committee (MREC) for Wales. MREC approval was granted in August 2011 and site-specific NHS research and development forms were submitted to the newly established NISCHR Permissions Co-ordinating Unit. Following this, full ethical and research governance permissions were obtained from Cardiff Business School, Cardiff University, and research passports were obtained for Herepath and Kitchener. Research validation and global governance approval was obtained in September 2011. The research and development committees of the seven health boards granted site-specific research permission and researcher access by December 2011, and Herepath and Kitchener received either honorary research contracts or letters of access.

Anonymisation

All seven health boards in NHS Wales participated in the study. Summary data describing each organisation are presented in *Appendix 1*. To ensure anonymity from this stage of the report onwards, participant health boards are identified via a randomly assigned code letter from A to G. Numeric subscripts are then used to identify a constituent major hospital (X_1), a constituent district general hospital (X_2) or a constituent small local community hospital (X_3).

Comparative case study approach

The study set out to examine which contextual factors matter and how they matter, and to explain why they matter in the hope that this may lead to improvement in the design, processes and outcomes of patient safety programmes. A comparative case study research design is appropriate for research of this nature³⁶¹ and was therefore adopted and aligned to realist analysis as discussed below.

Comparative case studies in realist informed research are shaped by five methodological principles: (1) explication of structure and context; (2) explication of events; (3) abduction and retrodution^{362–364} (see *Ontological and epistemological alignment to realist analysis*, below); (4) empirical corroboration (ensuring that proposed mechanisms have causal power and better explanatory power than alternatives³⁶⁵); and (5) triangulation and multimethods (using multiple approaches to support causal analysis based on a variety of data types and sources, analytical methods, investigators and theories³⁶⁵). Each of these features are employed throughout *Chapters 4–8*.

Ontological and epistemological alignment to realist analysis

The basic premise, or ontology, of critical realist informed research is that the world may be viewed as stratified into three domains in which are apparent structures, mechanisms, powers and relations; events and actions; and experiences and perceptions.^{362,363} Research in this tradition focuses on the identification and explanation of the underlying generative mechanisms that shape structure, agency and the social relations that are reproduced and/or transformed.²⁵²

The nature of the approach taken by realist research does impose limitations on what may be revealed through a comparative case study research design. However, it is a viable means for discerning structures and mechanisms, conveyed through our understanding of the social world and, thus, subject to revision as our collective knowledge is refined.^{363,365} Nevertheless, one cannot connect powers or causal mechanisms to events and perceptions easily or securely by simple inspection.³⁶⁶ This is because, once set in motion, they continue to have an influence even if other countervailing powers and mechanisms prevent this influence manifesting itself. The act of drawing conclusions from a comparative case study is, therefore, a complex matter. It is informed by epistemology (what we think is known), the nature of the comparisons made between cases and the mode of inference employed.

Comparative case study research designs using a critical realist approach must, therefore, seek to define constraining and enabling social structures, encompassing organisations, groups and individuals, together with the rules, practices, technological artefacts, discourse and culture which they manifest.³⁶⁵ In addition, social actors' interpretations of such structures, and their beliefs, values and theories, require detailed consideration. The comparisons made between cases draw on abductive and retroductive modes of inference as opposed to inductive and deductive.^{363,364} Abduction involves the production of an elementary account of a basic process or mechanism.³⁶³ Retrodution builds on this analytical stage to reconstruct the basic conditions for such phenomena to be what they are, so fostering knowledge of the conditions, structures and mechanisms in play.^{362,363} Abstraction forms the basis of both abduction and retrodution. As empirically demonstrated by Herepath,³⁴² abstraction draws out the various components within the situated context so that the researcher may gain new insight into the way they combine and interact.

Case site selection and sampling strategy

Case site selection was based on a two-stage sampling strategy. In phase 1, four clear and readily operable criteria – corporate parent, complexity, function and geographical coverage – were employed to define the purposive sample of case-site hospitals within each health board (see *Appendix 1*), and three within-case comparators were selected from each health board: (1) a major hospital, (2) a district general hospital and (3) a small community hospital. This approach ensured theoretical variation in I-CMAO configurations by optimising the scope for description, interpretation and explanatory analysis, while reducing chance associations.^{367–369} In contrast, in phase 2, the focus of the study was narrowed to four local health boards, and centred on deeper examination of the most promising I-CMAO configurations for the three focal interventions examined from the 1000 Lives+ programme.

Data collection, coding and analysis

In adopting an overarching approach that combined realist inquiry with regard to the explication of I-CMAO configurations, this study sought to examine the contextual conditioning which predated the launch of the 1000 Lives+ programme, together with the mechanisms which emerged from the social interaction of different groups of health-care workers engaged in its implementation, and the subsequent outcome on the embedded practices of day-to-day health-care practice. As illustrated by the schedule of data methods and sources illustrated in *Figure 7*, and expanded in the following four sections, a wide range of data collection methods were used.²⁵⁶

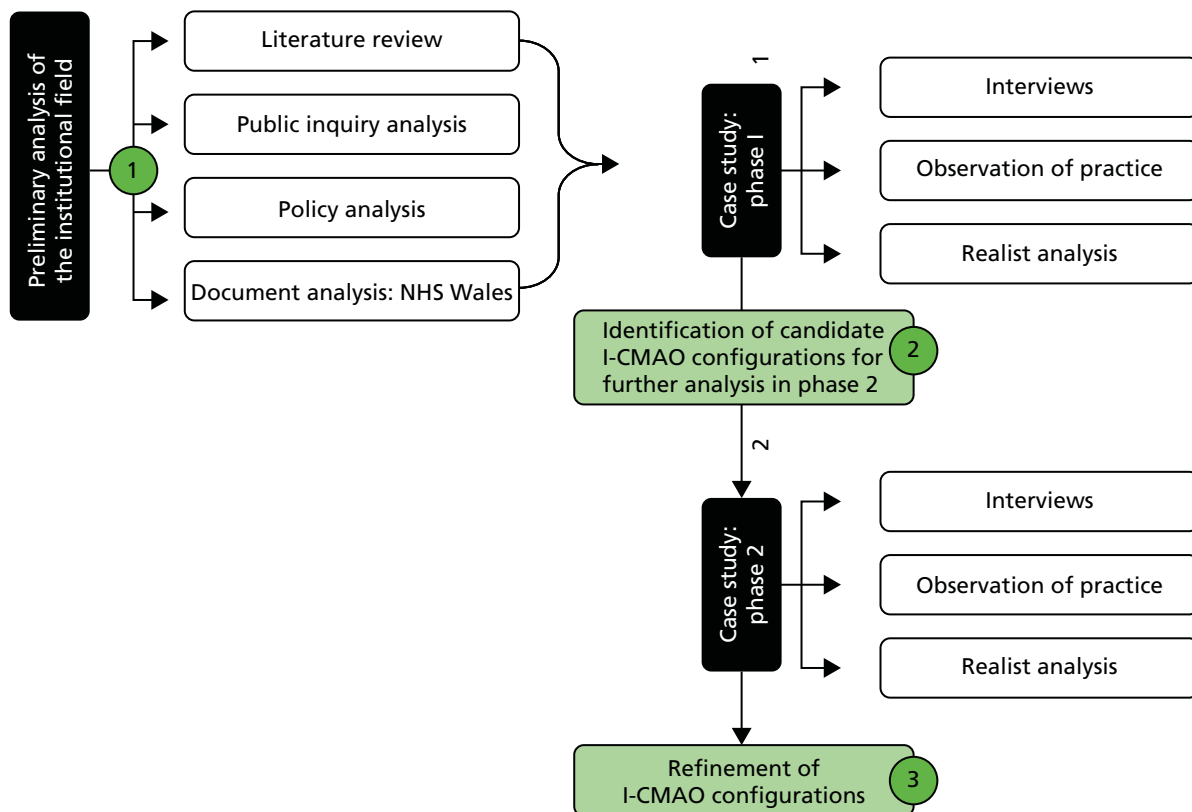


FIGURE 7 Schedule of data methods and sources.

Figure 7: key point summary

In *Figure 7* we set out a schematic of data methods and sources, expanded below.

As set out in point 1, a series of data searches were undertaken. These included one that centred on public inquiries (see *Table 5*) as a means of gaining rapid awareness of significant systemic health-care delivery and patient safety failures. The literature review, policy and document analysis was maintained throughout the duration of the study. Points 2 and 3 depict the preliminary identification of candidate I-CMAO configurations and their progressive refinement throughout the study.

Welsh health-care policy context data

To build a coherent explanatory analysis of the context and events that led to the development and implementation of the 1000 Lives+ programme, our research commenced with an analysis of UK and devolved Welsh health-care policy spanning the period from 1997 to 2013. As indicated in *Table 2*, the UK coalition government's White and Green Papers, together with other key legislative proposals, were accessed and downloaded from the Department of Health's website. Those of the former UK New Labour government were sourced via the National Archives. Relevant Welsh Government documents, together with those from the National Assembly for Wales, were accessed from site-specific policy archives. In addition, Welsh health circulars and ministerial letters spanning the period 1997–2012 were accessed via the Health of Wales Information Service (HOWIS) intranet. A repository in excess of 1700 documents was established and archived in an electronic database to facilitate the exploration of the structural conditioning of the Welsh health-care system.

Three analytical frameworks informed the coding of these data: (1) Friedland and Alford's depiction of higher-order societal logics;³³¹ (2) Barber's three paradigms of public sector reform;³⁷⁰ and (3) Hood's doctrinal components of new public management.^{371,372} Collectively, these focused our approach to contextual conditioning and set out the requisite 'vocabulary'³⁷³ through which the infrastructural system – specifically, the organisational and professional governance processes structuring health-care quality and patient safety – could be abstracted from the policy archive. As illustrated in *Chapter 4*, this centred on the interplay of the higher-order societal logic of the bureaucratic state with the field-level logics of the market, professionalism and democracy in health policy.

Analysis of these data revealed the systemic, paradigmatic, dominant and subordinate institutional logics, which condition NHS Wales structurally and culturally, and impact on infrastructural systems underpinning hospital patient safety. In addition, our consideration of bureaucratisation and normalisation sensitised us to the generative mechanisms which foster institutional coupling to and decoupling from patient safety governance processes, as well as the complex web of constraints and enablements which impact on differently positioned social actors and condition their response to the development and implementation of the 1000 Lives+ programme.

TABLE 2 Policy analysis: data sources

UK government policy

- Current White and Green Papers (UK coalition government from 2010) were accessed via the Department of Health (www.dh.gov.uk/en/Publicationsandstatistics/Publications/DH_4122399)
- White and Green Papers (UK New Labour government from 1997 to 2010) were accessed via the National Archives (http://webarchive.nationalarchives.gov.uk/20100407034821/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/DH_4122399)

Welsh Government policy

- Welsh Government (<http://wales.gov.uk/topics/health/nhswales/healthstrategy?lang=en>)
- National Assembly for Wales (legislation) (www.assemblywales.org/bus-home/bus-legislation.htm)
- HOWIS intranet site (<http://howis.wales.nhs.uk>). Access to this third site was granted to the authors through the receipt of honorary research contracts or letters of access from NHS Wales' constituent health boards

Semistructured realist interviews

To refine our explanatory analysis of the context and events that led to the development and implementation of the 1000 Lives+ programme, we sought empirical corroboration from participants in the seven Welsh health boards. In each health board, an initial section of potential research participants was identified in close liaison with the study's local contact. As summarised in *Table 3*, individuals were purposively drawn from a wide range of organisational roles. These encompassed the corporate management structure, clinical professionals and those occupying hybrid positions such as health-care clinical professionals in managerial roles.

Following confirmation of individuals' consent to participate in the study, realist interviews were undertaken,²²⁸ guided by the questionnaire defined in *Appendix 2*. In addition, during each interview, respondents were asked to suggest further potential research participants. This 'snowball' approach helped to secure access to staff across NHS Wales with relevant knowledge and expertise in the three focal patient safety interventions examined. It also provided the opportunity to gain permission to observe meetings and the established practices of health-care delivery.

Additional research participants for the study were drawn from the research team's extensive network of contacts across the Welsh public service, comprising (i) the Welsh Government's Department of Health and Social Services; (ii) external organisations tasked with the strategic oversight of patient safety in NHS Wales; and (iii) health-care professional bodies.

Finally, to help refine the study's emergent findings, world-leading academics with research interests in health-care quality and patient safety were also interviewed. Therefore, as summarised in *Table 3*, a total of 160 interviews, face to face or by telephone, digitally recorded and professionally transcribed, were undertaken across phases 1 and 2 of the study. Interviews ranged in duration from 30 minutes to 90 minutes, with a mean time of 40 minutes.

TABLE 3 Research participants

Exemplar roles	Number
Welsh Government	10
<ul style="list-style-type: none"> Policy leads 	
NHS Wales, board-level executive directors	20
<ul style="list-style-type: none"> Chair, Chief Executive, Director of Medicine, Director of Nursing, Director of Therapies and Health Science, Director of Workforce and Organisational Development Non-executive directors, health board stakeholder representatives 	
NHS Wales, sub-board-level associate directors	20
<ul style="list-style-type: none"> Associate Director of Medicine, Associate Director of Nursing, Associate Director of Therapies and Health Science, Associate Director of Workforce and Organisational Development, Associate Director Corporate Performance 	
NHS Wales, medical and surgical staff	20
<ul style="list-style-type: none"> Consultant-grade staff, 1000 Lives+ local leads, junior doctors in training 	
NHS Wales, nursing staff	40
<ul style="list-style-type: none"> Ward managers, ward sisters, band 6 through to band 2 	
NHS Wales, pharmacy staff	20
<ul style="list-style-type: none"> Departmental managers, clinical pharmacists—antibiotic medicines management, clinical pharmacists—surgical/theatre department management, 1000 Lives+ leads 	
1000 Lives+ national programme	10
<ul style="list-style-type: none"> Team members 	
External stakeholders	20
<ul style="list-style-type: none"> Public sector partner agencies with external oversight of patient safety Advocacy groups Academics with expertise in patient safety 	
Total	160

The transcript of each interview was validated by (i) correcting errors, predominantly typographical, that arose most typically from the use of complex medical terminology; and (ii) correcting queries, annotated and time-marked by the transcriber, that arose from the use of medical and health policy acronyms (e.g. 'VTE' meaning venous thromboembolism; 'AQF' meaning 'annual quality framework'). These data were then coded in a two-stage process.

First, a central registry data file was created on an external hard drive, including (i) the interviewee's assigned anonymisation code; (ii) their name; (iii) their gender; (iv) their profession; (v) their role; (vi) their hybrid status; (vii) the anonymisation codes for their employing health board (or other organisation) and, if relevant, (viii) the anonymisation codes for their base site hospital. Access to this data file was password protected and restricted to Herepath and Kitchener. Second, transcripts were coded in accordance with the framework defined in *Table 4*, and records linked to the central registry data file.

TABLE 4 Data coding: preliminary and supplementary frameworks

Theme	Subtheme
<i>Preliminary coding framework: NHS inquiries recommendations impacting health-care quality</i>	
Regulation	<ul style="list-style-type: none"> ● Acts of Parliament ● Health-care quality standards ● Higher education ● Regulatory oversight via external public sector agency ● Regulatory oversight via NHS organisation ● Regulatory oversight via professional body
Corporate governance	<ul style="list-style-type: none"> ● Financial management ● Human resource management ● Performance management: <ul style="list-style-type: none"> ○ interagency collaboration ○ reconfiguration
Clinical governance	<ul style="list-style-type: none"> ● Clinical audit ● Continuous professional development ● Professional standards management: <ul style="list-style-type: none"> ○ revalidation ○ relicensure
Patient engagement	<ul style="list-style-type: none"> ● Consumer ● Citizen ● Patient
<i>Supplementary coding framework: infrastructural system – Welsh Government</i>	
Health-care policy and patient safety	<ul style="list-style-type: none"> ● Political advocacy for health-care quality and patient safety ● Policy commitment to 1000 Lives+ national programme ● Institutionalisation – bureaucratisation/normalisation: <ul style="list-style-type: none"> ○ co-optation ○ formalisation ○ legitimisation ○ negotiation ○ transmission ● Policy commitment to patient safety

TABLE 4 Data coding: preliminary and supplementary frameworks (*continued*)

Theme	Subtheme
Developing an ethos of patient safety	<ul style="list-style-type: none"> ● Leadership of patient safety ● Political advocacy for health-care quality and patient safety ● Policy commitment to 1000 Lives+ national programme ● Policy commitment to patient safety
Internal oversight of patient safety	<ul style="list-style-type: none"> ● Health-care quality standards ● Performance management frameworks: <ul style="list-style-type: none"> ○ constraints and enablers
External oversight of patient safety	<ul style="list-style-type: none"> ● Patient complaints procedures ● Relationship with external bodies tasked with external oversight of patient safety ● Institutionalisation – bureaucratisation/normalisation: <ul style="list-style-type: none"> ○ formalisation ○ democratisation ○ verification ● Relationship with professional bodies via policy leads
Supplementary coding framework: institutional setting – NHS Wales as a corporate whole/NHS Wales' health boards	
1000 Lives+ national programme	<ul style="list-style-type: none"> ● Emergence and institutionalisation in NHS Wales programme leadership and followership: <ul style="list-style-type: none"> ○ board-level leadership ○ clinical leadership ○ team work and distributed leadership ○ role of local champions for 1000 Lives+ focal interventions ● Institutionalisation – bureaucratisation/normalisation: <ul style="list-style-type: none"> ○ co-optation ○ formalisation ○ legitimisation
Developing an ethos of patient safety	<ul style="list-style-type: none"> ● Education and patient safety ● Leadership of patient safety ● Political advocacy for health-care quality and patient safety ● Organisational commitment to 1000 Lives+ national programme ● Organisational commitment to patient safety ● Organisational learning and patient safety
External oversight of patient safety	<ul style="list-style-type: none"> ● Patient complaints procedures ● Relationship with external bodies tasked with external oversight of patient safety ● Relationship with professional bodies ● Relationship with Welsh Government, Department of Health and Social Care
Internal oversight of patient safety	<ul style="list-style-type: none"> ● Governance structures ● Measuring and monitoring patient safety ● Patient complaints procedures (Putting Things Right) ● Risk assessment (Welsh Risk Pool)
Impact of reconfiguration of patient safety	<ul style="list-style-type: none"> ● Organisational reconfiguration ● Clinical services reconfiguration ● System and process realignment across health board

continued

TABLE 4 Data coding: preliminary and supplementary frameworks (continued)

Theme	Subtheme
Supplementary coding framework: institutional setting and interpersonal relations – hospital multisite department/hospital site-based ward (functional team)	
1000 Lives+ national programme	<ul style="list-style-type: none"> ● Engagement with 1000 Lives+ national programme: <ul style="list-style-type: none"> ○ local leadership and followership ○ role of champions ○ constraints and enablements ● Engagement with 1000 Lives+ national programme team and associated resources: <ul style="list-style-type: none"> ○ resources employed within focal intervention ○ networking events ○ site-specific engagement ● Adoption of MI-PDSA approach: <ul style="list-style-type: none"> ○ constraints and enablements
Context of health-care delivery	<ul style="list-style-type: none"> ● Perception of context: <ul style="list-style-type: none"> ○ perception of strata – sense of enablements and constraints from ‘above’ and ‘below’ ○ perception of links and permeability ● Team work: <ul style="list-style-type: none"> ○ distributed leadership – heterarchical/hierarchical authority ○ relational structure ● Institutionalisation – bureaucratisation/normalisation: <ul style="list-style-type: none"> ○ emancipation ○ identification ○ innovation ○ knowledge mobilisation ○ legitimisation ○ validation
Supplementary coding framework: mechanism	
Institutionalisation	<ul style="list-style-type: none"> ● Coercive institutional isomorphism ● Mimetic institutional isomorphism ● Normative institutional isomorphism
Normalisation	<ul style="list-style-type: none"> ● Coherence ● Cognitive participation ● Reflexive monitoring
Reflexive theorisation	<ul style="list-style-type: none"> ● Discernment ● Deliberation ● Dedication ● Reason
Supplementary coding framework: agency	
Institutional work mode and disposition to act	<ul style="list-style-type: none"> ● Creative ● Disruptive ● Maintenance ● Multimodal ● Beliefs and values ● Knowledge, practical skills ● Micro-competence development
Supplementary coding framework: outcome	
Perception of outcome	<ul style="list-style-type: none"> ● Structural elaboration, reproduction or focal invariance ● Cultural elaboration, reproduction or focal invariance ● Agential elaboration, reproduction or focal invariance

Initially, as described in *Chapter 2*, our data were analysed to examine the bureaucratisation of 1000 Lives+ programme (see *Chapter 4*), and its ensuing normalisation at the level of the functional team within each health board (see *Chapter 5*). This stage of our analysis drew on two institutional theories. First, as noted in *Chapter 2*, we utilised the work of Greenwood *et al.*²²⁷ and their six linked institutional mechanisms: disconfirmation, deinstitutionalisation, preinstitutionalisation, theorisation, diffusion and reinstitutionalisation. Second, guided by the work of May *et al.*,^{352,353} the process of local implementation was framed through the mechanisms that foster the normalisation of complex interventions in daily health-care practice. These stages shaped our deliberation and explication of the 1000 Lives+ programme's I-CMAO configuration spanning the Welsh health-care institutional field.

These data were further interrogated through our innovative approach to realist analysis, as illustrated in *Chapters 6–8*. Drawing on the work of Herepath,³⁴² interview transcripts were analysed to identify first-, second- and third-order emergents. In this manner, interviewees' perceptions of their situated context were ascertained, together with the power play inherent to strategic negotiation of change, and ensuing outcome. These latter stages involved abstraction to draw out various components of the focal intervention and so facilitate the conceptualisation of their interplay, through combination and interaction, in the situated context. This was then supplemented by retroduction. Therefore, the generative mechanisms that operated through an emergent causal configuration were surfaced through a combination of theory and experimental observation.²²⁸

Given the number of interview data collected, the selection of excerpts for inclusion in the report had to be constrained. To respond to this requirement we adopted the following format for references to transcription data in *Chapters 4–8*. First, succinct statements, which captured interviewees' perceptions of context and their beliefs, values and reflections – and, thus, the reflexive theorisation inherent to mechanisms – together with ensuing actions, and outcomes, were prioritised. Throughout *Chapters 4–8*, such data excerpts are identified by a chapter code and number. For example, 'transcription 4:01, below', indicates the first transcription excerpt included in *Chapter 4*. Where data from interviews are used to make a point but excerpts are not included in the text, this is indicated in a similar way, but without 'below'. Full transcripts of all interview data, including those discussed but not illustrated in the report owing to editorial word constraints, are archived in a supplementary data file. These may be obtained for personal research use only from the corresponding author of this report.

In contrast to the wealth of interview data included, limited observational data are alluded to in this report. This deliberate restriction is a result of the marked disparity between overt observation of practice undertaken during the study and inherently opportunistic covert observation of practice that arose across multiple case sites.

Supplementary organisational data

Six supplementary forms of case site-specific data were also collected. These encompassed (i) Executive Board papers; (ii) health board mortality data; (iii) Welsh health-care-associated infection programme data; (iv) external inspection reports from Healthcare Inspectorate Wales (HIW), Community Health Councils (CHCs) across Wales, the Wales Audit Office and the Public Services Ombudsman for Wales (PSOW); (v) 50 hours' observation of established day-to-day health-care practice undertaken to discern embedded leadership, theatre and infection prevention and control (IPAC) practices; and (vi) feedback sessions to NHS Wales and the 1000 Lives+ team, during which our posited I-CMAO configurations were tested and refined.

Supplementary secondary data

To gain an in-depth appreciation of the contextual issues impacting on hospital patient safety, and sensitise our subsequent analysis, the reports generated by six public inquiries into safety failures in the NHS, listed in *Table 5*, were collected.

TABLE 5 Public inquiries into patient safety failures: data sources

-
1. Inquiry into quality and practice within the National Health Service arising from the actions of Rodney Ledward (published June 2000)³⁷⁴
 2. The Kerr/Haslam Inquiry (published July 2005)³⁷⁵
 3. The Shipman Inquiry (published January 2002 to January 2005):⁸⁴
 - i. Third Report: Death Certification and the Investigation of Deaths by Coroners (published July 2003)
 - ii. Fourth Report: The Regulation of Controlled Drugs in the Community (published July 2004)
 - iii. Fifth Report: Safeguarding Patients: Lessons from the Past – Proposals for the Future (published December 2004)
 4. Royal Liverpool Children’s Hospital Inquiry (Alder Hey) (published January 2001)³⁷⁶
 5. Bristol Royal Infirmary Inquiry (published July 2001)⁸²
 6. Mid Staffordshire NHS Foundation Trust Inquiry (published February 2010)³⁷⁷
 7. Mid Staffordshire NHS Foundation Trust Public Inquiry (published February 2013)⁸¹
-

For the purposes of this study, data in the form of 954 reported recommendations – the espoused lessons to be learned for the future – to improve the design, delivery and sustainability of safe health-care services were collected and archived in an electronic database. This provided further rich insight into the infrastructural system underpinning hospital patient safety, its complex nature and embedded institutions.

Acknowledging that the notion of comparing the reports and recommendations from different public inquiries is somewhat ‘contestable’,³⁷⁸ we therefore coded the abstracted recommendations descriptively, across (i) regulatory oversight, (ii) corporate governance, (iii) clinical governance and (iv) patient engagement. These data were then coded once more in accordance with the nature of the ‘problems/issues’ identified, as depicted in *Table 4*.

The analysis of these data with respect to extant NHS governance processes helped to identify institutional decoupling – the creation and maintenance of gaps between symbolically adopted formal policies and actual organisational practices³⁷⁹ – which foster institutionalisation of aberrant practice.³⁴⁶ In this manner, we identified the common vulnerabilities which impact adversely on patient safety, and their advocated remedies. This analysis informed both the development of our interview tool and the selection of our preliminary I-CMAO configurations.

Patient and public involvement

Current hospital patients were not involved in the design, development or operationalisation of this study. However, a broader lay (and patient) perspective was actively sought. Working in close liaison with the NISCHR Clinical Research Centre’s Involving People Programme, two lay representatives were appointed to the study’s advisory board. Each provided insight into the patient experience of health care. Moreover, this was augmented by their collective insight into (i) patient advocacy, (ii) participation in health-board-level stakeholder reference groups and (iii) prior experience of advisory board roles in other health-care studies implemented in NHS Wales.

Challenges encountered in the operationalisation of the study

Two issues arose during the operation of our study that required deviation from the original research protocol.

Access to patient stories and organisational culture survey data

During the design and development of the grant application for this study, the research team was assured of access to an archive of patient stories and organisational culture survey data held by the 1000 Lives+ programme team. Following the commencement of the study, working in close liaison with the

1000 Lives+ programme team, three critical issues emerged on review of these data. First, and most importantly, these data lacked ethical approval and informed patient consent for use for research purposes. Second, the patient stories data had been collected via inconsistent means and lacked the requisite information to verify or contact data sources. Given such issues, these data were, therefore, used in a restricted manner to inform the phase 1 interview guide. Third, with respect to the organisational culture survey data, that archive reflected the organisational boundaries prior to the reconfiguration of NHS Wales. The research teams therefore considered that such historical data provide limited insight into NHS Wales' evolving cultural composition post reconfiguration. These data were, therefore, used only to inform the research team's understanding of organisational context, and the organisational legacy effect that it imparts, within each reconfigured health board.

Supplementary quantitative data quality

During phases 1 and 2 of the study, data from interviews and documentary analysis indicated that, with respect to the focal interventions ILQI and RSC, the desired supplementary quantitative data were of inconsistent quality. This issue did not impact RHA1 because mandatory surveillance data were available via the Welsh Healthcare Associated Infection Programme (WHAIP) led by Public Health Wales. The research team discussed this issue at length with the study's advisory board and commissioners, who advocated the continued investigation of the three focal interventions adjusted to reflect the broader organisational outcomes of the 1000 Lives+ programme and focal interventions.

Chapter 4 Institutionalisation of the 1000 Lives+ national programme in NHS Wales: bureaucratisation, health-care policy and patient safety

Overview

Chapters 4 and 5 present our analysis of the implementation and institutionalisation of the 1000 Lives+ programme in NHS Wales. Together, they form the foundation for our analyses of the three focal interventions – ILQI, RSC and RHA – that are presented in *Chapters 6, 7 and 8*, respectively. This chapter presents our analysis of the bureaucratisation of the 1000 Lives+ programme at the higher, infrastructural system level of the Welsh health-care field. In contrast, *Chapter 5* is focused at lower contextual levels and explores interpersonal and individual engagement with 1000 Lives+ to offer an account of the normalisation of the programme at the level of the functional team.

In this chapter, we first explore the institutional logics moulding the Welsh health-care field and explain how these conditioning influences have framed the implementation and ensuing bureaucratisation of the 1000 Lives+ programme. Second, to penetrate beyond the rhetoric of policy and espoused best practice, we examine actors' perceptions of the manner in which the 1000 Lives+ programme has become an integral part of Welsh health-care policy. Specifically, we consider its integration with organisational and professional patient safety governance processes operating across the Welsh health-care field. In doing so, we gain further insight into the bureaucratisation of 1000 Lives+ and set out our understanding of the pragmatic issues which foster institutional coupling to, or decoupling from, these governance processes. This chapter, therefore, serves to sensitise our subsequent analyses to the development of patient safety practices in NHS Wales. Finally, we set out our understanding of the local implementation of the 1000 Lives+ programme, anchored to the underpinning MI-PDSA approach.

Institutional logics framing the bureaucratisation of 1000 Lives+

At a systemic level, the post-devolution Welsh health-care field parallels that of the UK – English – NHS and is characterised by the central role of government in overseeing the collective production, provision and consumption of health care.³⁸⁰ The underlying principles and values underpinning the NHS in Wales remain grounded in the traditional social democratic communitarian ethos apparent at the inception of the NHS in the 1940s³⁸¹ and access to its operational service infrastructure remains based on the principle of citizenship.³⁸²

When considering the provision of public services at the infrastructural level, Barber³⁷⁰ suggests three paradigms – bureaucratic command and control, quasi-markets, and devolution and transparency^{370,383} – which may be deployed within a government system if it is to balance equity and diversity with support for high quality.

The classical notion of bureaucratic command and control is forwarded as the means of pursuing change to address public service failure, policy or program priorities, and to demonstrate this response to a wider public and political audience. The alternative formation of a quasi-market logic is supported by governments that wish to introduce market forces within a public service system to provide the individual with choice across a range of providers to improve performance. Finally, the devolution of responsibility to frontline units, augmented by the overt communication of performance measures to patients and staff to enable informed comparisons to be made (transparency), stems from a logic of choice. This is deemed necessary to reform a service where the conditions for the success of quasi-markets are not present.

In practice, according to Barber,³⁷⁰ all of these paradigms are likely to co-exist within large-scale systems, such as health care, although the precise balance of paradigmatic institutional logics within a given health-care field positions one into dominance while the remainder function in a subordinate capacity. Hence we would argue that, while the UK remains emblematic of new public management,³⁸⁴ our data suggest that NHS Wales is far more representative of a new public service logic with the paradigmatic logic of bureaucratic command and control occupying a dominant position, tempering the logics of the market, professionalism and democracy in health policy. Patient safety and associated governance processes appear, therefore, to be primarily structured and directed by the regulatory agency of the Welsh Government.

Bureaucratic state logic

As illustrated in *Figure 8*, the logic of the bureaucratic state is expressed through an array of structural features that inculcate a pervasive performance measurement and management ethos across the Welsh health-care field.^{385,386} Much of this was introduced under the UK New Labour government, such as new systems for clinical governance, a statutory duty of quality and evidence-based national service frameworks. That government also laid the foundations for an array of arm's-length bodies that retain the scope for direct intervention in the NHS in England and Wales.³⁸⁷ Some have even seen this as a precursor to the legitimisation of the role of the state as the guarantor of social provision, rather than as the sole provider,³⁸⁸ a stance which resonated with the policy approach of the 2010 UK Conservative–Liberal Democrat coalition government. However, while the logic of the bureaucratic state imposes a sense of control, the efficient use of resources resides largely within the control of discrete professionals.³⁸⁹ This logic is, therefore, tempered by the wielding of professional power at the individual and group level,³⁹⁰ as illustrated in *Figures 8* and *9*.

In Wales, the bureaucratic state logic of the Welsh Government orchestrates the top-down performance measurement and management of the 1000 Lives campaign and the successor 1000 Lives+ programme. For example, under the mantle of 1000 Lives+, NHS Wales' constituent organisations are tasked to (i) set appropriate local targets for the reduction of harm and hospital mortality, initially by employing the Trigger Tool for hospitals; (ii) demonstrate participation in 1000 Lives+ through the appointment of executive leads; and (iii) collect robust data so that local variation in service provision may be identified, analysed and understood, resulting in the development of intelligent targets for service improvement and patient safety.³⁹¹ Strategic oversight of such actions rests with the National Quality and Safety Forum instituted in 2012.

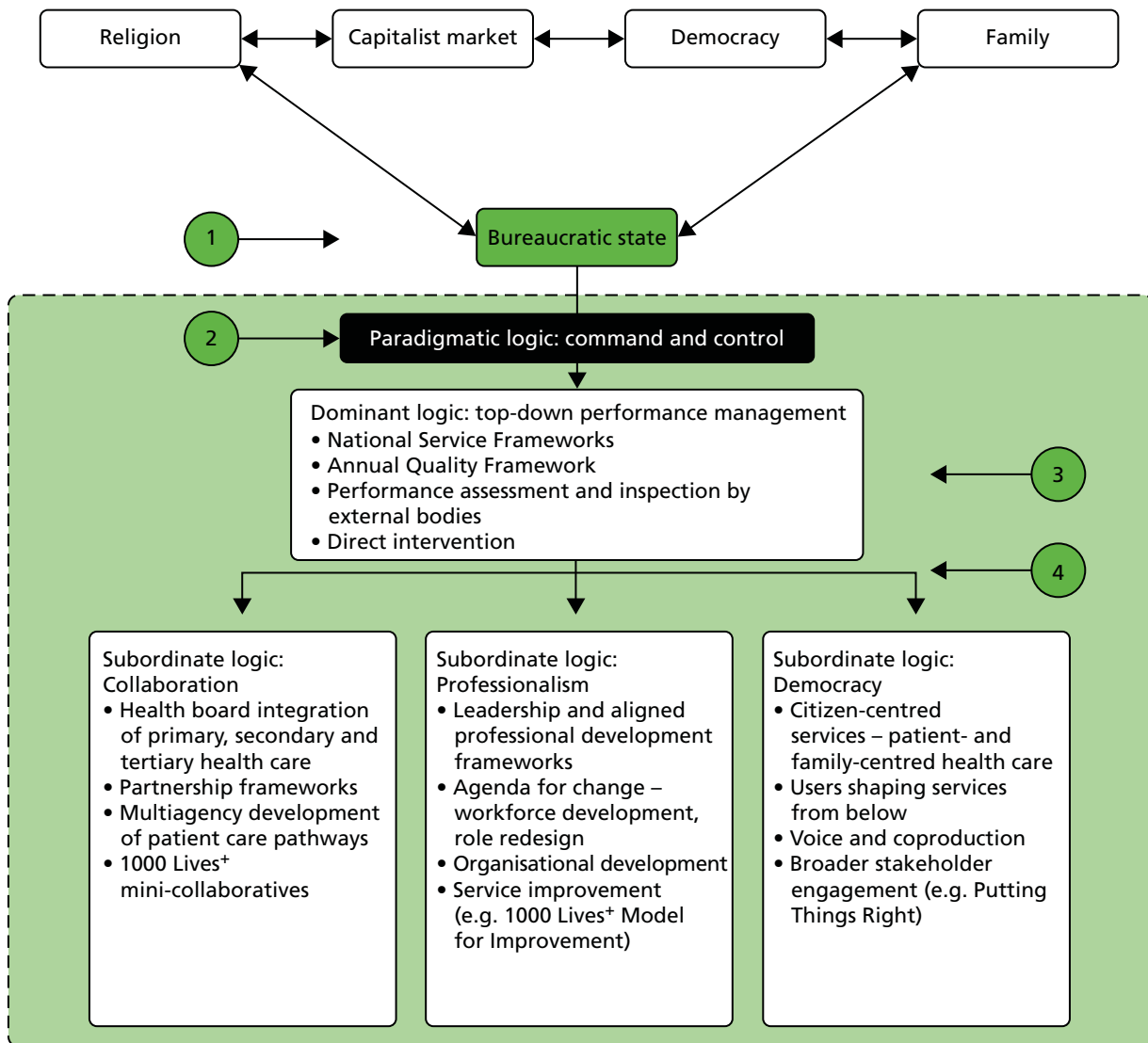


FIGURE 8 Institutional logics in the Welsh health-care institutional field.

Figure 8: key point summary

In *Figure 8* we depict a schematic representation of the Welsh health-care institutional field. As indicated in *Chapter 2* (see *Sociological institutionalism*), the multiplicity of logics in this domain are represented as some combinations of (i) higher-order societal logics; (ii) field-level logics; and (iii) institutions or 'cultural logics', each composed of regulative, normative and cultural-cognitive pillars.

Point 1 illustrates the heterogeneous higher-order logics (the bureaucratic state, capitalist market, democracy, nuclear family and religion) that sculpt the social world, conveying the core organising principles of these different sectors. In both connection and contention with each other, they are held in dynamic tension due to their inherent complementarities and contradictions. Such institutional logics, therefore, orchestrate lower-level institutional strata and ensuing practices: shaping organisational interests; individual preferences; and the ensuing repertoire of anticipated behaviours which define actors' expectations about each other's behaviour and organise their enduring relations with each other.

Point 2 depicts the expression of this interplay at the level of the Welsh health-care field. Here, the higher-order societal logic of the bureaucratic state is dominant. Accordingly, the paradigmatic logic of bureaucratic command and control predominates.

Point 3 of our explanatory schematic illustrates the field-level expression of the dominant logic of the bureaucratic state, expressed through an array of structural features that inculcate a pervasive performance measurement and management ethos across the Welsh health-care field.

Point 4 depicts the field-level expression of the subordinate logics of collaboration, professionalism and democracy.

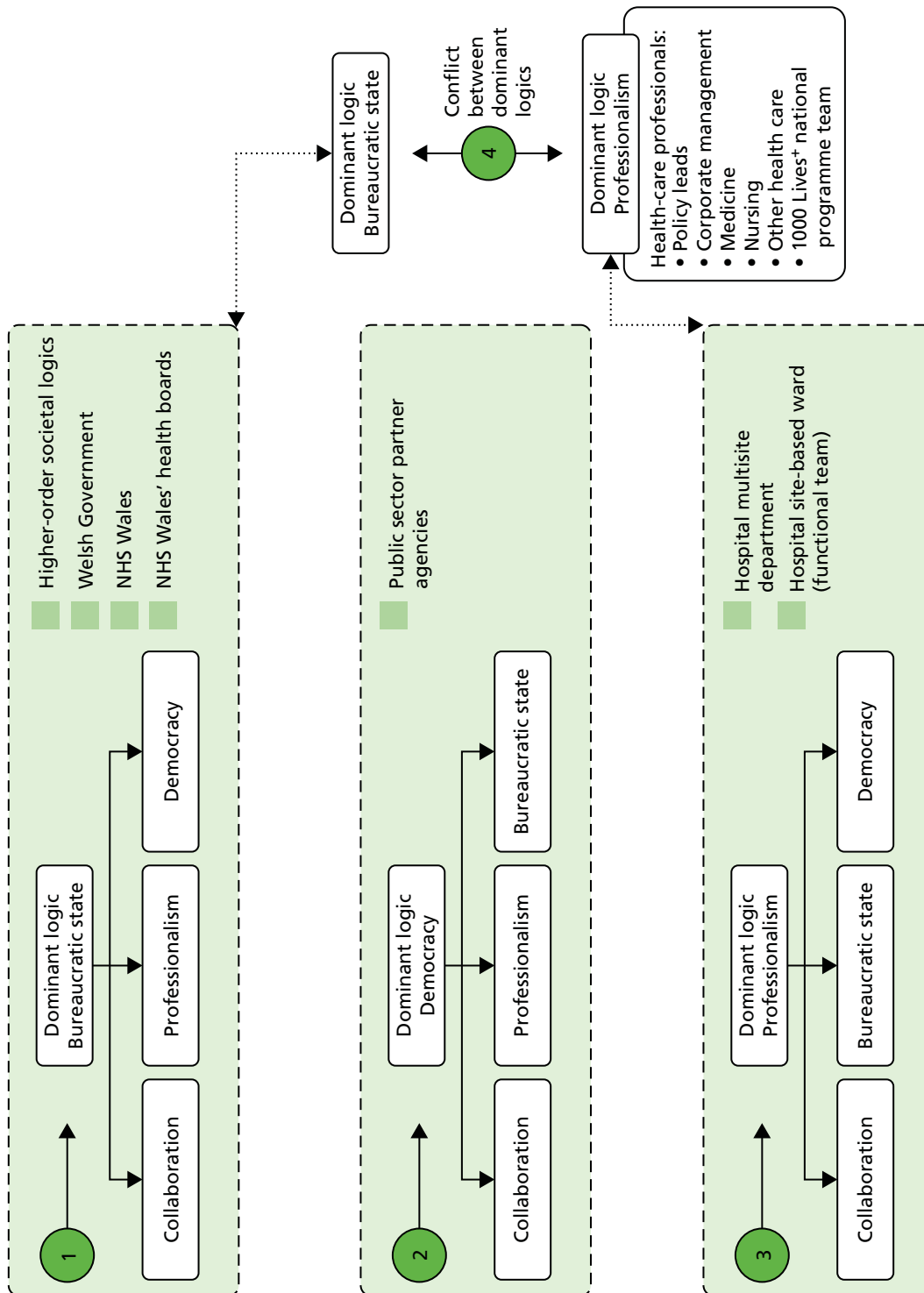


FIGURE 9 Institutional logics in the Welsh health-care institutional field: dominant and subordinate logics in a complementary, co-existent or countervailing alignment.

Figure 9: key point summary

In *Figure 9*, informed by the findings of our realist analysis in *Overview*, we illustrate how the dominance of one logic vs. another is influenced by contextual strata.

Point 1 depicts the logic of the bureaucratic state as dominant across the infrastructural and institutional setting of our study.

However, as indicated at point 2, the logic of democracy is dominant for public sector partner agencies with strategic oversight of patient safety.

In addition, as indicated at point 3, at lower contextual strata – specifically, a hospital multisite department or site-based ward – the functional team is orchestrated by a dominant professional logic.

As indicated in point 4, this therefore draws different professional logics into contention and potential conflict with that of the bureaucratic state.

Capitalist market logic replaced by collaboration

The UK New Labour government followed the Conservative adherence to new public management, aiming to increase the efficiency and quality of service provision through the logic of the capitalist market. For the UK health-care field this approach could be seen in the encouragement of aspects of competition, contestability and practice-based commissioning, and the same stance lingered on in the 2010 UK Conservative–Liberal Democrat coalition government’s health-care policy. However, in the post-devolution Welsh health-care field, this logic has been opposed and replaced by collaboration.³⁹² Importantly, the Government of Wales Act (2006) requires the Welsh Government to work in formal partnership with the voluntary sector, local government and businesses. This constitutes a set of operational requirements not paralleled elsewhere in the UK.³⁹³

The NHS reforms in Wales have, therefore, sought to inculcate a new set of behaviours – replacing competition with collaboration, joint working and whole-systems thinking – to foster a greater emphasis on quality and patient safety outcomes. This collaborative logic is interwoven throughout the 1000 Lives+ programme, as evidenced by its integral mini-collaboratives, and national learning and networking events, which foster co-operation, knowledge sharing and peer challenge. Furthermore, strategic oversight of health-care standards and patient safety performance in Wales requires collaboration across the National Quality and Safety Forum, Welsh Government, HIW, PSOW, CHCs and health-care providers, including those in the independent sector.

Professional logic

Despite Wales' adoption of a collaborative approach, the ideological approach to public management reform adopted by the UK government still impacts on Wales through its reserved powers. Thus, at the field level, professional logic – be that corporate management or the array of hierarchically positioned health-care professionals³⁹⁴ – remains constrained. Indeed, what can be seen is an explicit focus on workforce development (and, thus, organisational development) through a managerialist variant of transformational leadership,³⁹⁵ role redesign and adherence to prescriptive standards that seek to build staff capacity and capability while reducing service variation.³⁹⁶ This logic is inescapably interwoven with performance management. As asserted in the current quality delivery plan for NHS Wales,³⁹¹ the operationalisation of the 1000 Lives+ programme is central to the building of staff capacity and capability across NHS Wales:

1000 Lives+ will continue to be the core NHS improvement programme, ensuring a common and consistent language and approach to improvement.

Health Boards and Trusts will agree a plan to train 25 per cent of their directly employed and contractor workforce in quality improvement methodology (at basic, expert or leadership level) by the end of March 2014, supported by 1000 Lives+.

*Achieving Excellence: The Quality Delivery Plan for the NHS in Wales 2012–2016 (2012)*³⁹¹

Democratic logic

Although the logic of democracy, expressed in policy through the desire for heightened user participation, engagement and control over public services, appeared in the Conservative Party's general election manifesto of 1979, it reached new heights during the first term of the New Labour government. Beginning with the promotion of openness and public involvement in the NHS,³⁹⁷ it progressed to the heightened legitimacy and authority of lay voices³⁹⁸ and the later adoption of a Scandinavian model of explicit patient choice which evolved into individualisation and coproduction. However, it is uncertain if this approach can or will be fully realised, as its implementation is dependent on many factors, not least that appropriate program design is essential if engagement with the citizen-consumer is to be effective.^{399,400}

In the Welsh health-care field, given the overt rejection of market logic, the policy levers for provider pluralism and ensuing choice were not available. Wales has, therefore, embraced a citizen-centred model,³⁹² adhering to notions of collectivism and standardisation as in the traditional socialist values of equality, social justice and social inclusion in policy.⁴⁰¹ The 1000 Lives+ programme explicitly seeks to actively engage patients in the coproduction of their health care. Indeed, as expanded in *Chapter 6*, patient stories represent an important means of gaining feedback. In addition, an aligned programme, Putting Things Right, launched in April 2011 (www.wales.nhs.uk/sites3/home.cfm?orgid=932), facilitates the communication of what are collectively termed 'concerns' (complaints, claims and incidents reports) into the standards of health-care delivery and patient safety in NHS Wales. This operates in parallel with NHS Wales' governance framework.

1000 Lives+, health policy and patient safety

The 1000 Lives+ programme is a complex, multicomponent patient safety intervention and is an integral part of the Welsh Government's policy framework for NHS Wales.^{391,402} All health boards and trusts are involved in its operation. The Welsh Government and Public Health Wales host its codirectors and core team of improvement facilitators. Strategic oversight is provided by a dedicated programme board. 1000 Lives+ is supported by a faculty comprising a small group of senior clinical and managerial leaders who are tasked to ensure the rigour and clinical credibility of the evidence-based interventions promoted. In addition, the faculty builds capacity and capability at local and national levels by providing mentorship within clinical arenas, and through its contribution to the design and delivery of resources and training

materials. The 1000 Lives+ core team and faculty are augmented by an active network of students and academics committed to quality improvement and patient safety in NHS Wales.

As outlined in *Chapter 1*, the 1000 Lives+ programme seeks to support organisations and individuals to deliver health care of the highest quality for the people of Wales. Composed of an array of aligned improvement programmes, summarised in *Figure 1*, it adheres to an internationally recognised MI-PDSA¹⁷⁸ approach. This supports the use of small tests of change to establish new ways of working that can be replicated and adapted across NHS Wales. The broader infrastructure of 1000 Lives+ includes a website (www.1000livesplus.wales.nhs.uk) that enables access to publications and resources. These provide tailored support for each improvement area, together with notification of national events, opportunities for networking, knowledge mobilisation and collective learning. These resources are aligned to a web-based national learning programme for all NHS Wales staff and contractors (Improving Quality Together: www.iqt.wales.nhs.uk/home) together with the resources offered by Patient Safety Wales (www.patientsafetywales.org.uk).

Our discussions with policy leads, drawn from the upper echelons of the Welsh Government, highlighted the manner in which the 1000 Lives+ programme has become established in the Welsh health-care field and a core policy lever for health-care transformation in NHS Wales, as expressed in the excerpt from transcription 4:01, below (N.B. the full text of all transcriptions can be found in a supplementary data file; see *Chapter 3, Data collection, coding and analysis, Semistructured realist interviews*).

1000 Lives+ has become institutionalised – it's become part of the fabric – it's part of the way in which policy is being delivered and therefore all of the mechanisms that report progress on policy are by proxy reporting 1000 Lives+ progress; albeit I don't think it's quite that explicit. But I think the bureaucracy that sits behind the politics of policy have become enmeshed with 1000 Lives+.

Policy lead, Welsh Government (146); transcription 4:01

The 1000 Lives+ programme was widely viewed to have been built around the Welsh Government's tier 1 performance targets for NHS Wales (transcriptions 4:02 and 4:03). Indeed, the relative success of 1000 Lives+ had enabled other policy programmes to be associated with and linked to this complex intervention (transcription 4:04, below).

1000 Lives+ is something that people are using in order to be able to engage NHS staff in improvement work – it's a badge, a brand – and, what has happened here is that things have ended up being tagged onto 1000 Lives+. Through its own relative success 1000 Lives+ has become a magnet for lots of other things that people want to get in on the back of; it's almost become a Trojan horse way of getting something in the policy system! But it's mandated now, it's how we do change.

Policy lead, Welsh Government (150); transcription 4:04

Respondents also saw ministerial advocacy as important to the institutionalisation of the 1000 Lives+ programme (transcription 4:05, below).

[T]hey stuck their head out, well above the political parapet by coming out and publically endorsing, or at least acknowledging that, in health care, things can go wrong – we can cause harm, be it through variation, misjudgement, error or malpractice: we damage patients.

Policy lead, Welsh Government (081); transcription 4:05

Such advocacy was augmented by elite engagement across NHS Wales (transcription 4:06). Isomorphic institutionalism (increased similarity over time), vectored through the work of the IHI, was also perceived to have played a central role in brokering ministerial and wider elite engagement (transcriptions 4:07 and 4:08, below).

There was an awareness, back in 2006 and 2007, that we should be doing better in terms of patient safety. I think that awareness was raised by the work of the Institute for Healthcare Improvement to some extent – some of the key protagonists in the original campaign were closely involved with the IHI – but it was a bold commitment by the minister, the decision to actually launch the 1000 Lives Campaign. The label – 1000 Lives – that label, it implied that there were 1000 avoidable deaths, which is quite a brave thing to say. I'm not sure that we're still that brave.

Policy lead, Welsh Government (145); transcription 4:08

However, such elite engagement had also given rise to a context marred by coercive isomorphism³²⁹ (enforced similarity), one in which it was difficult to criticise the 1000 Lives+ national programme for fear of jeopardising relationships with future leaders of the Welsh NHS (transcription 4:09, below).

Wearing my naive yet political hat, the one thing you do not do is tell 1000 Lives+ it's failing – that is like insulting their firstborn and saying it's ugly – too many people high up the food chain – politicians, chief executive, medical directors – have signed up to this, and to publicly say it's not working is dangerous, not just for getting the process done but dangerous for individuals. So you need to be a bit more savvy about that!

Wales is a very small community – everyone knows everyone – so I am very mindful that if I pissed off someone here: you piss off today's medical director, you are enemies with tomorrow's chief exec of NHS Wales!

Policy lead, Welsh Government (144); transcription 4:09

Indeed, the human factors inherent to policy development – the barriers created through personal enmity and petty jealousies – compounded this note of discord (transcription 4:10, below).

*The 1000 Lives+ national programme is a source of hostility. [Why do you think it is a source of hostility?] There're a number of elements in play but, to be frank, it comes down to personalities and personal jealousies. It's about how, and with whom, it all started. In the beginning, we had [Name 1] and [Name 2] – both strong, charismatic personality types, who have their advocates and detractors, and who were, especially [Name 1], closely tied to the minister [Minister for Health and Social Services]. Now, these were the key figures, and some people across the service are advocates of them – not the 1000 Lives+ national programme – whilst others are not: but that's just the way it is, in all walks of life, some people reject what you're saying, not because they've thought about it, or hold a contrary view but just because you're saying it: so it's personal enmity. There're a number of ****ed-up relationships out there! God, you know how bloody parochial it can be. So, these personal tensions and jealousies – because that's what they are, jealousies about who's standing in the ministerial limelight; who is flavour of the month – these cause significant barriers to programme uptake, buy-in, and implementation.*

Policy lead, Welsh Government (081); transcription 4:10

Patient safety governance processes in NHS Wales

The 1000 Lives+ programme has now become integrated within organisational and professional patient safety governance processes operating across the Welsh health-care field and this complex patient safety intervention was perceived to symbolise and be part of the language of working together (transcription 4:11, below).

I think 1000 Lives+, certainly, because by its very nature it's a collaborative approach, it gives you a way of getting people in a room. Also, because it's badged 1000 Lives+ it probably doesn't feel as threatening to some board-level stakeholders – it's a convenient badge that's become a metaphor for working together – the terminology, it's become part of the patient safety language of NHS Wales.

Policy lead, Welsh Government (146); transcription 4:11

Strategic oversight of patient safety

The 1000 Lives+ programme functions under the auspices of the statutory Quality and Safety Committee in each health board. The programme was typically supported by a local steering group at hospital level (transcription 4:12, below, and transcriptions 4:13 and 4:14).

We have a structure that, I think, is pretty much standard for health boards in Wales. Our main committee is the Quality and Safety Committee – every organisation has statutory duty to have a Quality and Safety Committee or something termed along those lines – but we also have a subgroup of the Quality and Safety Committee called the Clinical Effectiveness Committee, which is a group led by the Medical Director, and, as the name implies, that receives the reports of the 1000 Lives+ work as well as internal, external audits, research and development, and stuff like that.

Associate Director, case site G, (011); transcription 4:12

Within this organisational structure, delegated strategic oversight routinely rested with three core board-level roles (transcription 4:15, below).

We have a 1000 Lives+ implementation group that's chaired by the medical director, the director of nursing and the director of therapies and health sciences – the three with the clinical portfolio – but it's also supported and attended by the director of public health.

Associate Director, case site D, (049); transcription 4:15

The strategic oversight of patient safety was supported by other board-level and non-executive positions, and this had impacted the culture of the organisations (transcription 4:16, below, and transcription 4:17).

My view is that everything that's in the portfolio of the Workforce and Organisation Development Director is about safety. It's about quality and safety because that is the ultimate aim. The quality and the safety of the services provided are as high as they can be achieved within the resources available. So, that's at the heart of everything that's in the portfolio – from recruitment, job design, right away through to performance management and ongoing development, CPD [continuous professional development] and leadership development – I think that all of those elements, which are central to human resource management, are around systems and processes that build or undermine the culture of patient safety. They are all core planks of my role, I think, and the role of my team.

Executive Director, Workforce and Organisation Development, case site G, (012); transcription 4:16

Sub-board-level managers also played a role in supporting the operation of 1000 Lives+. This was typically centred on data collation and reporting to the Quality and Safety Committee (transcriptions 4:18 and 4:19).

Patient safety practices and the burden of proof

The 1000 Lives+ programme was perceived to have improved front-line practitioners' awareness of the safety of their patients. However, this was dependent on the successful embedding of the underpinning MI-PDSA methodology¹⁷⁸ (transcriptions 4:20 and 4:21). The programme was also associated with increased paperwork and audit processes (transcriptions 4:22 and 4:26, below).

1000 Lives+ generates a lot of paperwork but it's not just 1000 Lives+ that generates paperwork. I think, with nursing, it's just that, you know, we have to keep records – it's proof, proof, proof all the time; prove that you've done it, prove that you've done it – and now there is just so much documentation just to admit a patient takes an awfully long time. But the government want proof, they want us to know that yes we've got 1000 Lives+ in place. But there's so much paperwork and some of it doesn't always follow the patient because we share notes now, sometimes, and that almost muddies the water in some respect. It's a huge amount on notes and things! Plus there's the amount of audits we do – we get audited to death – [What do you get audited on?] We get audited on use of sharps bins; we get audited on the environment and whether we're using the correct bins; we get audited on infection control; documentation audits, you know, it just seems that there's so much auditing. Mattresses get audited: there's just heaps of audits that go on.

Ward manager, case site G₃ (086); transcription 4:24

There's an awful lot of paperwork involved in patient care today. With 1000 Lives+ for every bundle that is developed you think: 'oh boy, here we go!' The delivery of care has got to be the paramount importance to us, it's no good thinking: 'yes, I can tick all the boxes but not actually doing the care'. So, you give the care, and then you have to find the time to do the assessments, the evaluations, and tick the boxes and everything. Also, you have to have the care plans that go with the bundle or care pathway, and they have to be linked and cross-referenced. Those have to be updated every week, sometimes more than that, depending on the stability of the patient because obviously that can vary. It would be nice if the documentation could be streamlined in such a way that, instead of having so many new documents, perhaps we could have one document that encompasses many things.

Ward manager, case site B₂ (056); transcription 4:26

The burden of data collection in order to document adherence to prescribed care practices, together with the growth of nursing metrics (transcription 4:27, below), may pose a fundamental risk to 1000 Lives+, as it may foster disengagement from the purpose of the programme and threaten reducing adherence to a tick-box exercise. One respondent commented that it could become simply 'a massive bureaucracy to feed the minister' (transcription 4:28).

[What performance indicators and nursing metrics are collected at ward level to monitor patient safety?] Bloody hell, what are the performance indicators? Everything! There's a whole set – they go through to the Welsh Government – there's a whole section on patient safety, infection control, workload, sickness absence, 1000 Lives+! It's just measures: it's a way of auditing us at a ward level. It's split into different sections but the one section you'd be interested in with 1000 Lives+ is the one with patient safety. [What issues do they monitor?] They look at things like, well there's quite a few parts which would relate to it, like you audit how many patients have had their armbands on. So you say, choose 12 patients, go round the 12, how many of the 12 have got armbands on, and it gives you a percentage figure. Once you've clicked that button and it's gone in, you can't change anything. So it does help, at the ward level, it gives me an indication, it gives me an indication if things are lacking.

Ward manager, case site B₁ (060); transcription 4:27

In addition, decoupling of practice from the intent of policy was fostered through the failure to validate data and to enforce adherence to guidelines (transcriptions 4:29 and 4:30).

External oversight of health-care quality and patient safety

In Wales, HIW, CHCs and the PSOW provide external oversight of health-care quality and patient safety. Such audit processes were seen as helping to validate the delivery of appropriate health-care standards, promoting change through identifying service failings (transcription 4:31, below).

Healthcare Inspectorate Wales did a spot audit here, last October I think it was, and on the particular morning they came in – I wasn't here, I wasn't on duty, and the sister wasn't here and there were a couple of staff off – it was absolutely bedlam! There were two patients dying, so two lots of family in and there were doctors everywhere, because it was after 9 o'clock and a load of medical students came to the ward. The linen trolley with the fresh linen for the day had been thrown in. People were doing breakfast; they were still doing breakfast! It looked like an absolute bombsite apparently. And in the audit they completely floored us . . . but, since then, I think it did us a favour because there were some things that we'd been fighting to get done because, as you know, this is an old ward. So there are things that we've managed to get changed on the back of this audit. So it's done us little favours.

Ward manager, case site B, (060); transcription 4:31

Furthermore, audits provided an important external source of data, countering parochialism and strengthening democratic challenge across NHS Wales (transcription 4:32, below).

[Do you report back to the Welsh Government?] For Welsh Government – well, there's a firewall between them and us [a CHC in Wales] – but we are an agent of government. However, having said that, we are a pain in their side – we say things they don't want to hear – the political view is obviously very different. But it's my duty to tell the truth to government, to tell them: 'actually you're not providing sufficient care, or your health boards with sufficient money to provide that care, and patients are struggling. Ultimately, you're to blame guys – don't blame the health boards – you're to blame'. Basically, we're seeing the NHS being removed by stealth. The government are going to be very cross with me, but I have a duty to speak on behalf of patients, so there you go!

[Does the politicisation of health care make it difficult for you to expose problems?] Yes, if it lands in the minister's lap and the minister doesn't like it! There'll be a level of 'ball bouncing' between government civil servants and the CHCs simply because they don't want that to land on the Minister's desk. I can't say I blame them. But it is my job to speak honestly on behalf of patients. Patients are David to the NHS' Goliath and how on earth can they possibly fight that giant?

Chief Executive, CHC in Wales (073); transcription 4:32

The role of 'critical friend', working in creative tension with a partner health board, is central to the scrutiny of local health services and advocacy support to complainants (transcription 4:33). However, for some health boards, these vital relationships may be fraught (transcription 4:34). Moreover, in discussions with such external organisations, though awareness of the 1000 Lives+ programme was evident, monitoring of adherence to its practices was overshadowed by the use of competing performance measures. Health boards were also concerned with this issue (transcription 4:35, below).

The Healthcare Standard we've just got used to, well, for me, it's now much more of a narrative – you tell your story – it's like we've gone from a series of MOTs and driving tests and garage inspections to a sticker on the back of the car saying: 'How's my driving?'. It's a bit like: 'here's the standards for health care, how do you think you are doing?'. Not one of them is a genuine standard, which really confuses staff; they're basically a list of aspirational statements and we're left essentially to our own devices about how we decide whether we meet them or not. My joke was that they could have saved a lot of time and money by just printing a lot of mouse-mats with the standards on because it's an aide memoire – it's basically a wish list. So that's a different approach to quality improvement. We're now encouraged to be more self-reflective and self-reliant but it is difficult because people always get things wrong and screw up and how do you legislate for that?

Executive Director, case site G, (011); transcription 4:35

Patient safety and competing contextual challenges

The 1000 Lives+ programme, and the predecessor 1000 Lives campaign, have been implemented during a major structural reconfiguration of NHS Wales. This has created a contextual challenge, specifically for the leadership and communication of the patient safety agenda (transcription 4:36, below) adding to the potential for distraction (transcriptions 4:37 and 4:38).

Post reconfiguration, I suppose, the size of the organisation brings its own challenges – it's a huge challenge – how do you communicate things effectively when you're that big? For 1000 Lives+ and other health board strategies, my biggest challenge is keeping in touch with what the organisation's priorities are – what is [name] chief priority as chief executive, how is he driving that forward – if we're going to make things change in line with his strategy, you've got to know what it is. If you don't know what it is, how on earth are we going to do that? There're so many tiers to go through now. I don't want to harp back all the time but it's a valid comparison because before I could talk directly to the chief executive because I'd see him in the corridor, and the medical director; those relationships were direct then, weren't they? Before you had the key people in your organisation – that physical proximity, almost a direct route on a formal and informal basis – you would be kept up to speed when things were going on. But now, it's lost.

Associate Director, case site B₂ (009); transcription 4:36

However, the greatest challenge arises, unsurprisingly, from unstinting financial pressures. All areas of NHS Wales are expected to do more with less and this confronts the 1000 Lives+ programme with a stark challenge (transcriptions 4:39 and 4:40, below).

If we are to keep up the momentum on 1000 Lives+ the area that we need to keep pushing is the business case for quality – to have the evidence from all of the 1000 Lives+ improvement programmes to show where the cost savings are – to build that bank of evidence for cost savings through quality improvement; that's where we need to get to.

Policy lead, Welsh Government (065); transcription 4:40

1000 Lives+ institutionalisation: preliminary understanding of local implementation

Our study focused on the complex interplay of the 1000 Lives+ national programme in the context of the Welsh health-care institutional field. The unit of analysis in this study was the process of local implementation of 1000 Lives+ and the three focal interventions selected for detailed consideration: ILQI, RSC and RHAI.

The first stage of our analysis sought to examine the process of institutional change as it emerged during the progressive bureaucratisation of 1000 Lives+ programme, in order to understand the manner in which the programme has become part of the context of the Welsh health-care institutional field. Drawing on the work of Greenwood *et al.*,²²⁷ as well as terminology used by Lewin³⁵⁰ and Schein,³⁵¹ we framed such institutional change through six linked stages: disconfirmation (Greenwood *et al.*²²⁷ see this stage as triggered by 'precipitating jolts', in this instance recognition that patient safety is a continuing problem), deinstitutionalisation, preinstitutionalisation, theorisation, diffusion and reinstitutionalisation. We also reflect on the impact and interplay of institutional logics in the Welsh health-care field and, as illustrated in *Figures 8 and 9*, consider the relationships between dominant and subordinate logics, be they complementary, co-existent or countervailing.

Disconfirmation

The overarching goals of 1000 Lives+ signal the need for institutional change through an admission that patients are not being cared for as well as they should be: what Schein, building on Lewin's theories of planned change, calls an act of disconfirmation^{350,351} (Figures 10 and 11 and Tables 6–9). Thus, the process of institutional change in the Welsh health-care field begins with the transmission of the IHI's influential MI-PDSA approach via elite institutional carriers,^{403,404} such as ministers and government officials, who, by conveying their political advocacy for such change – 'sticking their heads above the political parapet', as one respondent put it – promote the concept, encouraging others to introduce its ethos and practices by processes of imitation (mimetic institutional isomorphism³²⁹) and/or official directive (coercive institutional isomorphism³²⁹). In this context, the logic of the bureaucratic state is dominant, rendering the logics of collaboration, profession and democracy into a complementary stance under the influence of ministerial authorisation. However, it should be noted that implementation may be undermined when actors find it difficult to meet the organisational goals by using the explicit policies and procedures, and proceed to modify them, a process known as 'gaming'⁴⁰⁵ (see Figure 11, point 2, and Chapter 7, *Realist analysis and comparative case study, Sociocultural interaction: agency and strategic negotiation*).

At the level of the infrastructural system (see Table 6), the systemic legitimisation of the IHI's MI-PDSA approach is signalled by the aligned names: 1000 Lives campaign and 1000 Lives+ national programme. Meanwhile, its formalisation is marked through the embedding of these patient safety interventions in Welsh health-care policy and governance systems.

As expanded in Table 7, both added democracy and authentication come from public sector partner agencies tasked with the external oversight of health-care quality and patient safety, with their inspection regimens encouraging adherence to 1000 Lives+ standards, beliefs and norms. Indeed, during the transition from the campaign to the national programme, the use of the 1000 Lives+ and associated MI-PDSA approach became embedded in the Welsh Government's health-care policy, notably in its tier 1 targets and aligned performance metrics.

Deinstitutionalisation

At the level of NHS Wales and its constituent health boards, deinstitutionalisation, the second facet of the 1000 Lives+ local implementation, can be seen as the 1000 Lives+ programme's mandate is legitimised via the Welsh Government's Department of Health and Social Care (see Table 8). Formalisation then ensues as the programme is placed under the statutory oversight of local Quality and Safety Committees (see Figure 11). Through local acts of co-optation in each health board, leaders are assigned to each focal intervention. They are tasked to identify potential systemic failures, anticipate adverse events and reframe such issues as a social problem to be addressed through collaboration with health-care professionals across NHS Wales' constituent health boards.

A wider range of health-care actors are gradually co-opted into 1000 Lives+ contributing to the multiprofessional and multisite co-ordination of patient safety. This generates internal challenge through which previously accepted standards of quality and safety – for example, the nature and frequency of adverse outcomes in theatre^{169,191,406} or for central venous catheter-related bloodstream infections⁴⁰⁷ – are viewed in a pejorative light. Practitioners, acting as institutional entrepreneurs,⁴¹ now collectively adopt a new normative standard leading to practice-based change¹⁸¹ and the rejection of old habits. This leads to institutional change and strengthens the collective will to create an organisational culture attuned to quality improvement.⁴⁰⁸

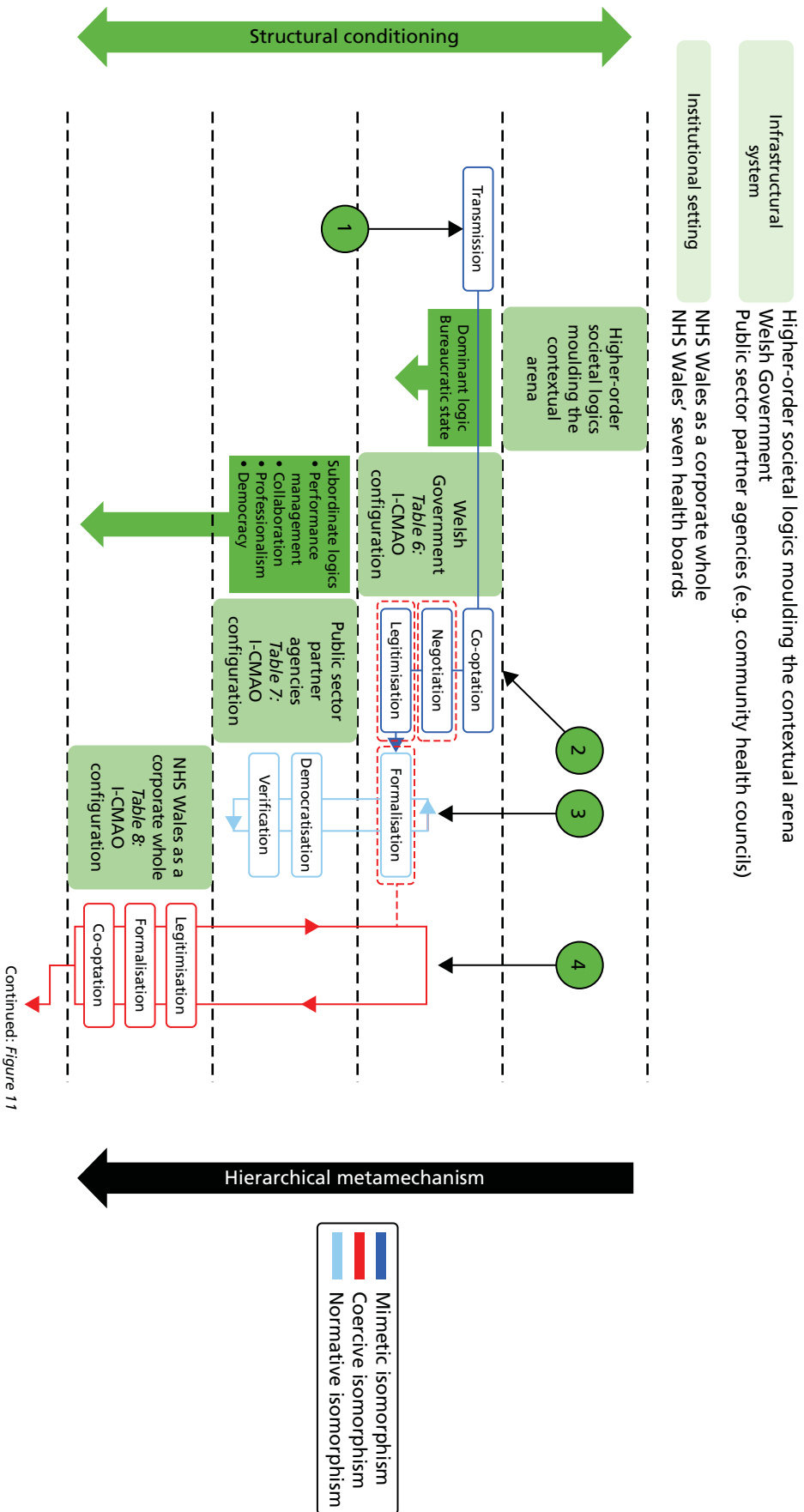


FIGURE 10 Bureaucratisation of 1000 Lives: hierarchical metamechanism operating across the contextual strata of the infrastructural system and institutional setting.

Figure 10: key point summary

In *Figure 10* we depict the bureaucratisation of the 1000 Lives+ national programme across the infrastructural system and institutional setting of the Welsh health-care field.

In point 1 the process of institutional change begins with the transmission of the IHI's hegemonic MI-PDSA approach via elite institutional carriers, who enact mimetic institutional isomorphism to introduce its practices within the Welsh health-care field.

In point 2 elite institutional agents, through acts of co-optation and negotiation, spread and legitimise the MI-PDSA approach, gradually co-opt others through mimetic and coercive institutional isomorphism. The legitimisation of the IHI's MI-PDSA approach is signalled by the aligned names – 1000 Lives+ campaign and 1000 Lives+ national programme.

In point 3 the formalisation of the 1000 Lives+ national programme is marked by the embedding of its patient safety interventions in Welsh health-care policy – notably tier 1 performance targets – and associated internal and external governance systems. In this manner, the context is conditioned for NHS Wales, its constituent health boards and their employees at the departmental level or that of the ward-based functional team.

In point 4 following the legitimisation of the 1000 Lives+ programme's mandate, adverse events are reframed as a social problem to be addressed through the collaborative engagement and the ensuing agency of health-care professionals in NHS Wales' constituent health boards. Localised formalisation is seen, catalysing multiprofessional and multisite co-ordination of patient safety via the statutory Quality and Safety Committee and aligned governance structures, augmented by distributed leadership of the patient safety agenda across the managerial strata.

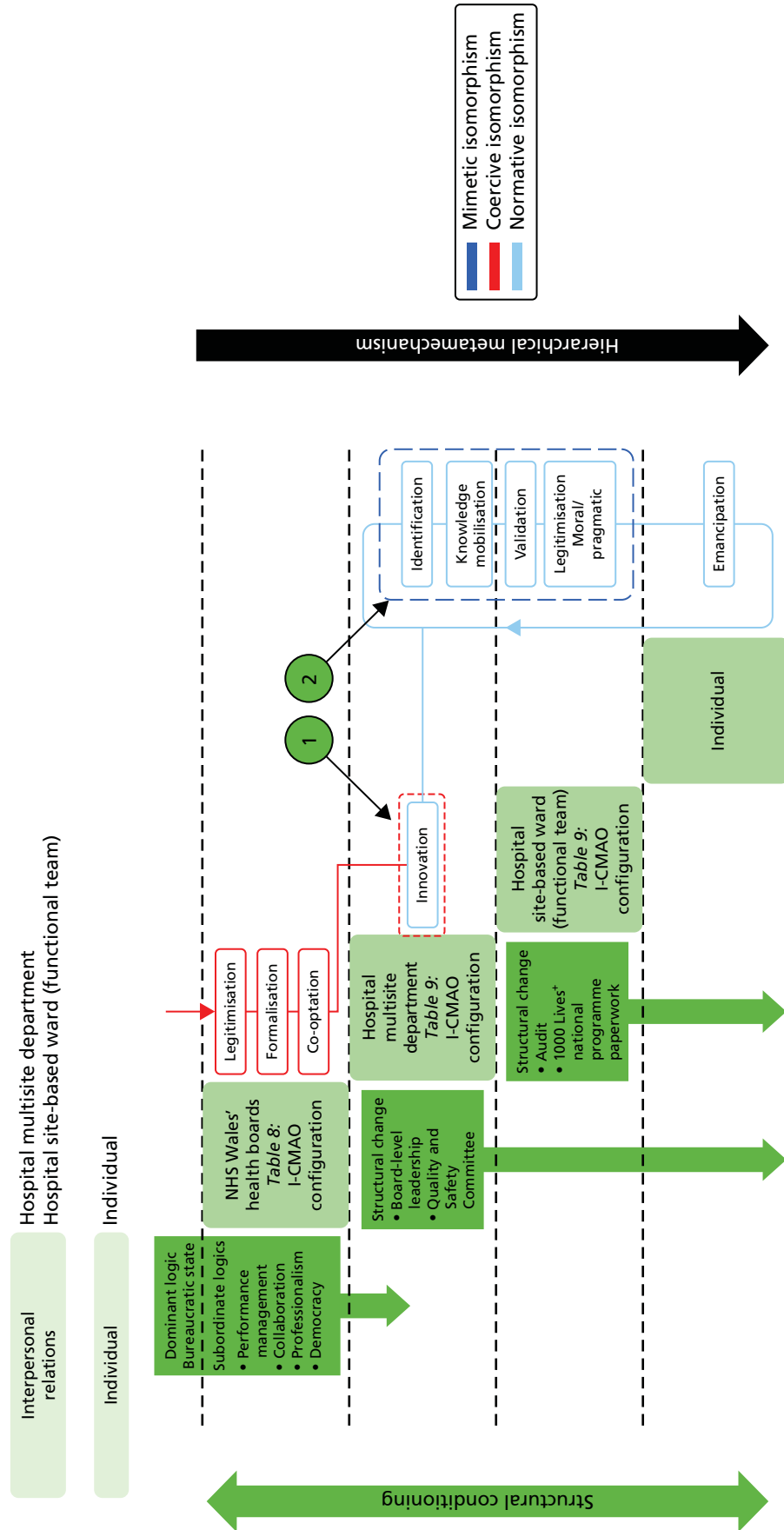


FIGURE 11 Bureaucratisation of 1000 Lives*: hierarchical metamechanism operating across the contextual strata of the interpersonal system within NHS Wales' health boards.

Figure 11: key point summary

In *Figure 11* we extend our depiction of the bureaucratisation of the 1000 Lives+ national programme to consider the interpersonal level.

In point 1 innovation is seen to be brokered through the pragmatic evidence-based learning of the 1000 Lives+ embedded MI-PDSA approach. This is driven by coercive, mimetic and normative institutional isomorphism. Importantly, at this juncture, as illustrated in *Figure 9*, professional logic asserts dominance, thereby generating the potential for discord.

In point 2 identification and awareness of systemic patient safety failings, fostered through the testing of a rapid cycle of change with the MI-PDSA approach, heightens collaboration and communication across the multidisciplinary team, giving rise to knowledge mobilisation and greater understanding of variation in health-care service delivery. Yet the burden of data collection and demands of validation may retard meaningful engagement and give rise to the situated practice of gaming. This increased knowledge and understanding of the unfolding change reveals common areas of failing – systemic and human – so that the conceptualisation of the desired institutional change is further refined. In this manner, the moral and pragmatic legitimisation of 1000 Lives+ arises, helping to overcome reluctance and resistance to engage and its institutionalisation across NHS Wales.

TABLE 6 Intervention–context–mechanism–agency–outcome configuration: infrastructural system – Welsh Government

Intervention	1000 Lives+ national programme	
Context	Welsh Government	
Mechanism	Institutional isomorphism: mimetic, coercive and normative	
Agency and institutional work	<ul style="list-style-type: none"> Agency – transmission – elite institutional carriers enact mimetic institutional isomorphism, adopting the IHI's hegemonic MI-PDSA approach to patient safety Institutional work – creation – elite institutional actors reconfigure key actors' belief systems Agency – co-optation – elite institutional actors employ their political advocacy and social position to foster the co-optation of others across their managerial and professional networks Institutional work – creation – elite institutional actors reconfigure key actors' belief systems Agency – negotiation – elite institutional actors and co-opted others set the strategic direction Institutional work – creation – elite institutional actors enact political work to reconstruct rules, rights and access to resources, thereby linking 1000 Lives+ national programme to tier 1 performance targets Agency – legitimisation – elite institutional actors and co-opted others embrace 1000 Lives+ and MI-PDSA approach and embed in health-care policy and performance frameworks Institutional work – creation – elite institutional actors enact political work to reconstruct rules, rights and access to resources, thereby linking 1000 Lives+ national programme to tier 1 performance targets Institutional work – disruption – elite institutional actors dissociate from 1000 Lives+, fostering decoupling Agency – formalisation – mandated engagement with 1000 Lives+ and the MI-PDSA approach to address NHS Wales' organisational failings and attain national health-care standards Institutional work – creation – elite institutional carriers enact political work to reconstruct rules, rights and access to resources, thereby linking 1000 Lives+ national programme to tier 1 performance targets 	<p>Exemplar transcriptions:</p> <ul style="list-style-type: none"> 4:05 (T145) – coupling 4:07 (T081) – coupling <p>Exemplar transcriptions:</p> <ul style="list-style-type: none"> 4:06 (T054) – coupling 4:09 (T054) – decoupling 4:10 (T081) – coupling <p>Exemplar transcriptions:</p> <ul style="list-style-type: none"> 4:02 (T145) – coupling 4:07 (T081) – coupling <p>Exemplar transcriptions:</p> <ul style="list-style-type: none"> 4:01 (T146) – coupling 4:02 (T145) – coupling <p>Exemplar transcriptions:</p> <ul style="list-style-type: none"> 4:03 (T124) – coupling 4:04 (T150) – coupling 4:08 (T143) – coupling
Outcome	1000 Lives+ national programme institutionalised into policy processes	

TABLE 7 Intervention–context–mechanism–agency–outcome configuration: infrastructural system – public sector partner agencies

Intervention	1000 Lives+ national programme
Context	Public sector partner agencies
Mechanism	Institutional isomorphism: predominantly normative
Agency and institutional work	<ul style="list-style-type: none"> • Agency – formalisation – mandated engagement with 1000 Lives+ and the MI-PDSA informs the inspection regimens adopted by public sector partner agencies • Institutional work – maintenance – public sector partner agencies’ inspection regimens foster adherence to 1000 Lives+ standards, espoused beliefs and norms • Agency – democratisation – patient and public voice harnessed providing democratic challenge to improve patient safety • Institutional work – maintenance – public sector partner agencies’ inspection regimens foster adherence to 1000 Lives+ standards, espoused beliefs and norms • Agency – verification – level of attainment of 1000 Lives+ standards informs the external oversight of patient safety and further informs internal NHS and Welsh Government monitoring of health-care standards • Institutional work – maintenance – public sector partner agencies’ inspection regimens foster adherence to 1000 Lives+ standards, espoused beliefs and norms
Outcome	1000 Lives+ national programme institutionalised within existing processes supporting the external oversight of patient safety

Exemplar transcriptions:

- 4:32 (T073) – coupling
- 4:33 (T087) – coupling

Exemplar transcriptions:

- 4:31 (T060) – coupling
- 4:34 (T075) – coupling
- 4:35 (T011) – decoupling

TABLE 8 Intervention–context–mechanism–agency–outcome configuration: institutional setting – NHS Wales and constituent health boards

Intervention	1000 Lives+ national programme
Context	NHS Wales as a corporate whole/NHS Wales’ health boards
Mechanism	Institutional isomorphism: coercive
Agency and institutional work	<ul style="list-style-type: none"> • Agency – legitimisation – 1000 Lives+ becomes part of the language and practice of patient safety in NHS Wales. Institutional entrepreneurs reassert a normative standard to hasten practice-based change • Institutional work – creation – elite board-level institutional actors undertake political work to reconstruct rules, rights and access to resources, thereby linking 1000 Lives+ national programme to the attainment of the Welsh Government’s tier 1 performance targets • Agency – formalisation – multiprofessional and multisite co-ordination of patient safety via the statutory Quality and Safety Committee and aligned governance structures • Institutional work – creation – elite board-level institutional actors undertake political work to reconstruct rules, rights and access to resources, thereby linking 1000 Lives+ national programme to the attainment of the Welsh Government’s tier 1 performance targets • Agency – co-optation – distributed leadership of the patient safety agenda across the managerial strata • Institutional work – creation – elite board-level institutional actors undertake political work to reconstruct rules, rights and access to resources, thereby linking 1000 Lives+ national programme to the attainment of the Welsh Government’s tier 1 performance targets
Outcome	1000 Lives+ national programme institutionalised within existing processes supporting the internal oversight of patient safety

Exemplar transcriptions:

- 4:11 (T146) – coupling

Exemplar transcriptions:

- 4:12 (T011) – coupling
- 4:13 (T074) – coupling
- 4:14 (T026) – coupling
- 4:15 (T049) – coupling

Exemplar transcriptions:

- 4:16 (T012) – coupling
- 4:17 (T043) – coupling
- 4:18 (T022) – coupling
- 4:19 (T025) – coupling

TABLE 9 Intervention–context–mechanism–agency–outcome configuration: interpersonal relations – hospital multisite department/hospital site-based ward (functional team)

Intervention	1000 Lives+ national programme	
Context	Hospital multisite department/hospital site-based ward (functional team)	
Mechanism	Institutional isomorphism: coercive, mimetic, progressing to normative	
Agency and institutional work	<ul style="list-style-type: none"> Agency – innovation – individual and organisational pragmatic evidence-based learning is demonstrated through adherence to the MI-PDSA approach Institutional work – creation – functional team’s belief and meaning systems reconfigured Agency – identification – performance measurement and monitoring of patient safety heighten awareness of failings Institutional work – creation – functional team’s belief and meaning systems reconfigured Agency – knowledge mobilisation – collaboration and heightened communication across the multidisciplinary team promotes individual, team and organisational learning Institutional work – creation – functional team’s belief and meaning systems reconfigured Agency – validation – data collection for formalised patient safety governance monitoring demonstrates attainment of tier 1 targets Institutional work – maintenance – functional team’s performance supports adherence to existing internal and external governance systems Agency – legitimisation (moral/pragmatic) – 1000 Lives+ moral and pragmatic legitimacy fosters mainstreaming of the intervention across NHS Wales Institutional work – creation – functional team’s belief and meaning systems reconfigured Agency – emancipation – 1000 Lives+ and the MI-PDSA approach facilitate informed challenge and change of the status quo Institutional work – disruptive – functional team’s underpinning core assumptions and beliefs adapted to new health-care role-position practices 	<p>Exemplar transcriptions:</p> <ul style="list-style-type: none"> 4:20 (T070) – coupling <p>Exemplar transcriptions:</p> <ul style="list-style-type: none"> 4:18 (T022) – coupling <p>Exemplar transcriptions:</p> <ul style="list-style-type: none"> 4:21 (T052) – coupling <p>Exemplar transcriptions:</p> <ul style="list-style-type: none"> 4:22 (T060) – coupling 4:26 (T056) – coupling 4:29 (T060) – coupling <p>Exemplar transcriptions:</p> <ul style="list-style-type: none"> 4:40 (T065) – coupling <p>Exemplar transcriptions:</p> <ul style="list-style-type: none"> 4:20 (T070) – coupling
Outcome	1000 Lives+ national programme institutionalised in daily health-care practice	

Preinstitutionalisation

This constitutes the third facet of the local implementation of the 1000 Lives+ programme and is demonstrated at the interpersonal level, impacting functional teams, be they the executive board or ward-based clinicians. Importantly, as illustrated in *Figure 9*, in the context of the hospital department or ward-based functional team, professional logic (re)gains dominance. This creates the potential for discord between the different professional logics of health-care management, medicine, nursing and other allied professional groups, although *Table 9* depicts this in a benign manner.

As illustrated in *Figure 11*, innovation can emerge from the evidence-based learning of the MI-PDSA approach.^{172,409,410} The use of data to inform practice heightens the identification and awareness of systemic patient safety failings.^{24,181,411} Furthermore, collaboration and communication across the multidisciplinary team is increased through testing of a rapid cycle of change.^{172,180,187,412} This gives rise to knowledge mobilisation and greater understanding of variation in health-care service delivery.¹⁸⁷ However, the burden of data collection and demands of validation may retard meaningful engagement and give rise to the practice of gaming.⁴⁰⁵ In addition, because performance measurement and monitoring systems are mandatory, the logic of the bureaucratic state again asserts dominance. This again creates the potential for discord among logics as illustrated by the decoupling expressed in the exemplar transcriptions.

Theorisation

This is central to the conceptual framework employed in our study. Greenwood *et al.*²²⁷ contend that this manifests through the (i) specification of general organisational failings; (ii) justification of abstract possible solutions; and (iii) assertions of moral and pragmatic legitimacy. Hence, in refining perceptions of cause and effect, reflexive theorisation represents a key stage in individual and collective social actors' adaptive response to institutional change.⁴¹³ It underpins the notion of mechanism, set out in *Chapter 2*, as the embodiment of an agent's reasoning and their selective attention to the disparate resources offered through the 1000 Lives+ national programme.

As depicted in *Figure 11*, the implementation and bureaucratisation of 1000 Lives+ increases knowledge and understanding of the unfolding change, revealing common areas of failing and enabling refinements to be made. Such legitimisation helps to overcome reluctance and resistance to engage,^{127,414,415} and so aids its institutionalisation across NHS Wales. This end may be achieved through multidisciplinary team-based discussion,^{169,189,219} including focus groups with patients^{151,416} and health-care professionals,⁴¹⁷ together with dedicated support for interorganisational learning.^{261,418} Such processes aid emancipation of staff, giving them the authority, whatever their rank, to insist on correct safety procedures being followed. However, should this theorisation stage fail to change people's values and attitudes appropriately, this may precipitate institutional decoupling,^{348,349} giving rise to the emergence of a legitimacy façade⁸⁵ and the failure of the intervention.

Diffusion

Diffusion through wider adoption constitutes the fifth facet of the local implementation of the 1000 Lives+ programme. However, as noted by Berwick,⁴¹⁹ continuous effort is required to maintain and spread the gain associated with such practice change. As illustrated in *Table 7*, at this interface the logic of democracy assumes dominance, fostering the external oversight of patient safety via public sector partner agencies' inspection regimens to support this goal.

Reinstitutionalisation

This is the final facet of the 1000 Lives+ local implementation, reflecting widespread organisational acceptance of and adherence to the new programme. However, this, too, in acknowledging an ongoing commitment to the embedded MI-PDSA approach, must evolve with the shifting dynamic of the evidence-base³⁻⁵ and progressive rehabitualisation.²²²

Summary

In *Chapter 4*, we analyse the structural change inherent to bureaucratisation of the 1000 Lives+ programme at the higher, infrastructural system level of the Welsh health-care field. This analysis defines our preliminary understanding of the programme's local implementation and how the 1000 Lives+ programme becomes part of the context of the Welsh health-care institutional field.

Chapter 5 Institutionalisation of the 1000 Lives+ programme in NHS Wales: normalisation, health-care practices and patient safety

Overview

This chapter continues our examination of the institutionalisation of the 1000 Lives+ patient safety programme in NHS Wales. Presented in three main parts, it is focused at contextual levels below the field level and explores interpersonal and individual engagement with 1000 Lives+ to gain a deeper understanding of its progressive normalisation across NHS Wales.

First, guided by the model proposed by May *et al.*,^{352,353} we analyse the patient safety literature to consider mechanisms that may foster the normalisation of complex interventions in daily health-care practice. Second, we enrich this explanatory analysis through consideration of in-depth discussions held with a wide range of health-care practitioners concerning their perceptions of the normalisation of 1000 Lives+ and the development of patient safety practices in NHS Wales. Specifically, we examine the 1000 Lives+ MI-PDSA approach, the distributed leadership and the teamwork inherent to its operationalisation. We then illustrate the nuanced impact of pride and shame in building the ethos of patient safety and examine the pragmatic issues that foster institutional coupling to, or decoupling from, such activities. Finally, we elaborate our understanding of the local implementation of the 1000 Lives+ programme. This forms the foundation for our analyses of the three focal interventions presented in *Chapters 6–8*.

Possible mechanisms fostering the normalisation of 1000 Lives+

As discussed in *Chapter 2*, we draw on institutional theory to inform our understanding of the generative mechanisms, specifically the roles of contextual constraints and enablements, and ensuing reflexive theorisation; and May's^{352,353} modulating roles of coherence, cognitive participation, collective action and reflexive monitoring, thought to foster the normalisation of 1000 Lives+ in NHS Wales.

Coherence

As expressed in May's normalisation process theory,^{352,353} coherence means that a practice – an ensemble of beliefs, behaviours and acts that manipulate or organise objects and others – is made possible by a set of ideas about its meaning, uses and utility and by socially defined and organised competencies.³⁵³ In this regard, the 1000 Lives+ programme may be seen as a material object which facilitates the improvement of the patient safety in NHS Wales through the way in which the health-care team, both individually and collectively, think about and understand its meaning and carry out the practices involved.

As evident from patient safety studies undertaken in NHS Wales,²¹⁰ the coherence and foundational competence of the 1000 Lives+ programme is clearly linked to the underpinning MI-PDSA approach.^{178,219} This method of service improvement has been advocated in health care for many years^{420–423} and its widespread adoption in developed health-care systems promotes health-care actors' awareness of the MI-PDSA approach as accepted practice,³⁵³ so aiding its embedding into day-to-day working.¹⁸⁶

Cognitive participation

The 1000 Lives+ programme is normalised through ongoing cognitive participation, defined by May and Finch³⁵³ as 'the symbolic and real enrolments and engagements of human actors that position them for the interactional and material work of collective action'.

Although cognitive participation in the 1000 Lives+ programme is underpinned by the MI-PDSA approach, specifically with regard to the promotion of a consistent approach across its multicomponent improvement programmes,⁴²⁴ other resources make valuable contributions. For example, the 1000 Lives+ programme team, improvement guides and local and national learning events each facilitate cognitive participation through education and practice-based skill development. Such learning, whether at an individual,^{187,421,425–427} an organisational^{12,411} or a system-wide level,^{24,428} is fundamental to health-care practice change, as is the need for senior organisational leaders to develop a comparable level of awareness of 1000 Lives+, the MI-PDSA approach and associated drivers.⁴²⁹ Cognitive participation thus helps to ensure that systemic and organisational factors giving rise to patient neglect are addressed,⁴³⁰ while knowledge sharing and trust are enhanced.⁴³¹

Collective action

The cognitive participation of social actors gives rise to collective purposive action aimed at some goal. However, with respect to the 1000 Lives+ programme, such goal-orientation may include resistance, subversion or reinvention, as well as affirmation and compliance with the core features of this patient safety programme. The normalisation of 1000 Lives+ is, therefore, dependent on institutional and professional work that defines and operationalises the desired features of 1000 Lives+, aligned factors which promote or inhibit social actors' enacting of 1000 Lives+ and social actors' collective investment of effort in such practices.³⁵³

For the 1000 Lives+ programme, two processes which facilitate collective action are interactional workability and relational integration.³⁵² These involve cross-team co-operation,⁴³² notably via enhanced communication;^{433,434} the development of shared goals, meanings and expectations;⁴³⁵ and accountability and confidence in the internal and external credibility fostered by mandated local and national monitoring of 1000 Lives+. Furthermore, given the explicit steps defined in each discrete patient safety intervention, 1000 Lives+ represents a valid and recognised practical aide memoire. In this way, the programme helps to increase awareness of patient-related issues, procedures and anticipated risks across functional health-care teams,⁴³⁶ including both public and population health care.⁴³⁷

Other processes which facilitate collective action are skill-set workability and contextual integration.³⁵² Skill-set workability describes how work is divided up among practitioners with different but complementary skills.³⁵³ For example, empirical investigation of the WHOSSC, the focal intervention discussed in *Chapter 7*, supports the view that defined allocation of work, where the assessment of intraoperative blood loss is apportioned to surgeons, patient-specific airways management to the anaesthesia team and sterility and equipment issues to nurses,⁴³⁸ enhances the performance of the operating theatre team. However, such task definition does remain susceptible to entrenched role boundaries and perceived surgical autonomy, which may impact adversely on safety culture.⁴³⁹ Contextual integration, as the term suggests, refers to the integration of 1000 Lives+ within a social context and its interplay with extant structures and organisational procedures. As May and Finch³⁵³ point out, integration may not be easy to achieve in some contexts and will require collective effort from those involved.

Reflexive monitoring

Practices, even when established, demand reflexive monitoring to ensure appropriate performance.^{338,353,440} Patterns of collective action, and their outcomes, are therefore continuously evaluated by participants in implementation processes, both formally and informally, and with a greater or lesser degree of intensity depending on their interest and involvement.³⁵³ The normalisation of the 1000 Lives+ programme in day-to-day practice is, therefore, dependent on institutional and professional work that defines and organises the everyday understanding of 1000 Lives+, aligned factors which promote or inhibit social actors' appraisal of 1000 Lives+ and social actors' collective investment in its ongoing theorisation and refined understanding.³⁵³

Individual and collective reflection of actual practice against explicit and more tacit norms, while central to the embedding of a practice,^{356,441–444} may differ markedly from formal governance procedures and standards, in some cases giving rise to a façade of legitimacy.⁸⁵ Empirical studies of patient safety have also highlighted the human barriers to incident reporting, despite its central role in organisational learning and the establishment of a stronger safety culture.⁴¹² In the following section, we seek to examine the views and experiences of individuals and groups during the institutionalisation of the 1000 Lives+ programme, and so to understand the processes involved in the operationalisation, subversion or reconstruction of its associated practices.

1000 Lives+, health-care practice and patient safety

During in-depth discussions with a wide range of health-care practitioners across NHS Wales, we asked each participant to reflect on the notion of context. As set out below, transcription 5:01 succinctly expresses the sense of context as situated, demarcated by relational ties and distinct from that of the wider organisation.

I think what is key, when you consider the way in which 1000 Lives+ is implemented, is consideration of context. [What do mean by context?] The immediate area of its implementation and the people involved. Look, you can work with one ward to implement it. They do it there, and you can then spread it; but when you do spread it you have to customise it to make it work for the people who are there – in that new context. You can't just pick up something developed in one area of your organisation and assume it will fit into another without you, at least, considering where they're coming from! So, you can't really define organisational context – to implement, context has to be kept really small – you work within that area, have a testing period, and then spread and renew. That's how it's done. I think that is key to a lot of what we can manage.

Associate Director, case site C₂ (014); transcription 5:01

This perception is replicated throughout our discussions and subsequent analysis of the implementation and operationalisation of 1000 Lives+. As one respondent described, 1000 Lives+ has normalised in discrete pockets. This has created disparity between adjacent wards within a given hospital case site (transcription 5:02, below).

What I see is pockets of interests in 1000 Lives+. It's led by individuals who have cultivated a team around them and given them work to do, so it's being led by people who are enthusiastic or buy into certain areas where their interests lie. But it's not systemic: there are good pockets in the organisation and areas that aren't reached – you can have wards on opposite sides of a corridor where one's engaged and the other isn't. As a consequence, it's relying on enthusiasm rather than a systematic approach. Sustainability at an organisational, corporate level is needed, so that everything is aligned toward patient safety.

Executive Director, Workforce and Organisation Development, case site G₁ (012); transcription 5:02

Normalisation is, thus, restricted to those who perceive meaning in 1000 Lives+ owing to alignment with their beliefs, and whose cognitive participation and commitment builds and co-ordinates the engagement of others. This finding offers explanatory insight into the perceived failure of such complex patient safety interventions¹⁶⁸ and underscores Pawson's iron law of evaluation: the expected value of any net impact assessment of any large scale social program is zero.²⁴¹

Acknowledgement of the fragmented nature of its normalisation does not, however, detract from the undeniable focus that 1000 Lives+ offers health-care practitioners in NHS Wales. Those who value the initiative consider it as something real and visible that they can use to help them to forward the cause of patient safety (transcription 5.03, below).

Before 1000 Lives and 1000 Lives+ – before SPI [Safer Patients Initiative] – people were saying: ‘we want to keep patients safe, we don’t want to do them harm’. Well, of course, that’s what we want to do, I mean, that’s a given. But with patient safety now, we have the 1000 Lives+ logo, we have information at the front of the hospital; there’s something you can hang your hat on! It has real organisation! It’s not just some nebulous patient safety concept. There’s somebody leading it, there were newsletters, there are graphs so that you can see, you can see the improvements that have been made. 1000 Lives+ is making it real, I would say – not that it wasn’t real before – but, you know, now it has something; it’s tangible, it’s all coordinated, it’s centralised. So, say if somebody had a good idea for improving patient safety, rather than saying: ‘shall I go to my line manager? Well, they’re never any good, they’ll nod but they won’t do anything, who else can I go to?’. They’ve got someone you can go to! You’ve got the 1000 Lives+ patient safety group, and you just go on the intranet and find out the relevant person, and you know they will take it seriously. They may or may not be managing it but you know they will take it seriously because that’s what they do – that’s the hat that they wear – so they’re not trying to juggle between clinical effectiveness, patient safety, and saving money. Patient safety isn’t just something competing for their time, their skills and resources. That is what 1000 Lives+ is: it starts and finishes with patient safety.

Pharmacist, Antibiotics Medicines Management, case site D₂ (020); transcription 5:03

Such coherence appears to resonate equally with patients and with the public (transcription 5:04).

On the other hand, there is a sense that bureaucratic impatience may be hampering the successful implementation of 1000 Lives+ across NHS Wales, leaving some staff in its wake (transcription 5:05, below).

I think with 1000 Lives+ we have been pushed on to get on to the next ones [improvement programmes] before it’s sort of embedded. For example, the NEWS Score [National Early Warning Score] is not embedded, it’s embedding.

Ward manager, case site C₃ (T080); transcription 5:05

For instance, although aware of the 1000 Lives+ programme, some key medical staff remain disengaged (transcriptions 5:06 and 5:07, below).

I’ve had doctors telling me that it’s, you know, not nonsense but it’s one of those fads. So they’ve obviously made up their mind they’re not going to pay any attention to 1000 Lives+ and it’s of no relevance to them. I think, as with anything, you have people just being bloody minded for whatever reason!

Associate Director, case site F₁ (026); transcription 5:06

I think some consultants aren’t aware of 1000 Lives+. They have it in their peripheral field. They are aware that it exists but it doesn’t impact on their lives, and some think it’s probably a good thing but it still doesn’t impact on their lives.

Consultant gastroenterologist, case site F₁ (027); transcription 5:07

The policy pacing and positioning of the 1000 Lives+ programme across NHS Wales is, therefore, contributing to the fragmentation of its normalisation. Unequal engagement with the resources offered by this patient safety intervention further stymies progress, as its main adherents are those who are involved in, and already agree with, the aspirations of the programme (transcription 5:09, below).

I think with 1000 Lives+ they're selling it to those who've bought in – you know, the people who are designing the programmes and delivering them – I think it's important to them. But whether staff in the NHS are really engaged, I don't know. I mean, here, and this is a small hospital, we don't get all doctors following the sticker initiative [antibiotic prescribing guidelines]. Some do, some don't: there's always an excuse not to do it, whether it's too much work, too time-consuming, whatever, they always have excuses. Another aspect to this, though, is the rate of turnover. FP1–2s [junior doctors undertaking foundation training] rotate so quickly, and they may not be within the same health board, let alone hospital, so there's little time for them to learn the system before they're off again. On the whole, it's the staff that don't rotate that maintain the system against, or despite, those who are just passing through.

Pharmacist, Antibiotics Medicines Management, case site B₂ (001); transcription 5:09

The meaningful engagement of wider NHS staff is undeniably key to the normalisation and sustainability of 1000 Lives+. Specifically, non-rotating staff are central, as they provide the contextual and relational continuity necessary for coherence. This is the foundation the programme must return to, and reinforce, to prevent the dissipation of its goals (transcription 5:10).

Model for Improvement, Plan-Do-Study-Act approach

The central role of the MI-PDSA approach, asserted in *Putative mechanisms fostering the normalisation of 1000 Lives+*, is clearly evident in the study's participant health boards. This approach provides a recognised framework for health-care practice change and feedback that, through the Improving Quality Together website, benefits from institutional work via the ongoing support of the 1000 Lives+ national programme (transcription 5:11, below, and transcription 5:12).

The PDSA approach provides a framework for improvement but you still need leadership, you need ideas and execution, so you've still got to generate the will in the people that you're working with first. Then you've got to have change ideas that are based on evidence and not just plucked out of the air – you actually have things that have to be tested – and then you test them; you don't just assume they'll work in practice. But the approach gives people the freedom to test them, measure and learn from the process. So, I think, if I was to say anything, it's a framework, and it's helped teams to focus on a name, on a measure, that will tell them whether or not they're getting towards their aim, and on a change that will hopefully help them to achieve that aim.

Welsh Government, policy lead (033); transcription 5:11

Transcription 5:13, below, describes the role of PDSA in building coherence, cognitive participation and collective action to enable health-care staff to design and deliver practice change.

The model for improvement [MI-PDSA], well it's, it's a tried and tested approach, part of improvement science. Look, traditionally we've gone: 'here's a problem; here's the solution', and we've tried to fit the problem to the solution even if it involves putting a square peg in a round hole just get on and do it! And, for all sorts of reasons, people don't just get on and do it because, because things aren't fit for purpose. So the issue of using the model for improvement is you enable people. You start from the very beginning, you know – you expose the need – you properly measure and identify the problem and enable people to understand that the problem lies with them and that they can do something about it, which is quite empowering. And then, obviously, you guide a solution, and some of those solutions are their own, though most of the time we take an evidence-based practice approach. We introduce them to the evidence-based practice and the methodology – the improvement methodology – so that they can go out and they can get started straight away by having an idea, testing it on one patient one time, one nurse, one doctor! It's quick and easy, it doesn't require whole

engagement of masses of staff, they can just go out and gradually, gradually build and learn from those very small tests of change and they can adapt existing material to make it fit for purpose. We've got the methodology – it's simple, it's safe – it requires little or no investment at the beginning in terms of staff resource. There is strong leadership over supporting all of these programmes, so that there is an accountability route, so you can't just go away and do nothing, there are lines of accountability through local working, through direct and divisional quality and safety meetings, and then through to the steering – the 1000 Lives+ steering group – and the quality and safety committee. But it's simple, the methodology is simple, it's intuitive, logical, and it's really enabling people to develop and make the system do what is right to do, easy to do.

Associate Director, case site D₁ (049); transcription 5:13

The inherent simplicity of the approach is viewed to aid its adoption and the sense of local ownership and engagement that underpin its normalisation across NHS Wales (transcriptions 5:14, 5:15 and 5:16). Moreover, as illustrated in transcription 5:17, below, the MI-PDSA approach helps in surfacing the need for improvement, and confidence in the efficacy of its structured processes gives a sense of security that facilitates positive small steps towards change.

Well, I think, fundamentally, it provides us with a focal point to get around the table – to actually acknowledge there's a problem in the first place – and that we've got a structure to follow that's going to take us in the direction towards solving it. That we might not necessarily solve it in the first place – it might take a couple of times of going through the process to resolve it – but it gives us that format to be able to: it's a building block to start to look at what the problem is, within a structured way. And I think it's something, it's almost like a baby's dummy, I think it's something that we just, it's almost a comfort blanket for us.

Ward manager, case site G₃ (084); transcription 5:17

This markedly positive stance places emphasis on the MI-PDSA's incremental approach to service development and the empowerment of staff (transcription 5:18). However, two issues countervail: the potential for misuse as an instrument of control (transcription 5:19), and disagreement over the validity of the evidence base for the efficacy of the 1000 Lives+ programme (transcription 5:20, below).

1000 Lives+ programme team are, in the main, focused on achieving practical, pragmatic activities across NHS Wales which seek to generate service improvements and change. But in NHS Wales, on the other side, you've got medical and other professionals – and academics – who work to a completely different standard of evidence in terms of rigorous knowledge-based scientific work: you know how explicit medical or epidemiological statistical modelling is! So, for them, the introduction of 1000 Lives+ is, well, it's completely counter-cultural. The reports that the 1000 Lives programme team were stating were the outcomes of the initial programme, in terms of mortality statistics, well some view it all as some political conspiracy that's being sold to the NHS, and the public – it's spin, fluff, crap – it's not valid data, it's not collected in a robust manner, it's flawed. Oh God: please save me from the tyranny of evidence! [What do you mean by the tyranny of evidence?] It's a killer phrase, isn't it, in fact it's the killer phrase. [What do you mean?] It's used by professionals in health care to stop action, to destroy the potential for change: 'Oh, we can't do that, the evidence-base is too weak; their argument is flawed, the data's mismanaged'. [Anything to maintain the status quo?] Status quo ante! The evidence-based for the 1000 Lives+ national programme has been systematically attacked by the other factions – for one side, it's evidence and truth; for the other, it's spin and fluff – and reality is caught in the middle.

Policy lead, Welsh Government (081); transcription 5:20

Board leadership, followership and change

Executive-level leadership of patient safety augments the normalisation of the 1000 Lives+ programme in NHS Wales (transcription 5:21, below).

If the job of the Executive Team is not about patient safety – organisational fitness, systems, processes, governance structures – then I don't understand the job!

Executive Director, Workforce and Organisation Development, case site G₁ (012); transcription 5:21

Beyond the board, there is acknowledgement of the need for leaders with expertise in quality improvement methodology to support staff and maintain their commitment to patient safety (transcription 5:22, below). Such roles are, therefore, pivotal for the successful transition of the ownership of the patient safety agenda from the 1000 Lives+ programme team to the health board.

My reflection on the PDSA process and instruction is, as a methodology, it's a very good one. The problem with regards to its application is that you need somebody who is a PDSA expert within the organisation – a leader and change management mentor who can support the various mini-collaboratives with quality improvement methodology – to harness what people are doing.

Associate Director, case site F₁ (026); transcription 5:22

However, some respondents indicated a degree of resentment about the obligatory nature of the 1000 Lives+ programme and suggested that such commands to engage may be left unheeded (transcriptions 5:23, and 5:24 below).

The 1000 Lives+ national programme and the campaign – it's command and control rather than a grass-roots culture change – it hasn't been created by the people. It's not of the people. It's an imposition. It's control. It's from Cardiff. It's very much a Cardiff thing that is being pushed to everyone else because: 'we know better'. Outside Cardiff, it feels remote and distant and not part of us, it's something that we all recognise as important, clearly, but we don't necessarily own it.

Consultant gastroenterologist, case site F₁ (T027); transcription 5:24

There was a widespread belief that effective board leadership of patient safety is paramount (transcriptions 5:25 and 5:26) but the importance of clinical leadership of patient safety throughout the organisation, so directing teamwork, communication and collaboration to deliver the desired practice change, was also emphasised (transcription 5:27, below).

Clinical leadership is key – credible clinical leadership – and that's all about empowerment of band 7 nurses. When we're in escalation, when beds are crazy, that's when it's hard. It's then you need your band 7 nurses to turn around and tell you what isn't safe. That's something we're working really hard at but that's a whole culture change. But the 1000 Lives+ PDSA cycles did give them a feeling of empowerment that they could make and own changes, they could take chances in the way that suited their ward or theatre or wherever they were doing it: it wasn't that we were telling them how to do it, it was about them trying it and seeing how it worked, and changing it until it did work in their area. So, I think that they, the areas that did feel empowered through 1000 Lives+, combined with the data that they were collecting, well they knew whether they were doing something good or not, and those two things would motivate change.

Associate Director, case site A₂ (T069); transcription 5:27

Teamwork, collaboration and emancipation

For health-care practitioners who have invested meaning in the 1000 Lives+ programme, and who adhere to its practices, the programme functions as a rallying point, building collective action and ensuing teamwork. This aids collaboration and communication across different areas of the employing health board and represents an important aspect of the institutional maintenance work that helps to reproduce the norms and beliefs inherent to 1000 Lives+ (transcription 5:28, below, and transcription 5:29).

There are other nurse managers and practice development nurses within the organisation that I tend to work with quite closely. For example, with my colleague in surgery, we delivery similar sort of teaching about 1000 Lives+, so we link up and deliver sessions together. That way we could pull staff from both of our Directorates, increase numbers, and it's easier when you've got someone else there. We also meet as a group four times a year, so any development and training needs, and that kind of thing, can be discussed and we can agree how things may be taken forward. I know certain of my colleagues were very heavily involved with the SPI [Safer Patients Initiative] work and the first phase of 1000 Lives – they delivered all the corporate training around the PDSA methodology and that type of thing. They're good contacts to have!

Ward manager, case site D, (T010); transcription 5:28

In teamwork situations, the 1000 Lives+ programme is perceived to empower health-care staff in roles traditionally subordinate to the profession of medicine. The emancipation of these staff helps to break down the entrenched barriers that prohibit challenge and scope for change (transcription 5:30, below).

1000 Lives+ gives them [nursing staff] the freedom to question, which they might not previously have had the confidence to do, as it gives them a format to do it and it's standardised. Also, you get less challenge back when you are questioning something because everybody here's been exposed to 1000 Lives+.

Theatre manager, case site A, (T008); transcription 5:30

Empowerment and engagement with others similarly motivated by 1000 Lives+ is seen to have led to patient safety improvements (transcription 5:31). However, there is a view that the latent potential of staff is yet to be realised in NHS Wales (transcription 5:32, below).

I think the key to the next step is, if you like, taking the stabilisers off the bike. 1000 Lives+ has supported staff to do specific projects and that has enabled them to have the confidence to say: 'this is why, and this is how we're going to do it'. The next step is: 'this is my idea, and this is what I want to do'. But how is that picked up and supported by the organisation when it's not an external prompt is the question. I think the NHS is quite bad at thinking about change normally because we're reeling from it being imposed.

Associate Director, case site G, (T011); transcription 5:32

Building the ethos of patient safety: pride and shame in health-care practice

During discussions with the wide range of health-care practitioners interviewed across NHS Wales, the 1000 Lives+ programme appeared to be aligned with feelings of both pride and shame in health-care practice.

On the one hand, a strong sense of achievement is depicted in transcriptions 5:33 and 5:34 (below) and highlights the reinforcing role of individual reflexive monitoring – and objective success – in fostering meaningful engagement.

Our last pressure ulcer was approximately – we've had two in the last three and a half years – we've got a very good record. I'm so proud of our record on pressure ulcer prevention. We have nurses, now, who've never seen pressure ulcers. I'm really proud of it. I have this massive thing about pressure ulcers; I have a zero tolerance of them!

Nurse manager, case site A₂ (T058); transcription 5:33

If you've had 300 days free of MRSA [meticillin-resistant Staphylococcus aureus], C. diff. [Clostridium difficile] or pressure ulcers in this organisation, it is celebrated with cake! I think, maybe a few years ago, I might have been: 'that's a bit gimmicky' but, actually, the feedback from staff and patients is really positive, and we make sure that patients are involved in that celebration. So, we'll do media, some publicity around it as well, there's always features in our local press about a team, ward or department that's working particularly well. I think that's positive for our organisation but actually it's positive from a public perspective because it gives some confidence in the service. Too often bad news is good news, isn't it?

Associate Director, case site A₁ (T025); transcription 5:34

Indeed, receiving praise for their efforts is seen as central to staff's continued motivation and commitment to 1000 Lives⁺ (transcription 5:35).

This positive stance is, however, balanced by the use of blame and shame, prompted via the reporting mechanisms inherent to its governance structures across NHS Wales (transcription 5:36).

Another respondent spoke of the 'desensitising' effect of being perceived to fail, suggesting that this led to an exaggerated determination not to go beyond the strict parameters of their current task (transcription 5:37, below).

Rather than bad practice being done, there are less opportunities for good practice. People are becoming desensitised by public perceptions of failure. It is normal, now, to sit next to a phone and not answer it because it isn't going to be for you, and you're going to be interrupted from your job. The nurse is in a tabard saying do not disturb me on my drug round; that's wonderful, but you've got three consultants doing their ward round too! In the good old days, a sister or staff nurse would come round with me. Now, I've got to try and find a nurse and all you get is: 'it's not my bay, I'm sorry, I'm on Bay B', so they don't know the patient – how many nurses does it take to change a light bulb? Oh sorry, that light bulb isn't in my bay – it's that compartmentalised. The sisters have got an awful time; they've got, they're getting kind of beaten at all ends. The number of staff you have on the wards – the ratio of nurses to patients has gone down – apparently, there's some paper which says that's safe but then there's all the other things as well. I think that's, you know, that's the concern.

Consultant, palliative medicine, case site A₁ (T052); transcription 5:37

In addition, for those who welcome the new emphasis on patient safety and take a pride in adhering to the precepts of 1000 Lives⁺, there may be a deep sense of shame when failures in patient safety do occur (transcription 5:38, below).

So, with 1000 Lives⁺ we thought we've cracked it, it's done! But I was walking out of the ward one evening at about 9 o'clock at night, and we have, always on our ward, we have a policy of putting our safety crosses in the public area. So, I was walking out of the ward and I saw this red square on the pressure ulcer monitoring, and I said to myself: 'some idiot's made a mistake on the safety cross'. I went back into the ward and they said: 'no, actually, we've had a pressure ulcer', and we all wanted to cut our wrists, really, it was a very depressing moment.

Consultant surgeon, case site B₁ (T062); transcription 5:38

The ethos of care stimulated by the 1000 Lives+ programme is, therefore, constrained by the fragmented nature of its normalisation. As expressed in transcription 5:39, and more so in transcription 5:40 below, there is a profound disjuncture. For some, 1000 Lives+ and its associated MI-PDSA approach have been actively embraced, resulting in its progressive normalisation: 1000 Lives+ is, therefore, *absorbed into* daily practice. Yet for others, although its mandated nature enforces engagement, this has been resisted: 1000 Lives+ is, therefore, only *adsorbed onto* (i.e. there is token commitment only and it is not properly integrated) daily practice – and, in this transitional state, it may fail to institutionalise across NHS Wales.

Sometimes it can feel we're doing 1000 Lives+ for the sake of 1000 Lives+! Well because, you know, people don't necessarily see their mini-collaborative within the context of the overall quality improvement, patient safety improvement – reducing waste, variation, and harm from the policy perspective – and I don't think as an organisation we've been very good at placing those mini-collaboratives within the context of the overall quality improvement and patient safety improvement agenda. I think that's why – it just sometimes feels like one of those stand alone things that people do – and, I think, we've lost a trick.

Associate Director, case site F, (T026); transcription 5:40

1000 Lives+ institutionalisation: elaborated understanding of local implementation

Previously, in *Chapter 4*, we set out our analysis of the bureaucratisation of 1000 Lives+ programme across the higher levels of context, thereby defining our preliminary understanding of the local implementation of 1000 Lives+. Building on the findings presented in this chapter, we now seek to integrate the role of the mechanisms that appear to be involved in the normalisation of the 1000 Lives+ programme at lower levels of context.

Figure 12 demonstrates three ways in which existing institutional logics, or the collective beliefs and value systems of those involved, may affect the outcomes of an intervention. First, where logics are not aligned, the intervention may be opposed, with people deliberately seeking to maintain existing and habitual practices, and actively challenging attempts to impose new ways of working. Second, where institutional logics co-exist, while they may not actively reject, people may nonetheless ignore or give little thought or attention to the imposed changes. While this may lead to apparent revision of practice, because people's values and belief systems have not been changed it is likely that if the coercive element is removed practice will revert to the status quo ante. Hence implementation of an intervention can be effective only when beliefs and value systems are aligned within a particular context, as shown in the third element of *Figure 12*. In these circumstances, coherence, cognitive participation and reflexive monitoring of the desired institutional change are fostered and new procedures are absorbed into daily practice and become routinised over time.

It is from such environments, which function as foci for change, that areas initially less receptive to the proposed changes may be gradually recruited through processes of imitation and normalisation.

Table 10 sets out aligned transcription dyads showing divergent stances to normalisation. These reveal the impact of coherence, cognitive participation, collective action and reflexive monitoring in a situated health-care context.

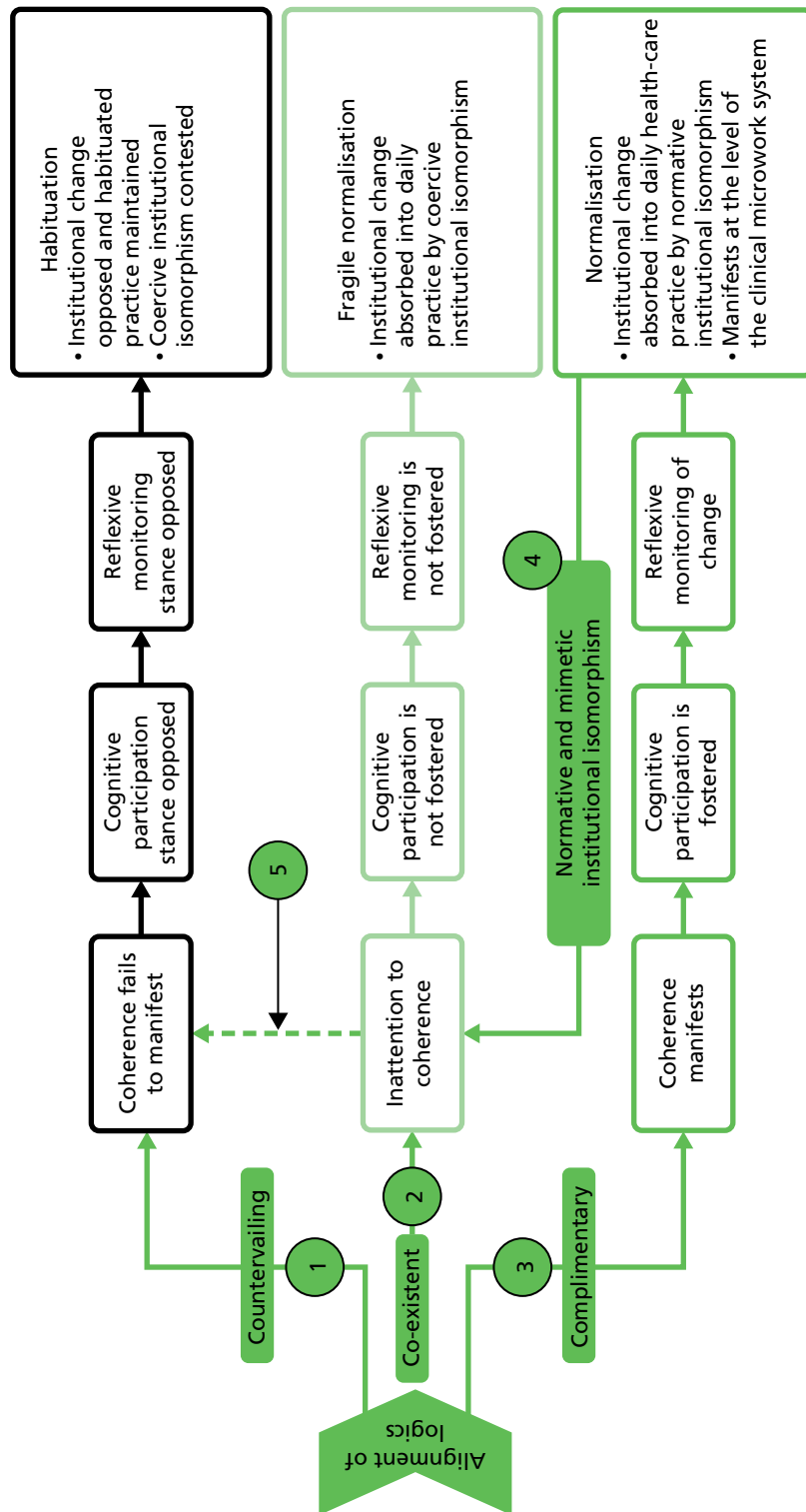


FIGURE 12 Normalisation of 1000 Lives: heterarchical meta-mechanism operating across contextual strata.

Figure 12: key point summary

In *Figure 12* we depict the mechanisms that foster normalisation – coherence, cognitive participation and reflexive monitoring – and set out the impact on the alignment of institutional logics, as expanded below.

In point 1, institutional logics are not aligned, limiting the potential for coherence. In such a scenario the desired institutional change is resisted, habituated practices continue and attempts to impose change are challenged.

- Under these situated contextual conditions, mechanisms to generate change, although operational, are ineffectual.

In point 2, institutional logics co-exist without fostering contradistinction and conflict. However, in this scenario, the potential for coherence to manifest is limited owing to inattention. Accordingly, cognitive participation and reflexive monitoring do not occur and people's beliefs and values are not revised. A fragile normalisation occurs, through which the mandated institutional change is compulsorily imposed onto, but not into, daily practice. However, if such forces are removed, the desired institutional change may revert to the status quo ante.

- Under these situated contextual conditions, such generative mechanisms, though operational, are limited.

In contrast, in point 3, the alignment of institutional logics is complementary. This, we assert, fosters coherence, cognitive participation and reflexive monitoring of the desired institutional change, and new practices are absorbed into daily practice.

- Under these situated contextual conditions such generative mechanisms catalyse the desired institutional change and facilitate the evolution of health-care practice. Furthermore, such sites act as foci for change through normative and mimetic isomorphic institutionalism (processes of imitation and normalisation) and will gradually influence change in initially less receptive areas (see points 4 and 5).

Importantly, as explored in later figures, such generative mechanisms are modulated by the relational structures within the situated context, specifically by the interplay of local leadership, team working and encultured values.

TABLE 10 Intervention–context–mechanism–agency–outcome configuration: interpersonal relations

Intervention	1000 Lives+ national programme	
Component	MI-PDSA	
Context	Hospital multisite department/hospital site-based ward (functional team)	
Mechanisms	<ul style="list-style-type: none"> • Institutional isomorphism: coercive, mimetic and normative • Coherence, cognitive participation, reflexive monitoring 	
Agency and institutional work	<p>Normalisation: coupling to 1000 Lives+ and MI-PDSA approach</p> <ul style="list-style-type: none"> • Agency – innovation • Institutional work – creation • Leadership: distributed leadership of evidence guided, practice-based change promoted • Team work: centred on practice-based learning to develop micro-competences across the clinical micro work system • Encultured values: creativity and accountability of evidence guided, practice-based change <ul style="list-style-type: none"> • Agency – identification • Institutional work – creation • Leadership: distributed leadership of evidence guided, practice-based change supports identification of patient safety failings • Team work: action oriented to address identified failings • Encultured values: 1000 Lives+ and confidence in the MI-PDSA approach gives a sense of security, facilitating challenge to suboptimal practices <ul style="list-style-type: none"> • Agency – knowledge mobilisation • Institutional work – creation • Leadership: continuous challenge to learn from poor practice that results in untoward patient harm • Team work: cohesive with a high value placed on learning and feedback to promote patient safety • Encultured values: reflexive, open, low-blame approach, responsive and receptive to learning opportunities <ul style="list-style-type: none"> • Agency – validation • Institutional work – maintenance • Leadership: distributed leadership of evidence guided, practice-based change promoted • Team work: heightened focus on measurement and management of practice-based change • Encultured values: ownership of change agenda within situated context, augmented by sense of 'doing something good' 	<p>Habituation: decoupling from 1000 Lives+ and MI-PDSA approach</p> <ul style="list-style-type: none"> • Agency – innovation • Institutional work – maintenance • Leadership: disparaging notions of the quality and rigor of practice-based evidence hinders innovation potential • Team work: the rejection of practice-based evidence impairs team working and innovation across the clinical micro work system • Encultured values: potential of change stymied by contested notion of evidence <ul style="list-style-type: none"> • Agency – identification • Institutional work – maintenance • Leadership: limited leadership of evidence guided, practice-based change • Team work: isolated, inward focused, with failure to connect to health-board-wide change agenda • Encultured values: 1000 Lives+ and MI-PDSA function as 'standalone things that people do', limiting organisational learning from the identification of suboptimal practices <ul style="list-style-type: none"> • Agency – knowledge mobilisation • Institutional work – maintenance • Leadership: limited challenge to learn from poor practice that results in untoward patient harm • Team work: low value placed on learning and feedback to promote patient safety • Encultured values: failure in patient safety is par for the course, to be expected, and matters only if 'people actually make a big deal about it' <ul style="list-style-type: none"> • Agency – validation • Institutional work – maintenance • Leadership: failure to adequately manage clinical team's perceptions of impact of 1000 Lives+ • Team work: demotivated by failure to engender positive change • Encultured values: failure to ensure feedback to staff that the practice-based change has resulted in the attainment of patient benefit erodes 1000 Lives+ value

continued

TABLE 10 Intervention–context–mechanism–agency–outcome configuration: interpersonal relations (*continued*)

<p>Agency and institutional work</p>	<ul style="list-style-type: none"> • Agency – legitimisation (moral/pragmatic) • Institutional work – creation • Leadership: heightened awareness of patient safety • Team work: 1000 Lives+ resonates with staff and functions as a focal point for patient safety • Encultured values: saving lives through high-quality, safe and effective health care • Institutional work – disruptive • Leadership: development of leadership roles in roles traditionally subordinate to medicine • Team work: heightened distributed leadership across health-care team, specifically band 7 nurses • Encultured values: nurse-led, evidence guided, practice-based change 	<ul style="list-style-type: none"> • Agency – legitimisation (moral/pragmatic) • Institutional work – maintenance • Leadership: dismissive clinical leadership • Team work: stymied by fragmented legitimacy • Encultured values: 1000 Lives+ is a 'management fad' not owned by clinical team • Agency – emancipation • Institutional work – maintenance • Leadership: traditional leadership role position-practices unchallenged and opposed to 1000 Lives+ • Team work: distributed leadership across health-care team unchanged • Encultured values: 1000 Lives+ is a 'management fad' not owned by clinical team 																								
<p>Outcome</p>	<ul style="list-style-type: none"> • Coupling 1000 Lives+ national programme and MI-PDSA approach embraced and absorbed into daily practice • Decoupling 1000 Lives+ national programme and MI-PDSA approach resisted and adsorbed into daily practice 																									
<p>Exemplar transcriptions</p> <table border="0"> <tr> <td>• Agency – innovation</td> <td>• 5:13 (T049) – Coupling</td> </tr> <tr> <td>• Institutional work – creation</td> <td>• 5:20 (T081) – Decoupling</td> </tr> <tr> <td>• Agency – identification</td> <td>• 5:17 (T084) – Coupling</td> </tr> <tr> <td>• Institutional work – creation</td> <td>• 5:40 (T026) – Decoupling</td> </tr> <tr> <td>• Agency – knowledge mobilisation</td> <td>• 5:38 (T062) – Coupling</td> </tr> <tr> <td>• Institutional work – creation</td> <td>• 5:39 (T062) – Decoupling</td> </tr> <tr> <td>• Agency – validation</td> <td>• 5:18 (T069) – Coupling</td> </tr> <tr> <td>• Institutional work – maintenance</td> <td>• 5:12 (T046) – Decoupling</td> </tr> <tr> <td>• Agency – legitimisation (moral/pragmatic)</td> <td>• 5:04 (T025) – Coupling</td> </tr> <tr> <td>• Institutional work – creation</td> <td>• 5:06 (T026) – Decoupling</td> </tr> <tr> <td>• Agency – emancipation</td> <td>• 5:27 (T069) – Coupling</td> </tr> <tr> <td>• Institutional work – disruptive</td> <td>• 5:24 (T027) – Decoupling</td> </tr> </table>			• Agency – innovation	• 5:13 (T049) – Coupling	• Institutional work – creation	• 5:20 (T081) – Decoupling	• Agency – identification	• 5:17 (T084) – Coupling	• Institutional work – creation	• 5:40 (T026) – Decoupling	• Agency – knowledge mobilisation	• 5:38 (T062) – Coupling	• Institutional work – creation	• 5:39 (T062) – Decoupling	• Agency – validation	• 5:18 (T069) – Coupling	• Institutional work – maintenance	• 5:12 (T046) – Decoupling	• Agency – legitimisation (moral/pragmatic)	• 5:04 (T025) – Coupling	• Institutional work – creation	• 5:06 (T026) – Decoupling	• Agency – emancipation	• 5:27 (T069) – Coupling	• Institutional work – disruptive	• 5:24 (T027) – Decoupling
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Figures 13–15 portray the institutional change driven by the bureaucratisation of 1000 Lives+. Our discussion considers three examples of processes involved in the normalisation of the 1000 Lives+ programme: (1) legitimisation, (2) formalisation and (3) innovation.

1. Legitimation: Table 10, transcriptions 5:02 and 5:24 and Figure 13 show how legitimisation is modulated. In transcription 5:02 (see *1000 Lives+, health-care practice and patient safety*), complementarity between bureaucratic state, professional and collaborative logics results in perceptions of coherence with 1000 Lives+. However, the ensuing cognitive participation of those who ‘buy into certain areas where their interests lie’ promotes contained collective action, directed to deliver the aligned vested interests of those who occupy the orchestrating leadership position in this situated context.

In contrast, transcription 5:24 (see *Building the ethos of patient safety: pride and shame in health-care practice*) depicts the overt rejection of the dominant logic of the bureaucratic state. Professional logic is, therefore, shifted from its subordinate role into an ascendant position. Given the contradiction between these co-existent logics, theorisation prevents coherence from developing. This inhibits cognitive participation and collective action. As a result, 1000 Lives+ is viewed as ‘not part of us’. In this context, decoupling from the national programme arises.

2. Formalisation: Table 10, Figure 14 and transcription 5:29 (see reference in *Teamwork, collaboration and emancipation*) suggest that formalisation is modulated by complementarity between bureaucratic state, professional and collaborative logics. This promotes adherence to the governance structures which support the 1000 Lives+ national programme. However, the subtleties of individuals’ reasoning and use of the resources provided by 1000 Lives+ are exposed in transcription 5:36 (see reference in *Building the ethos of patient safety: pride and shame in health-care practice*). Although no overt rejection of the dominant logic of the bureaucratic state is expressed, professional logic and collaborative logic are not held in a complementary stance. Instead, they occupy a co-existent stance that fosters professional protection and a lack of collaboration. In this context, coupling to the governance structures that support 1000 Lives+ is fragile.

3. Innovation: Table 10, Figure 15 and transcriptions 5:13 and 5:20 demonstrate how innovation is modulated, while transcription 5:13 (see *Model for improvement and PDSA approach*) illustrates the nuances of normalisation. Once again, the logic of the bureaucratic state is embraced and held in close alignment with professional and collaborative logics. This promotes strong coherence with the 1000 Lives+ national programme – ‘The model for improvement [MI-PDSA], well it’s, it’s a tried and tested approach, part of improvement science’ – resulting in the cognitive participation, collective action and reflexive monitoring of health-care staff who ‘can go out and they can get started straight away by having an idea, testing it on one patient one time, one nurse, one doctor!’. In contrast, transcription 5:20 (see *Model for improvement and PDSA approach*) highlights a profound disjuncture between the logic of the bureaucratic state and one facet of medical professional logic – the contestation between care and science³⁷³ – that stymies engagement with 1000 Lives+ owing to disagreement over the validity of the evidence base: what the respondent in this transcription calls the ‘tyranny of evidence’. This fundamental discord impacts on theorisation. It limits coherence and erodes the means for meaningful engagement with 1000 Lives+. As a result, normalisation and, thus, institutionalisation are hampered.

We suggest that the mechanisms that appear to foster normalisation modulate the processes of bureaucratisation through amplification of the complementarity or contradiction between logics in the institutional field. However, of those considered – coherence, cognitive participation, collective action and reflexive monitoring – only three are seen as generative mechanisms (coherence, cognitive participation and reflexive monitoring), while collective action is simply an outcome of such reflexive theorisation and, thus, an expression of agency.

In the next chapter we examine and develop I-CMAO configurations for three focal interventions from the 1000 Lives+ programme using theories of structure, agency and social change.

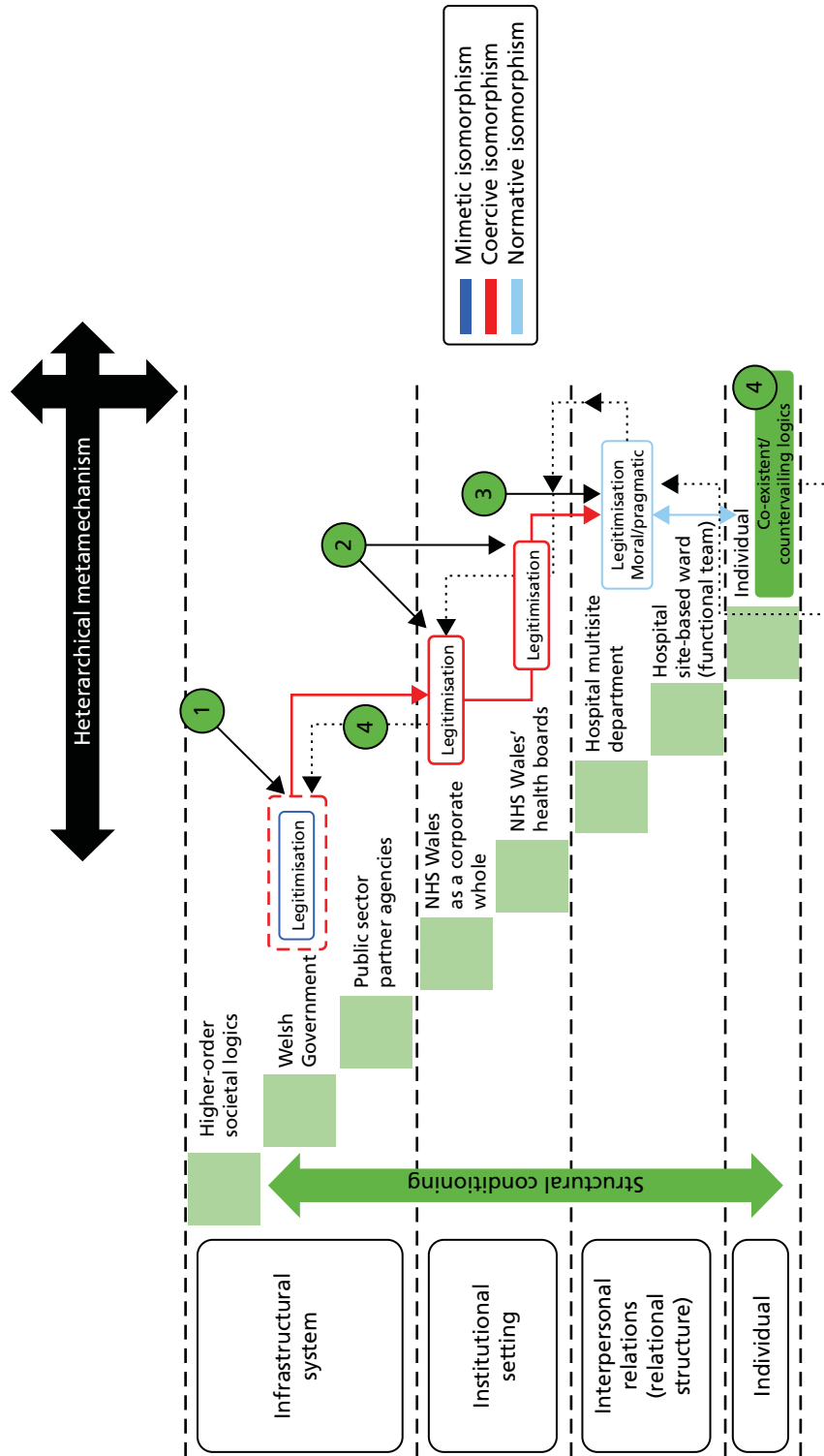


FIGURE 13 Normalisation of the 1000 Lives+ heterarchical metamechanism operating across contextual strata: legitimisation.

Figure 13: key point summary

In *Figure 13* we depict the legitimisation of the 1000 Lives+ national programme across the Welsh health-care institutional field, centred on lower contextual strata at health board, hospital multisite department, hospital site-based ward and individual levels.

In point 1, in situated contexts where logics are in alignment:

- Agency – legitimisation – elite institutional actors and co-opted others embrace 1000 Lives+ and MI-PDSA approach and embed in health-care policy and performance frameworks.
- Institutional work – creation – elite institutional actors enact political work to reconstruct rules, rights and access to resources, thereby linking 1000 Lives+ national programme to tier 1 performance targets.

In point 2, in situated contexts where logics are in alignment:

- Agency – legitimisation – 1000 Lives+ becomes part of the language and positioned-practices of patient safety in NHS Wales, fostering collaboration and systemic challenge among institutional entrepreneurs who reassert a new normative standard to precipitate practice-based change.
- Institutional work – creation – elite board-level institutional actors enact political work to reconstruct rules, rights and access to resources, thereby linking 1000 Lives+ national programme to the attainment of the Welsh Government's tier 1 performance targets.

In point 3, in situated contexts where logics are in alignment:

- Agency – legitimisation (moral/pragmatic) – 1000 Lives+ moral and pragmatic legitimacy fosters mainstreaming of the intervention across NHS Wales.
- Institutional work – creation – functional team's belief and meaning systems reconfigured.

In point 4, the impact of co-existent or countervailing institutional logics is depicted as corrosive feedback that challenges legitimisation and, therefore, normalisation.

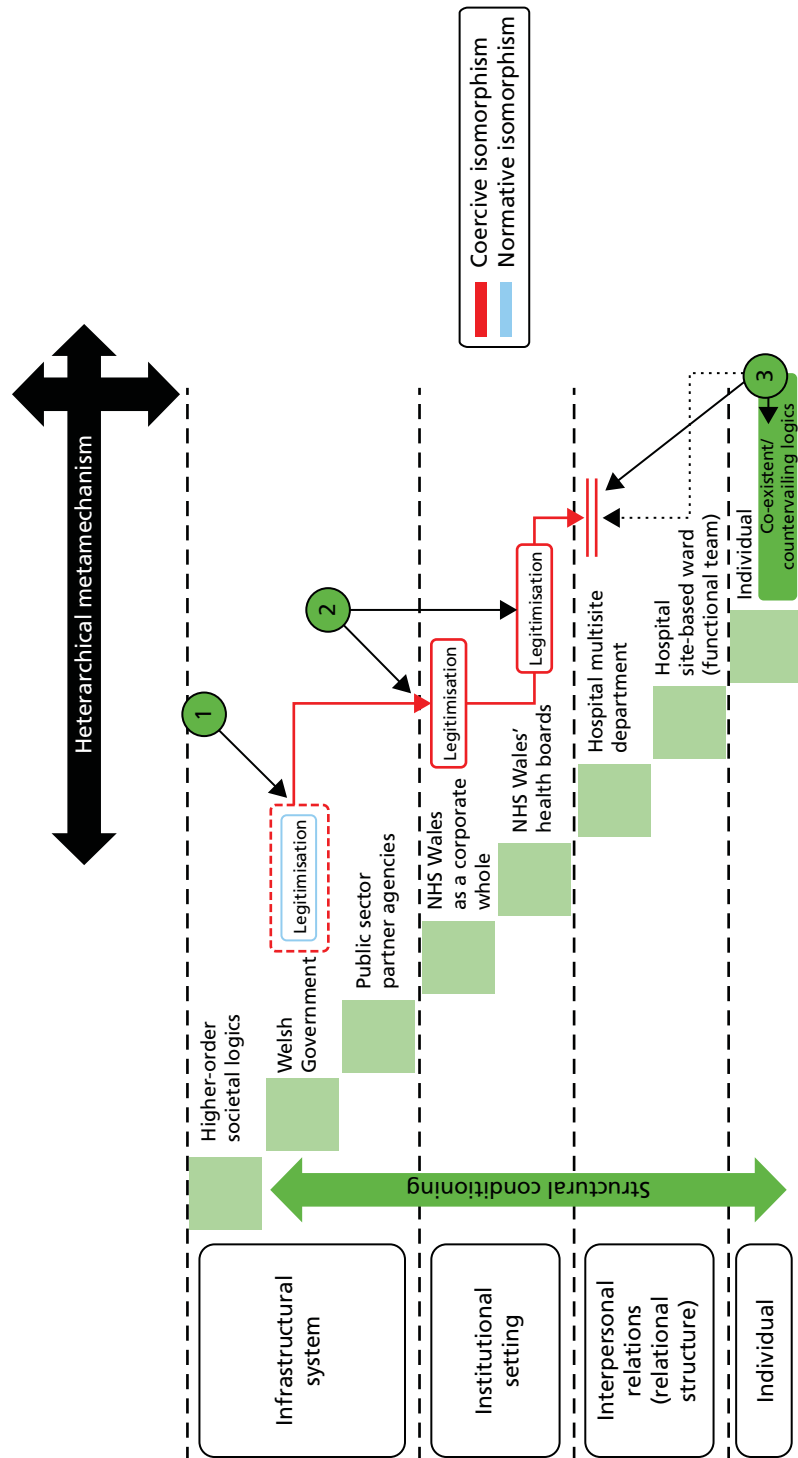


FIGURE 14 Normalisation of the 1000 Lives' heterarchical metamechanism operating across contextual strata: formalisation.

Figure 14: key point summary

In *Figure 14* we depict the formalisation of the 1000 Lives+ national programme across the Welsh health-care institutional field, centred on lower contextual strata at health board, hospital multisite department, hospital site-based ward and individual levels.

In point 1, in situated contexts where logics are in alignment:

- Agency – formalisation – mandated engagement with 1000 Lives+ and the MI-PDSA approach to address NHS Wales' organisational failings and attain national health-care standards.
- Institutional work – creation – elite institutional carriers enact political work to reconstruct rules, rights and access to resources, thereby linking 1000 Lives+ national programme to tier 1 performance targets.

In point 2, in situated contexts where logics are in alignment:

- Agency – formalisation – multiprofessional and multisite co-ordination of patient safety via the statutory Quality and Safety Committee and aligned governance structures.
- Institutional work – creation – elite board-level institutional actors enact political work to reconstruct rules, rights and access to resources, thereby linking 1000 Lives+ national programme to the attainment of the Welsh Government's tier 1 performance targets.

In point 3, the impact of co-existent or countervailing institutional logics is depicted as corrosive feedback. However, this is insufficient to over-ride mandated performance management and governance processes.

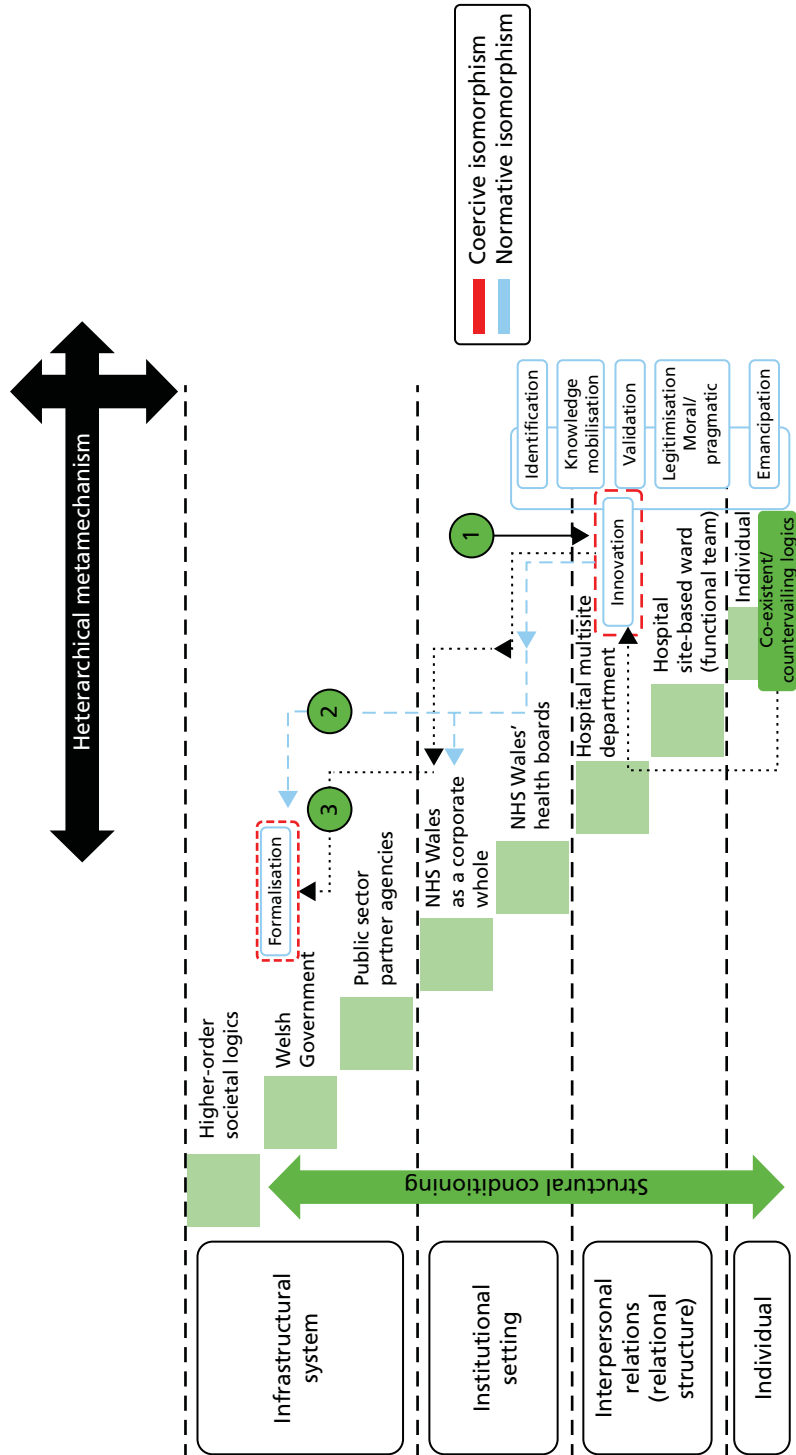


FIGURE 15 Normalisation of the 1000 Lives[†] heterarchical metamechanism operating across contextual strata: innovation.

Figure 15: key point summary

In *Figure 15* we depict innovation catalysed by the 1000 Lives+ national programme across the Welsh health-care institutional field, centred on lower contextual strata at health board, hospital multisite department, hospital site-based ward and individual levels.

In point 1, in situated contexts where logics are in alignment:

- Agency – innovation – individual and organisational pragmatic evidence-based learning manifests through adherence to the MI-PDSA approach.
- Institutional work – creation – functional team's belief and meaning systems reconfigured.

In point 2, the impact of complementary institutional logics is depicted as positive feedback that supports the formalisation of evidence-based innovation across NHS Wales.

In point 3, the impact of co-existent or countervailing institutional logics is depicted as corrosive feedback.

Summary

In *Chapter 5*, we analysed the cultural change inherent to normalisation of the 1000 Lives+ programme at the level of the functional team. We explored the role of contextual constraints and enablements, and ensuing reflexive theorisation, across the dynamic interplay of multiple logics, and considered the modulating roles of coherence, cognitive participation and reflexive monitoring.

Chapter 6 Improving leadership for quality improvement

Overview

Chapters 6–8 set out our realist analyses of the three focal interventions selected from the 1000 Lives+ programme in NHS Wales: ILQI, RSC and RHAI. To aid the explanation of our argument, each is structured in the same manner, as set out below.

In this chapter we examine ILQI, a programme aimed at helping organisational leaders to take a systematic approach to the implementation of practical interventions. We first consider three leadership activities designed to build the will to make measurable systemic improvement, specifically (i) setting aims and monitoring progress through local mortality reviews; (ii) demonstrating visible leadership via WalkRounds™; and (iii) the use of patient stories at board level. We review such practices to highlight their acknowledged benefits and the barriers that impede their normalisation into daily practice.

Second, we undertake a realist analysis of the progressive institutionalisation of ILQI, thereby setting out our comparative case study of sites A, B, C and D. In doing so, we explain the structural conditioning, sociocultural interaction and structural elaboration or reproduction fostered through the actions of three groups of key actors – directors of medicine, nursing, and therapies and health science – together with their colleagues in respective associate roles. We concentrate on these actors because they are formally tasked with the implementation of the ILQI under the 1000 Lives+ programme. In addition, to aid our understanding of context and mechanism, we examine the perspectives of policy leads, health board chairs, chief executive officers and other managerial staff aligned to these professional groups. Finally, informed by the findings of our realist analysis, we set out our understanding of the ILQI I-CMAO configuration.

Focal intervention, aim and drivers

Improving Leadership for Quality Improvement is the first of the three focal interventions considered in this study. This improvement programme aims to support board members and other organisational leaders to take a systematic approach to the implementation of practical leadership interventions to promote transformational quality improvement. ILQI has gradually become embedded in NHS Wales' annual operating frameworks,⁴⁴⁵ quality frameworks⁴⁴⁶ and associated delivery plans.^{391,402} Furthermore, ILQI is supported by an aligned organisational and workforce development strategy,⁴⁴⁷ a web-based national learning programme for all NHS Wales staff and contractors – Improving Quality Together (www.iqt.wales.nhs.uk/home) – and associated online resources offered by Patient Safety Wales (www.patientsafetywales.org.uk).

Improving Leadership for Quality Improvement is centred on the appointment of executive level leads for the different interventions within the 1000 Lives+ programme. It calls for the application of the underpinning MI-PDSA approach to inform the development of intelligent targets for priority clinical services. As illustrated in *Figure 16*, ILQI advocates three drivers for change. The first aims to build the will to make measurable improvement as quickly as possible. This directs senior leaders to cultivate staff engagement, enthusiasm and commitment at all levels of the organisation. The second aims to encourage and spread ideas about alternatives to the status quo, which are robust enough to form the basis of new working systems. This challenges senior leaders to support staff to implement such change. The third aims to oversee the implementation of a range of improvement initiatives within the organisation. This tasks senior leaders to develop a culture of health-care quality and patient safety. ILQI, as a core part of a Welsh health-service-wide governance agenda, therefore assists health boards to set local targets to reduce harm and mortality.

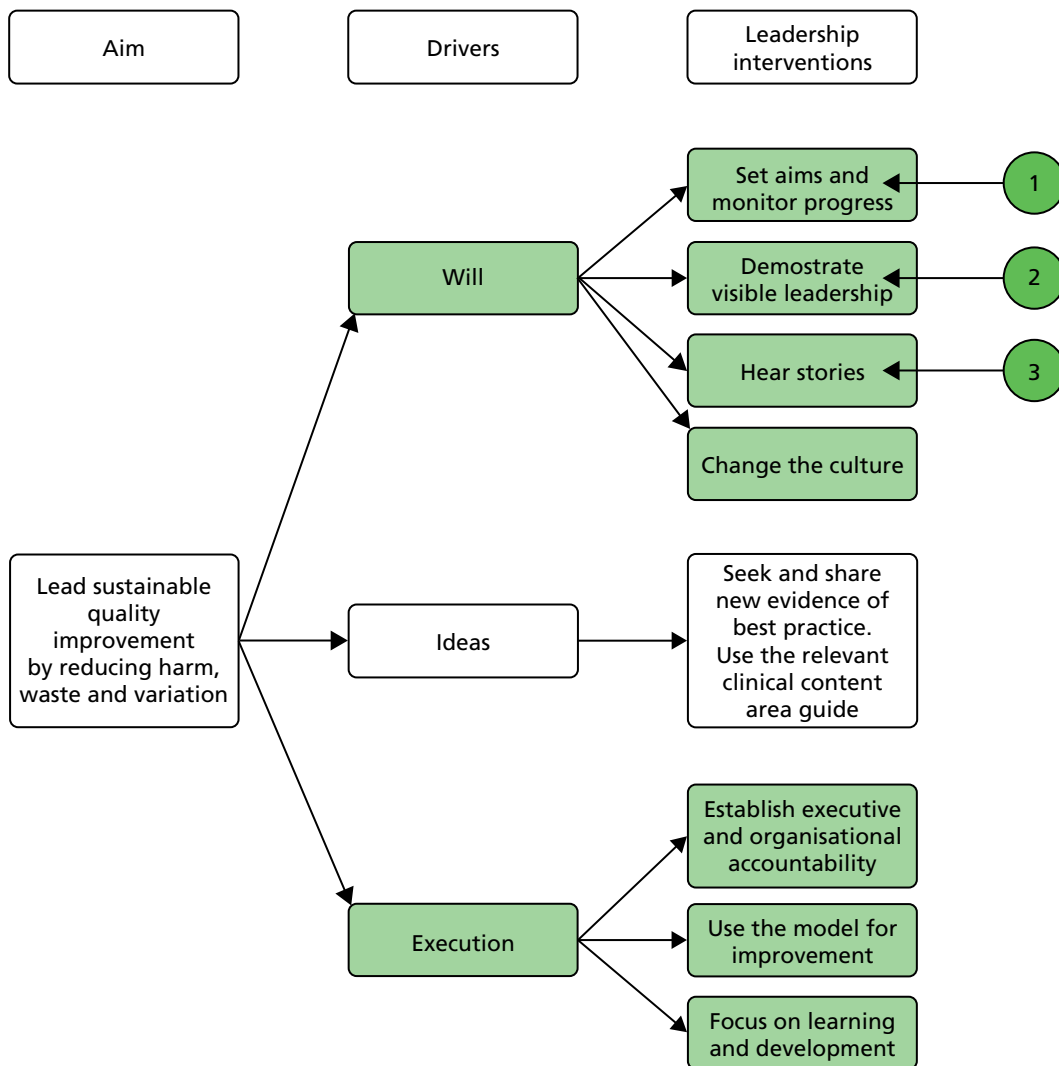


FIGURE 16 Driver diagram: ILQI.

Figure 16: key point summary

Figure 16 depicts the driver diagram for the focal intervention, ILQI. Attention is directed to three leadership activities designed to build the will to make measurable systemic improvement, as defined below:

- point 1, setting aims and monitoring progress through local mortality reviews
- point 2, demonstrating visible leadership via WalkRounds and
- point 3, the use of patient stories at board level.

To aid our understanding of the interplay of context and mechanism in the operationalisation of this focal intervention, the perspectives of policy leads, health board chairpersons, chief executive officers and other managerial staff aligned to these professional groups enrich our analysis.

Acknowledging the interconnected features of this intervention, our attention focused on three leadership activities designed to build the will to make measurable systemic improvement to patient safety, specifically (i) setting aims and monitoring progress through local mortality reviews; (ii) demonstrating visible leadership via WalkRounds; and (iii) the use of patient stories at board level.

Mortality reviews, WalkRounds and patient stories

As outlined in *Chapter 1*, health-care quality and patient safety demand effective and co-ordinated leadership from politicians,^{448,449} executive-level managers^{81,450} and their subordinate staff – whether corporate or clinical professionals⁴⁵¹ – who interact with patients, directly or indirectly,^{4,88,204,452,453} in the coproduction of their care.^{146,155,454} Health-care leadership is, therefore, inherently distributed^{30,36,455,456} and complex,⁴⁵⁷ and necessitates active followership.⁴⁵⁸ Furthermore, it is modulated by a range of other factors which impact patient safety and the culture of care,⁴⁵⁹⁻⁴⁶¹ most notably (i) organisational governance processes, audit and monitoring systems;⁴⁶²⁻⁴⁶⁵ (ii) management processes and their reception by staff;^{29,466-469} (iii) team-centred learning and local commitment to education;^{11,207,470-474} (iv) an individual and collective focus on practice innovation;^{43,475} and (v) the development of an organisational culture of care, wherein transparency, communication and mutual respect are valued.^{22,476-478}

Mortality reviews

In the aftermath of the public inquiry into failings at the Mid Staffordshire NHS Foundation Trust,⁸¹ excess mortality has been openly debated as a means to flag concerns with hospital patient care.⁴⁷⁹⁻⁴⁸² Beyond the NHS, this approach has been used in other developed health-care systems to monitor organisational performance and to compare such performance between hospitals.^{483,484} However, the validity and reliability of the Hospital Standardised Mortality Ratio (HSMR) and other means of measurement, such as the risk-adjusted mortality index (RAMI), is dependent on comprehensive, accurate and consistently applied clinical coding. Consequently, the use of such measures as HSMR as a screening tool for distinguishing low-quality hospitals from high-quality hospitals remains in doubt^{158-160,485} because the link between HSMR and organisational factors is ambiguous.¹⁶⁰ In addition, it has not yet been proved that HSMR reporting necessarily leads to worthwhile improvement in quality of care and patient outcomes.⁴⁸³

Given this unresolved debate, and wide variation in hospital mortality, the impact of leadership on mortality, whether or not adjusted for case-based severity and cross-linked with resource measures,^{486,487} appears somewhat unclear. However, hospital-based monitoring of all-cause mortality through review meetings constitutes an important board-level and medical governance resource and may provide deeper insight into emergent patterns, thereby helping to identify trends to guide local improvement efforts⁴⁸⁸ and to reveal their impact on the provision of care over time.^{489,490} In addition, they may provide assurance that patients are not dying as a consequence of unsafe clinical practices.⁴⁹¹

Other markers or proxy measures of leadership are associated with mortality. For example, a significant and positive association has been found between a higher percentage of clinicians on boards, the quality ratings of service providers and lower morbidity rates;³² Mortality rates have also been linked to greater use of high-performance human resource practices;⁴⁹² nursing staffing ratios and skill mix^{78,493} and hospital pay for performance.⁴⁹⁴ Wright *et al.*⁴⁹⁵ also found that good leadership, organisational management practices and information systems, supported by a quality improvement strategy based on robust local evidence, training and a community-wide approach, may be effective in reducing hospital mortality. The evidence suggests, therefore, that mortality measurement may assist boards in thinking strategically about what it takes, from a systems perspective, to achieve patient safety.⁴⁹⁶

WalkRounds

Board engagement in the patient safety agenda can also be increased by enhancing their collective literacy in health-care quality, governance processes and aligned service improvement methods.⁴⁹⁷ One means to achieve this is WalkRounds.⁴⁹⁸⁻⁵⁰⁰ Perceived as a key leadership practice in health care, WalkRounds foster situational awareness and help management to periodically assess new or unresolved vulnerabilities that may affect safety and care quality. WalkRounds, therefore, potentially provide (i) a forum for front-line

staff to report and discuss patient safety problems with local leaders, so that the voice of the caregiver influences the ongoing board-level debate;⁵⁰¹ (ii) an opportunity to improve teamwork and communication within and across units; and (iii) a supportive environment in which staff and leaders help to develop potential solutions for patient safety and service delivery issues^{502–505} – all refined through the underpinning MI-PDSA approach.⁵⁰⁶

Improvements in patient safety have been linked to the frequency of exposure to WalkRounds⁵⁰⁷ but their sustained operation demands significant organisational will, project management and commitment from board-level leaders.⁴⁹⁹ Research is now beginning to penetrate the complex social processes that underpin WalkRounds so that their potential to foster executive-level learning is enhanced.^{508,509} However, the development and maintenance of appropriate organisational feedback mechanisms is known to be a significant challenge.^{510,511}

Patient stories

These are a means for the patient and their family, advocate or carer to forward their personal narrative of harm in order to actively contribute to the coproduction of safe care.^{512,513} Considering the notion of harm from the perspective of the patient offers insight into alternative health-care priorities,⁵¹⁴ including (i) the psychological and emotional aspects of harm⁵¹⁵ and (ii) the harm and distrust caused by delays in communicating patient safety incidents to patients,⁵¹⁶ compounded by (iii) that which arises owing to their exclusion from the critical conversations which shape the provision of their individual care.^{132,153}

By providing rich insight into the reality of health-care provision through description and dialogue, patient stories can inform organisational governance processes^{517–519} and service redevelopment through experience-based design.⁵²⁰ However, although patient stories may inform, equip and challenge organisational leaders to improve the delivery of health care, they also expose them to the fear of reputational and financial risk generated by the broader dissemination of harrowing narratives of harm.⁵²¹ This presents a barrier to the development of a safety culture. Tasking board-level leaders to hear patient stories as the first agenda item at every board meeting may reveal the human face of harm.⁵²² However, if rendered down to just another performance measure, amid an array of others, such narratives will do little to foster appropriate remedial action.¹⁰⁵ Indeed, dysfunctional consequences may arise owing to entrenched historical and cultural precedents, specifically beliefs anchored to health-care performance and autonomy.^{523–527} Cognitive psychological explanations of the way such individuals process patient feedback of this type, together with the corresponding social rules which frame their ensuing action or inaction,^{303,527–529} therefore constitute an important arena of patient safety research for social scientists.⁵³⁰

Realist analysis and comparative case study

To examine the dynamic interaction of the focal intervention and context, ascertaining emergent mechanisms and ensuing outcomes, we now undertake a critical realist analysis of the progressive institutionalisation of the 1000 Lives+ programme's ILQI. Our case study considers sites A, B, C and D, which, owing to high levels of access and wide-ranging staff engagement, offered rich insights into the unfolding implementation of the ILQI. Our analysis focuses primarily on three groups of key actors – directors of medicine, nursing, and therapies and health science, together with their colleagues in respective associate roles – tasked with the implementation of the ILQI under the auspices of the 1000 Lives+ programme. However, we also use data from policy leads, health board chairpersons, chief executive officers and other managerial staff aligned to these professional groups.

First, we consider the focal intervention in context and explore the dominant structural and cultural emergent properties impacting board-level actors. Next, to reveal the generative mechanisms in play, we examine mediation via first- and second-order emergents and the resultant situational logic. Then, to examine the initiation of change, we explore the unfolding strategic negotiation of change and the mode of institutional work enacted. Finally, we reflect on the nature of any sustained outcome, be that elaborative or reproductive.

This analysis forms the foundation of our refinement of the I-CMAO configuration spanning the Welsh health-care field in *1000 Lives+ institutionalisation: ILQI – local implementation of the focal intervention and contribution to the I-CMAD configuration spanning the Welsh health-care field*.

Structural conditioning: structural and cultural emergent properties in the Welsh health-care field

Initially, we discussed the dominant structural and cultural influences impacting health board-level actors during the institutionalisation of the 1000 Lives+ programme and ILQI with policy leads in the Welsh Government. As commented in transcriptions 6:01 and 6:02 (below) – and as previously reflected in transcription 4:01 – the 1000 Lives+ programme was deeply integrated with health-care policy development in Wales.

The 1000 Lives+ national programme has been a vehicle to do lots and lots of things; it's been very useful. Now, for pretty much all projects – when we get to the stage where there's some policy that we need to do in Welsh Government and, I think, even more so following Francis – the implementation is designed with the methodology that sits behind 1000 Lives+ in mind because it's there, and people can understand it, and so they can use it in order to be able to move stuff forward.

Policy lead, Welsh Government (145); transcription 6:01

What we've started to introduce this year – this new financial year just started – is we've tweaked the tier 1 targets and we've created basically five domains of quality. So we've tried to reflect much more broadly what boards are doing. We've piloted alongside it the principle of what I would call a bit of improvement methodology. We've sort of laid out a series of matrixes or grids of competencies that we expect boards to be able to display on a scale of 1 to 5 – a scale of maturity – so what we're trying to do is to move it away, a bit, from just target driven to being more about development. As I'm trying to make it more developmental, it is starting to get closer to the 1000 Lives+ type approach.

Policy lead, Welsh Government (146); transcription 6:02

Such policy actors held robust views on the dominant structural emergent properties impacting health boards: 'it's finance, reconfiguration, staffing, and health-care quality performance' (transcription 6:03, below).

What are the structural constraints on the 1000 Lives+ national programme? That's an interesting question, we could probably spend the next hour just discussing that; but I'll do my best to be succinct. The first structural constraint is, obviously, the financial difficulties that all public services now face in light of the global economic downturn. Second, for NHS Wales, it's the major reconfiguration, and that's still ongoing, as we have to address the configuration of services and their provision across Wales, so there's a ripple effect across all health boards as they reconfigure. All that will create heated political and public debate because, in Wales, as elsewhere, people are fiercely protective of their health-care services – they still criticise them – but they don't want services shifted to other sites away from their locality. That creates staffing constraints for all health boards, especially those further off the M4 corridor. As I'm sure you are aware, there are major difficulties in some areas of Wales, in terms of the recruitment and retention of general practitioners, some acute specialisms, accident and emergency, and others. And then, of course, we have the Francis Report, which, I believe, will heighten governance and performance management systems, as we saw after the Kennedy Report into Bristol Royal Infirmary. So, it's finance, reconfiguration, staffing, and health-care quality performance, they're the main ones, at least!

Policy lead, Welsh Government (143); transcription 6:03

Financial constraints were also seen to have a specific adverse effect on patient safety (transcription 6:04).

Beyond the goals of 1000 Lives+ and ILQI, these acknowledged structural constraints shaped the strategic context to the delivery of the Welsh Governments' tier 1 targets, and their active management and mitigation was central to the bureaucratic control exerted over each health board (transcription 6:05, below).

[How do you hold NHS Wales' health boards to account for their performance?] We have an escalation framework – basically four levels of escalation, five if you include zero – we monitor health boards, as they have to perform against the targets that they're supposed to achieve, and if they're performing against all of the standards then they wouldn't be escalated. Basically, they're allowed to get on with it and, to a degree, we actually pull away from the level of assurance that we seek. So we could get to the stage where you might only, you know, touch them quarterly or half-yearly. But we're not at that point with anybody at the moment. Once things start to go wrong – somebody's missing their targets – we then escalate to level 1, 2, 3 and up to 4. At each of those levels there's a slightly higher level of intervention. Each of these would be just a bit more forceful: 'you need to have got to a recovery plan by this'; 'we need you to be showing you're doing a recovery plan', if they don't do that they go up another level and that carries on and the frequency increases. Basically, by the time we've got to level 4, the chair will probably be having conversations with the minister, and the chief executive will be probably having conversations with the chief executive of NHS Wales. Throughout this process what we're looking at is, essentially, what have we got to do with this board; is there something that's needed in way of turning around behaviour, turning around attitude, turning around performance? Does that mean we have to bring something or someone in? We can bring to bear quite a lot of sanctions, in terms of alterations to their allocation of money. Now, we don't normally get to that stage but we're very close with a few boards at the minute – we do have to recognise, as is happening in NHS England, that performance is very difficult in the current financial environment – so the whole system is just basically not quite as slick as it would have been even a year ago.

Policy lead, Welsh Government (146); transcription 6:05

Another respondent viewed the Francis Report to have been the main cultural impact on health boards during the institutionalisation of the 1000 Lives+ programme and ILQI (transcription 6:06).

Other structural and cultural constraints arose from the institutionalised delegation of strategic oversight of patient safety – and, thus, 1000 Lives+ and ILQI – to the leadership of directors and associate directors of medicine, nursing, and therapies and health science (transcriptions 6:07 and 6:08, below, and transcription 6:09).

Post Francis, I think that the cultural constraints which will impact on NHS Wales' health boards and 1000 Lives+ national programme stem from driving forward a transparent culture of compassionate care – we've set out our views on that – so, that is all about the professions, their traditional practices, turfs and turf wars, recognising that errors do happen, and that we can make change to mitigate some of them, though it will take real leadership and time to change the culture.

Policy lead, Welsh Government (145); transcription 6:07

The quality of our services and patient safety issues, though they fall within my remit as accountable officer, are delegated to other board members. You'll find this across NHS Wales. Certainly, for 1000 Lives+ it'll be the medical director, nursing director, and the one for therapies and health sciences – or whatever title is applied for this type of board-level role – that hold the strategic focus for the patient safety agenda. Typically, it'll be their associate directors who will be more involved, operationally, in the roll-out of 1000 Lives+. This isn't an abdication or abrogation of responsibility, it's delegation through to the clinical professionals who ultimately deliver care to patients and whose practices 1000 Lives+ is attempting to transform. [What about your engagement in mortality measurement, WalkRounds, and use of patient stories at board level?] Yes, we do those. But that is only part of what we do, there's more to managing this health board than addressing 1000 Lives+.

Chief Executive, case site A, (078); transcription 6:08

First-order emergents for board-level actors central to the institutionalisation of ILQI

The dominant structure and culture described in the previous section shaped the context and conditioned the actions of the board-level directors and associate directors central to the institutionalisation of the ILQI. Below, we set out how actors in such professional role-positions reflected on first-order emergents such as their delegated leadership of the ILQI, their vested interests and perceived opportunity costs associated with various courses of action, and seek to discern how this shaped their interpretive freedom and scope for purposive action to support patient safety.

Director of medicine and associates

The vested interests of directors of medicine and their associates, tasked with the strategic oversight of the 1000 Lives+ programme and ILQI, lay primarily in the successful development of a systematic locally agreed approach to undertaking the mortality review in the aftermath of the structural reconfiguration of NHS Wales (transcriptions 6:10 and 6:11, below, and transcriptions 6:12 and 6:13).

In terms of 1000 Lives+, my main focus is the mortality reviews, and reporting through the system that has been established with the Welsh Government. We've done a board paper, two board papers in a row, which address how do we measure harm, how do we measure our morbidity, our mortality. So it's a key role. With 1000 Lives+, the mortality reviews have been around a programme of work looking at how we, how do we actually understand where the harm is occurring. It's a systematic process – one of the main things that [name, NHS Wales Chief Executive and Director General, Welsh Government] asked the medical directors to do, probably in 2010, was to do systematic case notes reviews – so we have a system whereby I was probably looking at 25% of the deaths, not all the deaths, because we have 50 deaths a week! So we embarked upon learning through reviewing about 15 sets of notes a week with the senior governance adviser and with also one of the associate directors of medicine. We tried various different ways, in terms of pro formas, and we did all the PDSA-type work but in the end we've settled on a detailed notes review using the global trigger tool. I have to say that we continued that right up until January when there was the debate about publishing RAMI. Although we didn't feel that we learnt in excess, we did learn above and beyond what we knew about the organisation through that process.

Medical Director, case site D₁ (117); transcription 6:10

[Prior to 1000 Lives+ was there any systematic process for reviewing mortality across the health board's hospital sites?] Well the kick-off, actually, was, you know, when this organisation came into being; there had been chaos! There was the organisation, and predecessor organisation or organisations – as you know, we've had to endure a lot of change – we had the interim trust with a completely different executive team, and a completely different interim medical leadership and management structure, that was just basically trying to keep the thing ticking over really. Then we were presented as a new edition, [health board name], and more systematic scrutiny of our statistics started, and one them was that our RAMI which was worrying. So, that was the situation when the health board came into being and, obviously, as medical director, I was tasked to do something about it.

Certain parts of the organisation may well have been looking at quality initiatives before that but really I think getting a grip on the mortality review and embracing 1000 Lives+, which we did as organisation at that point, added coherence to the whole thing. So, when you asked me specifically what had been done before, I would say that it was very hit and miss. Now, with 1000 Lives+, I have a clear focus on mortality. I don't want to harp on about it, but you're asking about leadership and what we do as an organisation, I think that's a very good example how it's been successful. I mean, at the moment we're into year 3, something like week 12 or 13, where every single week, every single death in the organisation is looked at by a senior medical – a senior doctor – every single one, and a report

goes to the chief executive. The information from that review – which, of course, when we get concerns highlighted, concerns are investigated more deeply and reported back, hopefully through auspices of medical director – the lessons learned, the themes, and so forth are communicated back, right the way across the whole of the organisation, primary care and everything.

Medical Director, case site F, (042); transcription 6:11

Moreover, such vested interests were closely aligned to those of policy leads with the Welsh Government. Therefore, through the 1000 Lives+ programme and ILQI, the systematisation of mortality reviews brought bureaucratic state logic, professional (medical) logic and a collaborative logic into a complementary stance (transcription 6:14, below).

I think, in Wales, because we had a well-developed sort of collaborative approach, we were able to engage clinicians in the audit of their local mortality levels, and what was going on. But we're using the national indicator in a very, very simplistic way, which I think is good, to just say: 'hey look, this will tell us if there is a problem'. But we then go into that audit work – that real work on the ground, to say – well actually, are they doing all the things they should be doing to really understand and make sure that this is right. [Long pause]

In a way, what we've avoided, so far, is getting dragged into this idea that's going on in England where you keep hauling out the top five and sort of having a public process about their mortality levels. What we've tended to go for is: 'well let's get them working on it'. Now having done that, and it being, at least so far, quite a successful approach, we're now looking at how that set of principles could be carried into other areas. So when we start looking at developing unscheduled care markers, or planned care, or whatever it might be, we're looking at whether we could underpin it with an audit type approach, which says: these are all the good things you should be doing, how are you doing against all of these; if you're doing all these things, how are you monitoring your outcomes.

Actually, some of these higher-level measures are underpinned now with something that's a bit more substantial than just making sure you're getting everybody through. So we're trying to adopt almost a two-tier approach – a set of national standard type measures – which we'll try and keep as simple as we can, but underpin it with a different approach around a more detailed understanding and audit.

Policy lead, Welsh Government (146); transcription 6:14

Director of nursing and associates

In contrast to the directors of medicine, the vested interests of directors of nursing and their associates were aligned with the successful local co-ordination of the various patient safety interventions emergent from 1000 Lives and 1000 Lives+. Though the formal remit of their roles was to be professionally accountable for nursing practice, such roles typically absorbed a wide range of other 'stuff' (transcription 6:15, below).

As Director of Nursing, I'm professionally accountable for nurses and midwives across the health board – about 5500 registrants and 3000 health-care support workers – so I advise the board on the professional agenda. I've also hold joint executive responsibility with the medical director and director of therapies and health scientist for clinical governance. In respect of 1000 Lives+ I've got some key executive lead roles, for example infection prevent and control; but I also have executive lead roles for the Transforming Care programme. Directors of nursing often label ourselves directors of nursing and stuff because we tend to pick up a lot!

Director of Nursing, case site B, (030); transcription 6:15

Work associated with the 1000 Lives+ programme and ILQI was frequently co-ordinated with medical leads, highlighting the complementary alignment of professional (nursing) and professional (medical) logics (transcription 6:16, below).

I am one of the assistant directors of nursing – we're each site based in a district general hospital – and I work very closely with the site-based assistant medical director. We work together to ensure that we undertake safety WalkRounds, and other features of the 1000 Lives+ national programme to build leadership capacity, and to ensure that we provide that support and visibility for front-line staff. So it's very important that, between ourselves, that we undertake them jointly, preferably.

Assistant Director of nursing, case site C₁ (093); transcription 6:16

Executive nurse leadership was viewed as pivotal for the successful institutionalisation of the 1000 Lives+ intervention 'bundles' apportioned to nursing for their implementation (transcription 6:17, below).

The 1000 Lives+ skin bundle has got an executive lead – our assistant director of nursing – who's very active. They have study days are coordinated by her secretary, and they have three sessions that they run for each area. In contrast, my experience with the catheter bundle has been difficult. I couldn't facilitate that for my area because I haven't had an active executive lead. But the skin bundle, certainly with their executive lead, has worked really well, and spread to areas from across the health board, including private nursing homes and things! We'd love to do that with the catheters, but we just haven't been able to break down the barriers to get across and to access people who can make those links for us.

Senior nurse, IPAC, case site D₁ (034); transcription 6:17

Director of therapies and health science and associates

Directors of therapies and health science were newly established board-level roles (transcription 6:18). Consequently, their vested interests centred on 'coming up to speed' with the demands of the role as well as their executive leadership of 1000 Lives+ interventions associated with ILQI. In this regard, the professional logic enacted was firmly aligned to professional (medical), professional (nursing) and professional (management) logics in a complementary stance (transcription 6:18, below, and transcription 6:19).

My learning curve with the original 1000 Lives campaign and now the 1000 Lives+ national programme, you know, it's been particularly steep over the last 3 or 4 years! Just coming into the director role for therapies and health sciences – we didn't have these director roles previously, so we're all new to boards in the first place – and so the medical and nursing directors' portfolios have shifted around.

But this definitely felt like quite a daunting prospect, I felt it needed a level of expertise; I'd need to have an enormous amount of expertise. I have obviously been learning and asking questions, just the same with any board role, we all need to have teams, support around us, people who can give you expert advice. So I've had to ask questions and get into some of the detail, just to get my head around it, and I've come back out again. Do you see what I mean?

With the 1000 Lives+ national programme, I think, possibly, it's been even more challenging for my nurse director colleague. From an organisational perspective across Wales, 1000 Lives+, a great deal does come down to the director of nursing. It is very much a nursing domain.

Director of Therapies, case site C₁ (118); transcription 6:18

Second-order emergents and situational logic

In case sites A to D, the interplay of structural, cultural and agential emergent properties impacted on the three groups of actors central to the institutionalisation of the 1000 Lives+ programme and ILQI. Structurally, the presence of necessary and internal linkages of a complementary nature between structures such as the mandated bureaucratic performance management systems and associated 1000 Lives+ and ILQI goals, notably the RAMI, which was integrated into local mortality measurement practices, rendered these performance management and governance institutions mutually reinforcing. Similarly, structural resilience emerged from the co-ordinated action of directors of medicine, nursing, and therapies and health sciences, as collective champions of 1000 Lives+ and the broader patient safety agenda.

Second, at board level, the institutionalisation of 1000 Lives+ and ILQI draws professional logic into alignment with that of the bureaucratic state. Moreover, there is coalescence and cohesion across medical, nursing, allied professional and health-care management logics. This places each into a complementary stance, fosters the cross-cultural systematisation of facets of 1000 Lives+ and ILQI across NHS Wales and promotes the reproduction of such practices across each health board. Consequently, at board level, the ILQI operated under a situational logic of protection that moulded sociocultural interaction, agency, strategic negotiation and the ensuing mode of institutional work.

Sociocultural interaction: agency and strategic negotiation

A situational logic of protection emerged from a context of necessary and internal linkages of a complementary nature between systemic structures and harmonising logics. However, given the status of the people involved, the inherent change agenda overarching the 1000 Lives+ programme and, thus, the ILQI were executed from a position of high negotiating strength. Below, we highlight this complex interplay in both a discrete case site and across multiple case sites, drawing out different degrees of bureaucratisation and normalisation to help understand the interplay of the focal intervention, context and mechanism.

Power-induced compliance and political sanction

To examine the adoption of power-induced compliance under a board-level situational logic of protection and to trace its impact across management tiers, we reflect on some of our discussions with respondents in case site B. At this site the chief executive had visibly responded to the bureaucratic demand for engagement with 1000 Lives+ and ILQI, and WalkRounds had also become successfully integrated and thus normalised as an expected professional role-position practice (transcription 6:20, below).

Our approach to 1000 Lives+ is reflected by the leadership of the health board. WalkRounds are a central aspect of 1000 Lives+ but [name, chief executive officer] is out and about to each of the main hospital sites to deliver our monthly team brief, and that team brief is expected to be cascaded out to other managers – then they speak to their leads, their teams, on a one to one, that's the expectation – so that leadership and visibility is there in addition to the WalkRounds. That's about four a month, or eight a month with the team briefings and the open forums, on top of which the director of nursing also does theirs – about four a year – and goes out and about and meet the nurses and midwives across the organisation. So they try their best to communicate and be visible, but they can't be as visible as they used to be because of the size of the organisation.

Associate Director, case site B₂ (009); transcription 6:20

Thus, under a situational logic of protection, the chief executive enacted the practices mandated for his role, building them into an ambassadorial display that promoted similar enactment by other board-level and sub-board managerial actors. Furthermore, such activity was appreciated for its 'very hands-on' and 'approachable' manner (transcription 6:21).

Transcription 6:22 (below) reveals the impact of the Francis Report⁸¹ as a parallel driver for change across NHS Wales, one that was used in an overt act of professional role-positional power to deliver higher standards of care.

One of the things that I did, to address patient safety, was to remove a ward sister from the ward – and we changed the team – because there was a deep-rooted culture in that ward, that went back years and years and years. So I removed the ward sister and put two registered nurses through a disciplinary. It was like a volcano going up.

I don't want to turn this into a blame culture but where there are failings and poor standards of practice or poor leadership – they either want to be a ward sister and all that entails or they don't – so we're making some quite hard moves at the moment and I think that, given Francis, I think it's the right time to do that now.

Director of Nursing, case site B₁ (030); transcription 6:22

Such power was also used to enable those involved to drive forward their evolving patient safety agenda by the display of visible leadership ('walk the wards'); the engagement and co-option of medical staff to act as clinical champions for 1000 Lives+ ('we must have the medical champions out there'); and building the will for change across the functional health-care team ('strong clinical leadership to give teams the confidence to challenge') (transcriptions 6:23 to 6:25).

Reciprocal exchange and the harmonisation of desires

A more subtle deployment of power arose through reciprocal exchange and the harmonisation of desires with other key professional actors. At case site A, board-level actors exerted their managerial control and co-opted their associates who demonstrated interest and relevant clinical expertise to lead the implementation. Thus, the implementation of 1000 Lives+ gained further visible professional leadership closer to the point of care (transcription 6:26, below).

Given my professional background, and experience of service delivery, I've always been really interested in quality and safety, so as associate director, I was tasked with patient safety and patient experience. I'm responsible for sorting out the patient experience agenda – working out how we can capture the patient experience – and making sure that we close the loop. So if we discover something about patient experience through patient satisfaction, patient stories, complaints or anything like that, I aim to ensure that we close the loop in terms of the organisational learning. And for good practice as well because, obviously, as part of that feedback, I get to find out what's really good about our service. It's not always about what's really bad about our services. . .!

I also work with clinicians and managers to put in any action plans, in terms of any work, if things aren't up to standard, or if there's some developmental work that needs to be put in place. So, if my early warning system is telling me that I've got signs of a problem in an area then, obviously, I'll work with the area and the managers to see what needs to be done to improve quality and service. And I work with clinicians to make sure our policies and procedures are up to date and fit for purpose.

Associate Director, case site A₁ (048); transcription 6:26

Such leadership, in itself, fostered the engagement of consultant medical staff with aligned clinical interests. This promoted further medical engagement with 1000 Lives+, ['. . . if you've got somebody at that level that drives it, it's so much easier. Medical leadership makes it work a lot quicker than management' (transcription 6:28)] and, ultimately, the local leadership of discrete interventions ['it's local leadership because they understand the pressure within the organisation, and what makes a difference

within that particular area' (transcription 6:29)]. Creative institutional work, targeted at those who were believers in the aims of 1000 Lives+ programme and, therefore, motivated to engage by a strong sense of coherence, aided its normalisation in practice (transcription 6:27, below).

The thing that enabled it to happen [1000 Lives+ national programme], the places where it happened, it was due to the individuals who were committed to it. [Was that limited to consultant-level clinical leadership or were others involved?] Both. In our health board, here, there's myself and there's a consultant, and we're both who committed to it. You need – rightly or wrongly people listen to consultants, people listen to doctors – you can have the best nurse in the world, who's an expert in something, but they're still a nurse. It's a hierarchical culture in the NHS. Doctors don't learn – doctors are not prepared to learn from nurses – they'll learn from doctors: it's completely wrong. Some of the universities are now doing a lot more multiprofessional learning, the Peninsular Medical School, you know, they're fantastic at this sort of stuff. So, because there's this hierarchical thing, you do need consultant leadership but that can't work on its own. [You need nurse leadership and broader followership to embedded 1000 Lives+ into practice?] Yes.

Consultant, palliative medicine, case site A, (052); transcription 6:27

In case sites B, C and D, the deployment of power through reciprocal exchange and the harmonisation of desires led to similar patterns of expert co-optation to promote resource control of the 1000 Lives+ programme at the point of care. However, discussions at each case site exposed different features. For example, in case site B, reciprocal exchange, manifested through knowledge, flows from board to ward and to the 1000 Lives+ programme team (transcriptions 6:30 to 6:33). At case site C, reciprocal exchange was deployed to build intraprofessional coherence and commitment to 1000 Lives+ for medical and nursing professionals (transcriptions 6:34 and 6:35). Finally, at case site D, reciprocal exchange manifested, once again, through knowledge flows from board to ward (transcriptions 6:36 and 6:37). This was also marked by a subtle shift in expertise to lower management tiers, illustrating the normalisation of 1000 Lives+, and, thus, the inherent successful implementation of ILQI.

Structural elaboration or reproduction in the Welsh health-care field

We also sought to gauge key actors' perceptions of the structural elaboration or reproduction that had emerged under a situational logic of protection. A national programme team member described how, through the formalisation of ILQI, a network of patient safety leaders, health-care professionals from managerial, medical, nursing and other allied groups, had evolved (transcription 6:38, below).

Well, throughout the 1000 Lives campaign and 1000 Lives+, there were some specific interventions that were focused on board-level leaders. But we quickly recognised that, actually, the people that we needed to get at were often senior leaders who didn't have a formal board-level role. Another thing was that, because of the level of disruption with the NHS in Wales – due to the reconfiguration – there weren't people in all the formally appointed board roles, so you had a much more, a looser coalition of senior leaders that we needed to engage with. But one of the things that we have recognised, increasingly, is that to achieve a connection between the clinical teams working on programmes and an organisation level focus involves much more than board-level leaders and front line leaders. It involves a network of people throughout the organisation.

1000 Lives+ national programme team member (089); transcription 6:38

This notable structural change, in indoctrinating others, promoted the distributed leadership of patient safety and the local integration of the 1000 Lives+ programme at each case site. Furthermore, the structural change associated with the integration of mortality reviews into the Welsh Government's performance management framework was viewed to have added an important 'critical lens' through which to view patient safety, providing a valued means of organisational learning (transcriptions 6:39 to 6:41).

In contrast, cultural change was viewed as far more fragmented. This was viewed as owing partly to the pejorative perception of 1000 Lives+ as a nurse-dominated agenda and partly to the time demanded for such cultural evolution, if not revolution (transcriptions 6:42 to 6:44, below).

One success is that it's certainly been embraced by the nursing profession but I'd like to see it embraced by the multidisciplinary teams in a broader context. Some of the other professions are quite dismissive: 'it's a nurse-nurse thing'.

Policy lead, Welsh Government (140); transcription 6:42

I do think we have driven structural change through 1000 Lives+ but, I think, cultural change is slower. It's happening, no doubt, and the new website will, I hope, help NHS Wales to build a workforce that has a detailed understanding of service improvement – the skills and knowledge, the capabilities to sustain patient safety – and the sense of empowerment to act.

Policy lead, Welsh Government (145); transcription 6:43

That notion, that simple acknowledgement that, in the Welsh NHS, we do harm. It's politically difficult to stand-up and say that but I believe it's the start of real culture change: a revolution in care.

Policy lead, Welsh Government (081); transcription 6:44

Importantly, the cultural change that was in play included some notes of discord. For instance, the means of guiding care could become an end in itself, much to the detriment of the patient (transcription 6:45, below).

The nurses have become conditioned, in some respects to, if they're having a problem with a patient, they reach for a piece of paper to document behaviours. So I'll give you an example of one of the recent wards that I've been working on – it's a very, very busy trauma ward – and we have a big problem with older people becoming delayed transfers of care because it's difficult for us to discharge older people, with high intensity needs, out into a more appropriate setting once their orthopaedic and the trauma care is finished.

One of our patients on this particular ward has, is completely dependent, unable to verbalise her needs or her wants, bed bound, reliant on us for everything, from feeding, to turning, to toileting, to trying to interpret communication. And in that, clearly, she becomes very frustrated. So she's taken to grabbing out or grabbing nurses as they're turning her. Instead of the nurses stopping and thinking how can we better interact with her, and how can we reassure her more, they've reached for a behaviour chart. So now her behaviours are being documented – instead of actually stopping and thinking about what can we do differently – let's document the bad behaviour is their response. I think, as a nurse leader, that's what we're conditioning our nurses to do.

Associate Director, case site C₁ (119); transcription 6:45

In addition, some aspects of WalkRounds and the use of patient stories were found wanting. For some respondents, WalkRounds were centred on 'good news stories' that lacked feedback and action at ward level rather than providing a means for transparent and open discussions (transcriptions 6:46 to 6:49), and ownership of the voice behind the patient story was a source of concern for others. However, overall the 1000 Lives+ programme's ILQI was considered to be a catalyst for change (transcription 6:50).

In Wales, the NHS is characterised by a management style which is probably best described as pace setting, so it tends to have a pace setting management style. And 1000 Lives+ and collaborative working and engagement with the public and all of those sorts of things, is more about a coaching style. So for me, it's getting that right balance between targets setting a pace and underpinning it with something, which then coaches people at the best way of how they can do those maturely, so it's how we go about bringing that together, which for me is the absolute challenge that we've got. And it seems very easy to say that but when you think of the characteristics that you're changing to do that, it's immense.

Policy lead, Welsh Government (146); transcription 6:50

1000 Lives+ institutionalisation: ILQI – local implementation of the focal intervention and contribution to the I-CMAO configuration spanning the Welsh health-care field

In this section, we seek to further our understanding of the local implementation of ILQI and define its contribution to the 1000 Lives+ programmes' I-CMAO configuration spanning the Welsh health-care field.

In case sites A–D, ILQI was targeted primarily at executive board-level actors. Hence this focal intervention connected the infrastructural system of the Welsh Government and the Department of Health and Social Care to NHS Wales' health boards. Viewed at a high level of abstraction, as illustrated in *Figure 17*, the institutional change inherent to formalisation, therefore, shaped the context of action for such actors.

The 1000 Lives+ and the MI-PDSA approach were embedded in Welsh Government tier 1 targets and associated escalation framework. The ILQI, therefore, served to define expected performance across the Welsh health-care field. Such bureaucratisation, through command and control of board-level actors, signalled the legitimisation of the ILQI's mandate. Board-level negotiation, formalisation and co-optation of others promoted the deinstitutionalisation of redundant board practices and fostered the preinstitutionalisation of mortality reviews, associated RAMI (see *Tables 17–23*), WalkRounds and the use of patient stories at board level. Hence across each case site, with respect to the 1000 Lives+ programme and ILQI, the mandated context for all was comparable and overtly coercive.

In each health board, innovation emerged from the evidence-based learning arising from the MI-PDSA approach. As clearly illustrated with respect to mortality reviews in transcriptions 6:10 and 6:11 (see *Director of medicine and associates*), identification of problems and systematic failings, catalysed knowledge mobilisation and the validation of extant clinical coding practices, thus promoting the broader moral and pragmatic legitimisation of the newly normalised practice. In this manner, the actors involved drew on the resources of the 1000 Lives+ programme, notably RAMI monitoring guidelines.

Tables 11–13 show, respectively, I-CMAO configurations illustrating the infrastructural system of the Welsh Government, the institutional setting of NHS Wales and its constituent health boards and interpersonal relationships within the institutional settings.

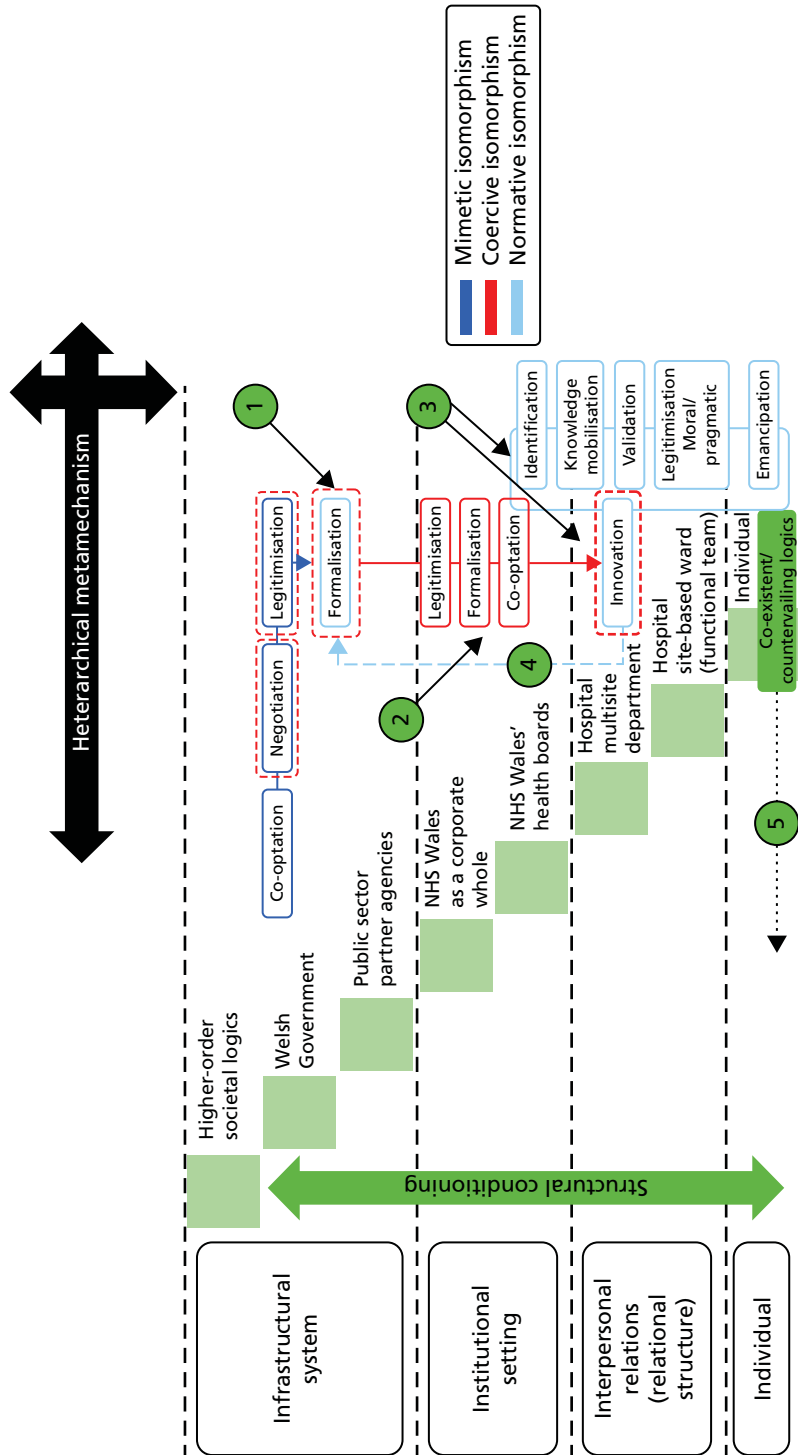


FIGURE 17 Improving Leadership for Quality Improvement: heterarchical metamechanism operating across contextual strata.

Figure 17: key point summary

In *Figure 17* we depict the implementation of the mortality review component of the ILQI focal intervention.

At point 1 we draw attention to the formalisation of this process in Welsh Government policy, thereby mandating engagement by all health boards, typically under the strategic oversight of the medical director.

In point 2 structural constraint impacts at the level of the executive team, fostering the co-optation of other medical leads and clinical coding staff, who are to operationalise the mortality review across the health board together with its associated audit practices.

In point 3 mandated engagement drives the innovation cycle in the situated context, so that new practices for measuring harm, morbidity and mortality emerge. This, therefore, functions as a fundamental stage in organisational learning with respect to health-care quality and patient safety.

In point 4 we depict feedback to Welsh Government and public sector partner agencies as the implementation and operationalisation of the mortality review component of the ILQI focal intervention gradually systematises across NHS Wales.

In point 5 co-existent and countervailing logics are muted by structural constraint.

TABLE 11 Improving Leadership for Quality Improvement I-CMAO configuration: infrastructural system – Welsh Government

Intervention	1000 Lives+ national programme	
Component	ILQI (centred on mortality review as an exemplar)	
Context	Welsh Government	
Mechanisms	<ul style="list-style-type: none"> • Institutional isomorphism – coercive, mimetic and normative • Coherence, cognitive participation and reflexive monitoring 	
Agency and institutional work	<p>Normalisation: coupling to 1000 Lives+, ILQI and mortality review</p> <ul style="list-style-type: none"> • Agency – formalisation • Institutional work – creation • Leadership: distributed across policy and professional domains • Team work: policy leads and professional engagement across aligned organisations • Encultured values: centred on defining ILQI and mortality review as mandated evidence-based practices 	<p>Habituation: decoupling to 1000 Lives+, ILQI and mortality review</p> <ul style="list-style-type: none"> • Decoupling limited by structural and cultural constraints within infrastructural system
Outcome	<p>1000 Lives+ national programme, ILQI and mortality review institutionalised into policy processes</p> <p>Exemplar transcriptions</p> <ul style="list-style-type: none"> • Agency – formalisation • Institutional work – creation • 6:01 (T145) – Coupling • 6:02 (T146) – Coupling • 6:03 (T143) – Coupling • 6:05 (T146) – Coupling 	

TABLE 12 Improving Leadership for Quality Improvement I-CMAO configuration: institutional setting – NHS Wales and constituent health boards

Intervention	1000 Lives+ national programme	
Component	ILQI (centred on mortality review as an exemplar)	
Context	NHS Wales/NHS Wales' health boards	
Mechanisms	<ul style="list-style-type: none"> • Institutional isomorphism – coercive, mimetic and normative • Coherence, cognitive participation and reflexive monitoring 	
Agency and institutional work	<p>Normalisation: coupling to 1000 Lives+, ILQI and mortality review</p> <ul style="list-style-type: none"> • Agency – negotiation under a situational logic of protection • Institutional work – creation/maintenance • Leadership: board-level • Team work: harnesses multiprofessional leadership at board level to foster adoption of ILQI and mortality review, in close liaison with and via co-optation of sub-board leadership • Encultured values: mandated adherence to ILQI and mortality review <ul style="list-style-type: none"> • Agency – legitimisation • Institutional work – creation • Leadership: board level • Team work: dependent on relational structure of three core board-level roles with oversight of patient safety: directors of medicine, nursing, therapies and health science • Encultured values: mandated adherence to ILQI and mortality review <ul style="list-style-type: none"> • Agency – formalisation • Institutional work – creation • Leadership: board level • Team work: centred on relational structure across director of medicine and associate roles • Encultured values: mandated adherence to LWSQI and mortality review <ul style="list-style-type: none"> • Agency – co-optation • Institutional work – creation • Leadership: board level • Team work: centred on relational structure across director of medicine and associate roles • Encultured values: mandated adherence to ILQI and mortality review 	<p>Habituation: decoupling to 1000 Lives+, ILQI and mortality review</p> <ul style="list-style-type: none"> • Decoupling limited by structural and cultural constraints within infrastructural system <ul style="list-style-type: none"> • Decoupling limited by structural and cultural constraints within infrastructural system <ul style="list-style-type: none"> • Decoupling limited by structural and cultural constraints within infrastructural system <ul style="list-style-type: none"> • Decoupling limited by structural and cultural constraints within infrastructural system
Outcome	<ul style="list-style-type: none"> • Coupling 1000 Lives+ national programme, ILQI and mortality review approach embraced and absorbed into extant management, internal governance and audit processes 	<ul style="list-style-type: none"> • Decoupling limited by structural and cultural constraints within infrastructural system

continued

TABLE 12 Improving Leadership for Quality Improvement I-CMAO configuration: institutional setting – NHS Wales and constituent health boards (*continued*)

	Exemplar transcriptions	
	<ul style="list-style-type: none"> Agency – negotiation under a situational logic of protection Institutional work – creation 	<ul style="list-style-type: none"> 6:08 (T076) – Coupling 6:10 (T117) – Coupling 6:26 (T048) – Coupling 6:31 (T016) – Decoupling 6:34 (T116) – Coupling
	<ul style="list-style-type: none"> Agency – legitimisation Institutional work – creation 	<ul style="list-style-type: none"> 6:04 (T051) – Coupling 6:07 (T078) – Coupling
	<ul style="list-style-type: none"> Agency – formalisation Institutional work – creation 	<ul style="list-style-type: none"> 6:08 (T076) – Coupling 6:16 (T093) – Coupling 6:22 (T030) – Coupling
	<ul style="list-style-type: none"> Agency – co-optation Institutional work – creation 	<ul style="list-style-type: none"> 6:07 (T078) – Coupling 6:09 (T117) – Coupling 6:11 (T042) – Coupling 6:13 (T116) – Coupling 6:17 (T034) – Decoupling
LWSQI, Leading the Ways to Safety and Quality Improvement.		

TABLE 13 Improving Leadership for Quality Improvement I-CMAO configuration: institutional setting – interpersonal relations

Intervention	1000 Lives+ national programme	
Component	ILQI (centred on mortality review as an exemplar)	
Context	Hospital multisite department/hospital site-based ward (functional team)	
Mechanisms	<ul style="list-style-type: none"> Institutional isomorphism – Coercive, mimetic and normative Coherence, cognitive participation and reflexive monitoring 	
Agency and institutional work	<p>Normalisation: coupling to 1000 Lives+, ILQI and mortality review</p> <ul style="list-style-type: none"> Agency – innovation Institutional work – creation Leadership: board level with mortality review primarily distributed across medical profession Team work: centred on relational structure across director of medicine and associate roles, with input from clinical coding Encultured values: mandated adherence to ILQI and mortality review 	<p>Habituation: decoupling to 1000 Lives+, ILQI and mortality review</p> <ul style="list-style-type: none"> Decoupling limited by structural and cultural constraints within infrastructural system
Agency and institutional work	<ul style="list-style-type: none"> Agency – identification Institutional work – creation Leadership: board level with mortality review primarily distributed across medical profession Team work: centred on relational structure across director of medicine and associate roles Encultured values: mandated adherence to ILQI and mortality review 	<ul style="list-style-type: none"> Decoupling limited by structural and cultural constraints within infrastructural system
Agency and institutional work	<ul style="list-style-type: none"> Agency – knowledge mobilisation Institutional work – creation Leadership: board level with mortality review primarily distributed across medical profession Team work: centred on relational structure across director of medicine and associate roles and wider board-level input Encultured values: mandated adherence to ILQI and mortality review 	<ul style="list-style-type: none"> Decoupling limited by structural and cultural constraints within infrastructural system

TABLE 13 Improving Leadership for Quality Improvement I-CMAO configuration: institutional setting – interpersonal relations (*continued*)

Agency and institutional work	<ul style="list-style-type: none"> • Agency – validation • Institutional work – creation • Leadership: board level with mortality review primarily distributed across medical profession • Team work: centred on relational structure across director of medicine and associate roles and wider board-level input • Encultured values: mandated adherence to ILQI and mortality review 	<ul style="list-style-type: none"> • Decoupling limited by structural and cultural constraints within infrastructural system 												
	<ul style="list-style-type: none"> • Agency – legitimisation (moral/pragmatic) • Institutional work – creation • Leadership: board level with mortality review primarily distributed across medical profession • Team work: centred on relational structure bridging infrastructural system and director of medicine roles • Encultured values: mandated adherence to ILQI and mortality review 	<ul style="list-style-type: none"> • Decoupling limited by structural and cultural constraints within infrastructural system 												
	<ul style="list-style-type: none"> • Agency – emancipation • Institutional work – disruptive • Top-down mandated task centred on elite board-level roles with limited scope of emancipation of lower-level roles in management hierarchy 	<ul style="list-style-type: none"> • Decoupling limited by structural and cultural constraints within infrastructural system 												
Outcome	<ul style="list-style-type: none"> • Coupling 1000 Lives+ national programme, ILQI and mortality review approach embraced and absorbed into daily practice 	<ul style="list-style-type: none"> • Decoupling limited by structural and cultural constraints within infrastructural system 												
<p>Exemplar transcriptions</p> <table border="0"> <tbody> <tr> <td data-bbox="416 1099 727 1151"> <ul style="list-style-type: none"> • Agency – innovation • Institutional work – creation </td> <td data-bbox="991 1099 1278 1202"> <ul style="list-style-type: none"> • 6:26 (T048) – Coupling • 6:30 (T079) – Coupling • 6:32 (T056) – Coupling • 6:46 (T052) – Decoupling </td> </tr> <tr> <td data-bbox="416 1225 727 1276"> <ul style="list-style-type: none"> • Agency – identification • Institutional work – creation </td> <td data-bbox="991 1225 1257 1328"> <ul style="list-style-type: none"> • 6:14 (T146) – Coupling • 6:36 (T050) – Coupling • 6:37 (T046) – Coupling • 6:39 (T022) – Coupling </td> </tr> <tr> <td data-bbox="416 1350 783 1402"> <ul style="list-style-type: none"> • Agency – knowledge mobilisation • Institutional work – creation </td> <td data-bbox="991 1350 1278 1505"> <ul style="list-style-type: none"> • 6:18 (T118) – Coupling • 6:20 (T009) – Coupling • 6:24 (T044) – Decoupling • 6:27 (T052) – Decoupling • 6:33 (T039) – Decoupling • 6:41 (T117) – Coupling </td> </tr> <tr> <td data-bbox="416 1527 772 1579"> <ul style="list-style-type: none"> • Agency – validation • Institutional work – maintenance </td> <td data-bbox="991 1527 1257 1579"> <ul style="list-style-type: none"> • 6:45 (T119) – Coupling • 6:48 (T069) – Coupling </td> </tr> <tr> <td data-bbox="416 1601 858 1653"> <ul style="list-style-type: none"> • Agency – legitimisation (moral/pragmatic) • Institutional work – creation </td> <td data-bbox="991 1601 1278 1704"> <ul style="list-style-type: none"> • 6:28 (T079) – Decoupling • 6:29 (T025) – Coupling • 6:43 (T145) – Decoupling • 6:47 (T010) – Decoupling </td> </tr> <tr> <td data-bbox="416 1727 743 1778"> <ul style="list-style-type: none"> • Agency – emancipation • Institutional work – disruptive </td> <td data-bbox="991 1727 1262 1800"> <ul style="list-style-type: none"> • 6:25 (T030) – Coupling • 6:35 (T080) – Coupling • 6:40 (T049s) – Coupling </td> </tr> </tbody> </table>			<ul style="list-style-type: none"> • Agency – innovation • Institutional work – creation 	<ul style="list-style-type: none"> • 6:26 (T048) – Coupling • 6:30 (T079) – Coupling • 6:32 (T056) – Coupling • 6:46 (T052) – Decoupling 	<ul style="list-style-type: none"> • Agency – identification • Institutional work – creation 	<ul style="list-style-type: none"> • 6:14 (T146) – Coupling • 6:36 (T050) – Coupling • 6:37 (T046) – Coupling • 6:39 (T022) – Coupling 	<ul style="list-style-type: none"> • Agency – knowledge mobilisation • Institutional work – creation 	<ul style="list-style-type: none"> • 6:18 (T118) – Coupling • 6:20 (T009) – Coupling • 6:24 (T044) – Decoupling • 6:27 (T052) – Decoupling • 6:33 (T039) – Decoupling • 6:41 (T117) – Coupling 	<ul style="list-style-type: none"> • Agency – validation • Institutional work – maintenance 	<ul style="list-style-type: none"> • 6:45 (T119) – Coupling • 6:48 (T069) – Coupling 	<ul style="list-style-type: none"> • Agency – legitimisation (moral/pragmatic) • Institutional work – creation 	<ul style="list-style-type: none"> • 6:28 (T079) – Decoupling • 6:29 (T025) – Coupling • 6:43 (T145) – Decoupling • 6:47 (T010) – Decoupling 	<ul style="list-style-type: none"> • Agency – emancipation • Institutional work – disruptive 	<ul style="list-style-type: none"> • 6:25 (T030) – Coupling • 6:35 (T080) – Coupling • 6:40 (T049s) – Coupling
<ul style="list-style-type: none"> • Agency – innovation • Institutional work – creation 	<ul style="list-style-type: none"> • 6:26 (T048) – Coupling • 6:30 (T079) – Coupling • 6:32 (T056) – Coupling • 6:46 (T052) – Decoupling 													
<ul style="list-style-type: none"> • Agency – identification • Institutional work – creation 	<ul style="list-style-type: none"> • 6:14 (T146) – Coupling • 6:36 (T050) – Coupling • 6:37 (T046) – Coupling • 6:39 (T022) – Coupling 													
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<ul style="list-style-type: none"> • Agency – legitimisation (moral/pragmatic) • Institutional work – creation 	<ul style="list-style-type: none"> • 6:28 (T079) – Decoupling • 6:29 (T025) – Coupling • 6:43 (T145) – Decoupling • 6:47 (T010) – Decoupling 													
<ul style="list-style-type: none"> • Agency – emancipation • Institutional work – disruptive 	<ul style="list-style-type: none"> • 6:25 (T030) – Coupling • 6:35 (T080) – Coupling • 6:40 (T049s) – Coupling 													

Tables 14–20 illustrate the type of information about mortality rates in hospitals made publicly available as part of the new emphasis on transparency in relation to patient safety.

We now turn to the findings of our realist analysis. For illustration, we focus only on the mortality review component of the ILQI, and thus primarily on the generative mechanisms and ensuing agency attributed to directors of medicine. *Figure 17* and *Table 21* support our discussion.

As signposted in *Table 21*, the bureaucratic sense of force majeure that drove engagement with ILQI gave rise to aligned first-order emergents in board-level actors. This included compliance with task allocation and appropriate action to ensure delivery in accordance with the dominant logic of the bureaucratic state. Given the complementary linkages between systemic structural and cultural logics, this fostered a situational logic of protection.²²⁹ In part, this was self-referential: board-level actors had to engage, visibly, in the leadership of patient safety, so aiding the normalisation of such practices within the board.

The sociocultural interaction encouraged by board-level activity centred on strategic negotiation across management tiers and professional networks. Driven by the board and honed through the 1000 Lives+ MI-PDSA approach, legitimisation, formalisation and co-optation ensued. This drove the innovation cycle, as illustrated in *Figure 17*.

An objective outcome of ILQI was the normalisation of the three practices – mortality reviews, WalkRounds and patient stories – examined in this chapter. The relational structure at each site had also evolved, encouraging the diffusion of the ILQI, and thus the 1000 Lives+ programme, and promoting a culture of organisational learning. However, cultural change was restricted by medical disengagement, notably via challenge to the moral and pragmatic legitimacy of some components of the 1000 Lives+ programme, the burden of documentation and weak feedback from boards to wards. We return to these issues in *Chapter 7*, where we examine the implementation of our second focal intervention under far more challenging constraints.

TABLE 14 Local implementation of ILQI: Abertawe Bro Morgannwg University Health Board RAMI

Reporting period	Health board	Morrison	Singleton	Neath Port Talbot	Princess of Wales
January 2011 to December 2011	122	115	122	123	125
February 2011 to January 2012	119	112	121	118	120
March 2011 to February 2012	115	109	117	119	115
April 2011 to March 2012	114	109	117	117	112
May 2011 to April 2012	113	107	112	120	112
June 2011 to May 2012	110	103	109	117	111
July 2011 to June 2012	109	102	107	113	111
August 2011 to July 2012	109	101	106	113	112
September 2011 to August 2012	107	100	106	112	114
October 2011 to September 2012	108	102	101	109	112
November 2011 to October 2012	105	100	100	107	112
December 2011 to November 2012	105	99	100	106	111
January 2012 to December 2012	104	98	102	109	109

RAMI data accessed via <http://wales.gov.uk/topics/health/publications/health/reports/mortality/?lang=en>.

TABLE 15 Local implementation of ILQI: Aneurin Bevan University Health Board RAMI

Reporting period	Health board	Royal Gwent	Neville Hall	Ystrad Fawr
January 2011 to December 2011	107	111	97	83
February 2011 to January 2012	107	111	97	105
March 2011 to February 2012	107	113	93	116
April 2011 to March 2012	107	115	91	101
May 2011 to April 2012	108	119	89	98
June 2011 to May 2012	107	118	87	99
July 2011 to June 2012	106	116	88	100
August 2011 to July 2012	106	117	87	96
September 2011 to August 2012	107	118	86	96
October 2011 to September 2012	106	117	86	92
November 2011 to October 2012	106	117	86	90
December 2011 to November 2012	106	118	87	93
January 2012 to December 2012	108	120	88	99

RAMI data accessed via <http://wales.gov.uk/topics/health/publications/health/reports/mortality/?lang=en>.

TABLE 16 Local implementation of ILQI: Betsi Cadwaladr University Health Board RAMI

Reporting period	Health board	Gwynedd	Glan Glwyd	Wrexham
January 2011 to December 2011	114	103	101	126
February 2011 to January 2012	112	101	99	124
March 2011 to February 2012	111	97	98	123
April 2011 to March 2012	109	95	98	124
May 2011 to April 2012	108	95	98	122
June 2011 to May 2012	107	94	97	119
July 2011 to June 2012	108	96	97	119
August 2011 to July 2012	107	95	98	118
September 2011 to August 2012	107	97	98	116
October 2011 to September 2012	108	97	99	115
November 2011 to October 2012	107	98	99	115
December 2011 to November 2012	107	100	99	115
January 2012 to December 2012	107	101	99	113

RAMI data accessed via <http://wales.gov.uk/topics/health/publications/health/reports/mortality/?lang=en>.

TABLE 17 Local implementation of ILQI: Cardiff and Vale University Health Board RAMI

Reporting period	Health board	Wales	LLandough
January 2011 to December 2011	99	104	85
February 2011 to January 2012	99	105	85
March 2011 to February 2012	100	106	86
April 2011 to March 2012	100	107	84
May 2011 to April 2012	101	108	83
June 2011 to May 2012	99	107	81
July 2011 to June 2012	99	105	81
August 2011 to July 2012	99	105	81
September 2011 to August 2012	97	103	81
October 2011 to September 2012	98	102	84
November 2011 to October 2012	98	102	83
December 2011 to November 2012	97	101	83
January 2012 to December 2012	97	99	85

RAMI data accessed via <http://wales.gov.uk/topics/health/publications/health/reports/mortality/?lang=en>.

TABLE 18 Local implementation of ILQI: Cwm Taf University Health Board RAMI

Reporting period	Health board	Royal Glamorgan	Prince Charles
January 2011 to December 2011	115	123	99
February 2011 to January 2012	114	121	98
March 2011 to February 2012	113	119	97
April 2011 to March 2012	113	120	97
May 2011 to April 2012	111	116	95
June 2011 to May 2012	111	115	94
July 2011 to June 2012	111	114	95
August 2011 to July 2012	117	113	98
September 2011 to August 2012	112	111	100
October 2011 to September 2012	113	112	100
November 2011 to October 2012	113	112	100
December 2011 to November 2012	114	114	99
January 2012 to December 2012	112	114	96

RAMI data accessed via <http://wales.gov.uk/topics/health/publications/health/reports/mortality/?lang=en>.

TABLE 19 Local implementation of ILQI: Hywel Dda University Health Board RAMI

Reporting period	Health board	Bronglais	Glangwili	Prince Philip	Withybush
January 2011 to December 2011	100	101	100	97	103
February 2011 to January 2012	99	97	98	95	104
March 2011 to February 2012	97	98	96	94	101
April 2011 to March 2012	96	97	94	92	100
May 2011 to April 2012	97	100	96	91	101
June 2011 to May 2012	96	98	95	92	99
July 2011 to June 2012	96	99	94	92	98
August 2011 to July 2012	95	99	94	91	98
September 2011 to August 2012	94	98	93	90	97
October 2011 to September 2012	94	95	95	89	97
November 2011 to October 2012	92	92	94	87	95
December 2011 to November 2012	91	90	94	84	93
January 2012 to December 2012	92	90	97	85	91

RAMI data accessed via <http://wales.gov.uk/topics/health/publications/health/reports/mortality/?lang=en>.

TABLE 20 Local implementation of ILQI: Powys (Teaching) Health Board RAMI

Hospital site	Discharges, <i>n</i>	Deaths, <i>n</i>	Mortality, %
Brecon	460	35	7.61
Bronllys	337	36	10.68
Ystradgynlais	242	23	9.50
Knighton	200	17	8.50
Llandrindod Wells	396	40	10.10
Machynlleth	153	19	12.42
Llanidloes	230	32	13.91
Newtown	230	10	4.35
Welshpool	264	30	11.36

Powys (Teaching) Health Board offers a specialist but more restricted range of services and therefore does not participate in the RAMI scheme owing to the tendency to produce inaccurate RAMI scores.

RAMI data accessed via <http://wales.gov.uk/topics/health/publications/health/reports/mortality/?lang=en>.

TABLE 21 Improving Leadership for Quality Improvement: realist analysis – signposting how the empirical data connect to I-CMAO

Intervention	Leading the Ways to Safety and Quality Improvement (ILQI)
Component	Mortality review
Context	Structural conditioning of the institutional setting: NHS Wales health boards' executive-level implementation of 1000 Lives+ national programme
Structural emergent properties	<ul style="list-style-type: none"> • Structural constraints and enablements shaped by the bureaucratic processes of formalisation emergent from the infrastructural system of the Department of Health and Social Care impact 1000 Lives+ and ILQI • Structural resilience was derived from the mutually reinforcing presence of necessary, internal and complementary linkages between systemic structures, e.g. the mandated bureaucratic performance management systems and associated 1000 Lives+ and ILQI goals, notably mortality measurement • Structural resilience also emerged from the tripartite interlock and solidarity between directors of medicine, nursing, and therapies and health sciences, as collective champions of, and advocates for, 1000 Lives+ and the broader patient safety agenda
Cultural emergent properties	<ul style="list-style-type: none"> • Cultural constraints, attributed to the Francis Report, impact on the directors of medicine, nursing, therapies and health science who have delegated strategic oversight of patient safety, and thus 1000 Lives+ and ILQI
Social actors	<ul style="list-style-type: none"> • Directors of medicine: the focal intervention, ILQI-mortality review is targeted to board-level actors but is primarily addressed by directors of medicine
Social position	<ul style="list-style-type: none"> • Elite power role with high social position, professional standing and widespread networks
Role-position practices	<ul style="list-style-type: none"> • Professional role-position practices encompass organisation wide management and, specifically, professional leadership of medical staff. They therefore permeate across the health boards' hospital site-based wards or multisite departments, through to the level of the functional team and individual doctor
Mechanism	Mediation of structural conditioning to core actors and their reflexive theorisation
Institutional logics and nature of alignment between core actors	The institutionalisation of 1000 Lives+ and ILQI draws professional logic into alignment with that of the bureaucratic state. Moreover, there is coalescence and cohesion across medical, nursing, allied professional and health-care management logics, thereby placing each into a complementary stance. This fosters the systematisation of 1000 Lives+ and ILQI across the cultural system level of NHS Wales, and promotes the reproduction of such practices across each health board
First-order emergents	The vested interests of directors of medicine and their associates, tasked with the strategic oversight of the 1000 Lives+ programme and ILQI, lay primarily in the successful development of a systematic locally agreed approach to undertaking the mortality review in the aftermath of the structural reconfiguration of NHS Wales
Second-order emergents	Necessary complementarities
Situational logic	Protection
Reflexive theorisation	Complementarity between the dominant logic of the bureaucratic state, professional (medical) logic and collaborative logic fosters coherence, cognitive participation and reflexive monitoring. This results in the discernment of issues, deliberation of their importance and dedication of ensuing agency in alignment to the goals of the ILQI

TABLE 21 Improving Leadership for Quality Improvement: realist analysis – signposting how the empirical data connect to I-CMAO (*continued*)

Agency and institutional work	Agency, the unfolding strategic negotiation of change, and the mode of institutional work enacted
Agential emergent properties	Given the high status of such actors, the inherent change agenda overarching the 1000 Lives+ programme, and thus the ILQI, was executed from a position of considerable negotiating strength
Strategic negotiation	<ul style="list-style-type: none"> • Power-induced compliance and political sanction • Reciprocal exchange and harmonisation of desires
Institutional work	Primarily creative and augmented by actions which maintain relevant associated practices
Outcome	Social elaboration, reproduction or invariance
Structural	Integration of mortality reviews into the Welsh Government's performance management framework was viewed to have added an important 'critical lens' through which to view patient safety and the maturation of the health-care quality agenda in NHS Wales amid organisational reconfiguration
Cultural	Cultural change was viewed to be far more fragmented
Agential	A network of patient safety leaders, health-care professionals from managerial, medical, nursing and other allied groups, evolved

Summary

In *Chapter 6*, we examined the local implementation of the focal intervention ILQI and discussed its contribution to the 1000 Lives+ programmes' I-CMAO configuration across the Welsh health-care field.

Chapter 7 Reducing Surgical Complications

Overview

In this chapter we examine RSC, the second focal intervention drawn from the 1000 Lives+ national programme. Our focus is explicitly directed to one strand of this complex intervention: the WHOSSC. To begin, we set out a brief overview of RSC, defining its multicomponent structure, aim and drivers. This we augment with a review of the WHOSSC, highlighting its emergence, acknowledged benefits and the perceived barriers that impede its normalisation into daily practice.

Second, we undertake a realist analysis of the institutionalisation of RSC and the WHOSSC, through a comparative case study of sites A, B, C and D. In doing so, we explain the structural conditioning, sociocultural interaction and structural elaboration or reproduction fostered through the actions of three groups of key actors: theatre managers, consultant surgeons and anaesthetists, and theatre nurses. We concentrate on these groups as they were formally tasked with the implementation of the RSC within the 1000 Lives+ programme. Again, to aid our understanding of context and mechanism, we also consider the perspectives of policy leads and other senior health-care management staff. Finally, informed by the findings of our realist analysis we set out our understanding of the RSC-WHOSSC I-CMAO configuration.

Focal intervention, aim and drivers

Reducing Surgical Complications aims to support theatre department staff to deliver high-quality, safe and effective care for adult patients undergoing surgical procedures in a hospital setting. As illustrated in *Figure 18*, RSC is composed of four interventions to reduce the number of infections after surgery, two interventions to improve teamwork and three to facilitate patient involvement in their care. In this study, attention focused on the WHOSSC,⁵³¹ a tool for clinical teams to improve the safety of surgery by reducing deaths and complications.

World Health Organization Surgical Safety Checklist

The WHOSSC evolved from the Safe Surgery Saves Lives initiative, established by the World Alliance for Patient Safety as part of the World Health Organization's (WHO) efforts to reduce the number of surgical deaths across the world. This initiative sought to harness political commitment and clinical will to address important safety issues. The principal concerns were poor communication among team members; inadequate surgical and anaesthetic safety practices; and avoidable surgical infection.⁵³¹

As illustrated in *Figure 19*, the WHOSSC is characterised by simplicity and brevity, and is composed of a series of questions to guide the co-ordinated actions of the theatre team. Notably, many of the individual steps advocated are accepted as routine practice. But, as expanded below, such acceptance does not reduce the barriers to its collective adoption.⁵³¹ It is, therefore, acknowledged that to foster engagement and enhance compliance,⁵³² each theatre team must adapt the WHOSSC to their needs and routine operative workflow and to address many different types of surgery.^{533–545}

With increasing acceptance of the WHOSSC,⁵⁴⁶ aligned approaches have been adapted to address broader surgical issues and hazards.^{547–550} There have also been more subtle changes such as the adjustment of the timing of questions likely to cause anxiety to patients.¹⁷³

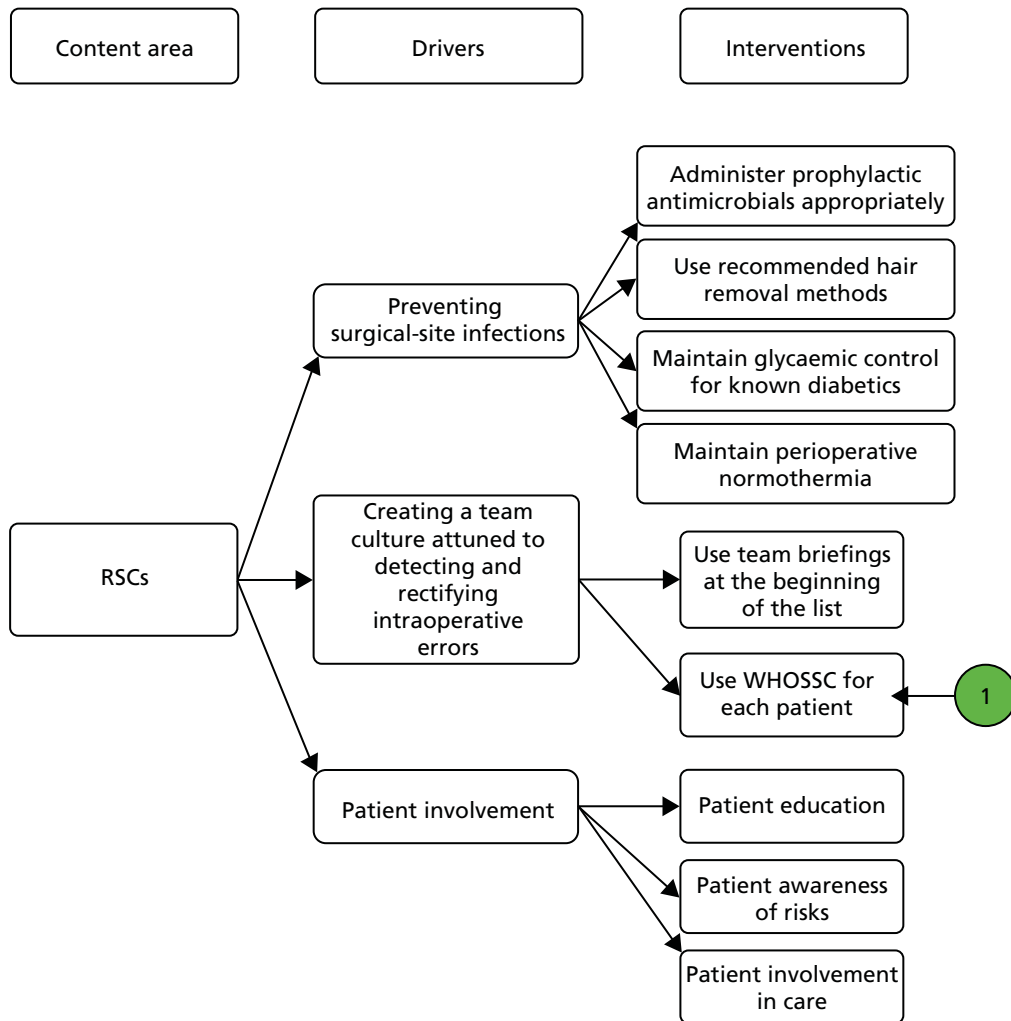


FIGURE 18 Driver diagram: RSC.

Figure 18: key point summary

Figure 18 depicts the driver diagram for the focal intervention, RSC, focusing specifically on one strand of this multicomponent intervention, the WHOSSC. To aid our understanding of the interplay of context and mechanism in the operationalisation of this intervention, we sought the perspectives of theatre managers, consultant surgeons and anaesthetists, and theatre nurses, each tasked with the implementation of the RSC and WHOSSC under the auspices of the 1000 Lives+ national programme.

Surgical Safety Checklist



World Health
Organization

Patient Safety
A World Alliance for Safer Health Care

Before induction of anaesthesia (with at least nurse and anaesthetist)	Before skin incision (with nurse, anaesthetist and surgeon)	Before patient leaves operating room (with nurse, anaesthetist and surgeon)
<p>Has the patient confirmed his/her identity, site, procedure, and consent?</p> <input type="checkbox"/> Yes	<p><input type="checkbox"/> Confirm all team members have introduced themselves by name and role.</p> <p><input type="checkbox"/> Confirm the patient's name, procedure, and where the incision will be made.</p> <p>Has antibiotic prophylaxis been given within the last 60 minutes?</p> <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	<p>Nurse Verbally Confirms:</p> <input type="checkbox"/> The name of the procedure <input type="checkbox"/> Completion of instrument, sponge and needle counts <input type="checkbox"/> Specimen labelling (read specimen labels aloud, including patient name) <input type="checkbox"/> Whether there are any equipment problems to be addressed
<p>Is the site marked?</p> <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	<p>Anticipated Critical Events</p> <p>To Surgeon:</p> <input type="checkbox"/> What are the critical or non-routine steps? <input type="checkbox"/> How long will the case take? <input type="checkbox"/> What is the anticipated blood loss? <p>To Anaesthetist:</p> <input type="checkbox"/> Are there any patient-specific concerns? <p>To Nursing Team:</p> <input type="checkbox"/> Has sterility (including indicator results) been confirmed? <input type="checkbox"/> Are there equipment issues or any concerns? <p>Is essential imaging displayed?</p> <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	<p>To Surgeon, Anaesthetist and Nurse:</p> <input type="checkbox"/> What are the key concerns for recovery and management of this patient?
<p>Is the anaesthesia machine and medication check complete?</p> <input type="checkbox"/> Yes		
<p>Is the pulse oximeter on the patient and functioning?</p> <input type="checkbox"/> Yes		
<p>Does the patient have a:</p> <p>Known allergy?</p> <input type="checkbox"/> No <input type="checkbox"/> Yes		
<p>Difficult airway or aspiration risk?</p> <input type="checkbox"/> No <input type="checkbox"/> Yes, and equipment/assistance available		
<p>Risk of >500ml blood loss (7ml/kg in children)?</p> <input type="checkbox"/> No <input type="checkbox"/> Yes, and two IVs/central access and fluids planned		

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

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FIGURE 19 The WHOSSC. Source: http://whqlibdoc.who.int/publications/2009/9789241598590_eng_Checklist.pdf. Reproduced with permission.

Since its inception, the WHOSSC has proved to be a robust means of reducing perioperative complications.^{70,406,551,552} Empirical research supports assertions that the WHOSSC (i) saves lives,^{553–557} (ii) improves communication across the surgical team,⁵⁵⁸ (iii) reduces the occurrence of wrong-site surgery,⁶³ (iv) promotes adherence to defined antibiotic protocols, thereby reducing the incidence of surgical-site infection,^{559–561} and (v) fosters more efficient use of theatre time and resources,⁵⁵⁶ while supporting appropriate staffing levels.⁴³⁹

Despite such obvious benefits, operationalisation of the WHOSSC may be poor.^{70,190,562–564} Failures to follow the checklist include not identifying the patient; undertaking a wrong-site surgery or procedure,⁵⁶⁵ and failing to identify staff members.^{123,566} In addition, pressure of time may lead to surgical procedures being started before the checklist is completed.^{567–569} Failure to complete sign out is another common deviation.¹²² Poor engagement by anaesthetists,⁷¹ surgeons⁵⁷⁰ and nursing staff due to resistance and gaps in knowledge has also been reported.^{435,543,571}

Realist analysis and comparative case study

We now undertake a critical realist analysis of the institutionalisation of the 1000 Lives+ national programme's RSC and WHOSSC. Again, our case study considered sites A, B, C and D. Our analysis focuses on three groups of key actors, theatre managers, consultant surgeons and anaesthetists, and theatre nurses, tasked with the implementation of the RSC under the auspices of the 1000 Lives+ national programme.

First, we consider the focal intervention in context and explore the dominant structural and cultural emergent properties impacting key personnel in the theatre departments at each case site. Next, to reveal the generative mechanisms in play, we examine mediation via first- and second-order emergents and the resultant situational logic. Then, to examine the initiation of change, we explore the unfolding strategic negotiation of change and the mode of institutional work enacted. Finally, we reflect on the nature of any sustained outcome, be that elaborative or reproductive, that occurred following the implementation of the RSC and WHOSSC. This analysis forms the foundation of our refinement of the I-CMAO configuration spanning the Welsh health-care field in *1000 Lives+ institutionalisation: RSC – local implementation of the focal intervention and contribution to the I-CMAO configuration spanning the Welsh health-care field*.

Structural conditioning: structural and cultural emergent properties in the Welsh health-care field

Completing the WHOSSC surgical checklist was a compulsory element of the overarching policy mandate of the 1000 Lives+ national programme (transcription 7:01, below).

1000 Lives+ – well, it's not rocket science by any stretch of the imagination – it's an incredibly simple approach and that is one of the reasons why it works. The PDSA cycles and all of that stuff it's created a language that they like: it's language that they all understand. The WHO checklist just adds another element to it, which is recognised world-wide. It's mandated as a practice – in policy and professionally – so they've just got to do it. After all it saves lives, we know it saves lives.

Policy lead, Welsh Government (146); transcription 7:01

In addition, the WHOSSC was strongly advocated by the WHO, the IHI and the array of associated medical professional Royal Colleges, placing the dominant logic of the bureaucratic state into close alignment with that of professional medical logic within the theatre environment (transcription 7:02, below).

The WHO checklist – it's compulsory – so it was a little bit more straightforward because, at the end of the day, if people didn't comply then they were in breach of contract with their controlling body. So that was it, essentially.

Consultant surgeon, case site D₁ (083); transcription 7:02

Such structural constraint was amplified by a parallel programme, Transforming Theatres, representing a Welsh adaptation of the NHS Institute for Innovation and Improvement's Productive Series, *The Productive Ward* and *The Productive Operating Theatre* (transcription 7:03).

The dominant cultural emergent properties, which moulded the institutionalisation of the 1000 Lives+ RSC and WHOSSC, arose from the institutional system of the theatre departments in case sites A–D. First, such theatre departments were perceived to function in relative isolation within the base hospital and parent health board (transcription 7:04, below).

Theatre attracts extroverts – you wouldn't work here if you didn't have thick skin and couldn't deal with some of the issues that we have to deal with – but they feel quite isolated from the organisational agenda in a way. Theatre is its own little world. There isn't that link between the theatre and the rest of the wards, and the larger organisation. But there is a link across the different operating theatres in the health board even though they are all different.

Theatre manager, case site A₁ (008); transcription 7:04

The perception of a distinctive functional and professional culture underscored this sense of separation (transcription 7:05) and this second cultural emergent property fostered the potential for conflict. Across each case site, the traditional view that the surgeon was in charge still lingered. This created a schism: a managerial logic aligned to the nursing profession versus a counterpoised stance aligned to surgeons and their medical colleagues. This tension was not a key issue at all case sites. However, such institutionalised

professional role-positions arose as a perceptible fault-line throughout many discussions (transcription 7:06, below).

In theatre, traditionally, the surgeon was the captain of their ship – they ran the show and all the rest of it – and people just did their bidding. But today that's completely the wrong way round! That's completely not what modern surgery's about because you're only as good as your parts. Now a lot of people won't believe that still! So if you're trying to get people to implement the WHO checklist and yet they believe that everything depends on them performing correctly and that they don't make errors [laughs] then it's a very difficult task! You're far more likely to engage with people that actually are slightly less self-assured because they understand there may be a better way to improve the care of the patients. So my gambit with some of my colleagues was to say: 'I'm not as perfect as you – but do you know your error rate? Are you perfect? Are you one in a million perfect? And if it is that one in a million then what are you going to do to improve' – but people have to accept there's a problem before they'll look for a solution. I think they have to see that it's a problem before they'll change their practice.

Consultant surgeon, case site A₁ (063); transcription 7:06

Such cultural constraints highlight the critical role of agential emergent properties. Most notably these include leadership and orchestrated collective action within the multidisciplinary theatre team to address perceived problems (transcription 7:07, below).

There was a surgeon I worked with – an orthopaedic surgeon – who I really respected. One day, because I'd just been on a course and knew the proper way of doing the procedure he was going to do, I realised he was going to use the wrong approach. Basically, he was going to go in from the other side of the leg. I knew he was wrong, so I told his registrar, because I couldn't tell him. The registrar knew he was wrong, and he couldn't tell him. That's the example I always use with theatre clinicians: 'if the most senior consultant was just about to stick a knife into someone, and the most junior member of the department walked in and said – excuse me, stop – what would be the response?' Would the response be: 'OK, what have you got to say?' or would it be 'get the hell out of my theatre' with somebody throwing something at him? That usually raises a smile, and once you start talking about it, they realise that the teams that they think were good teams are actually not. Getting back to my example, I said to him in the end: 'Mr [Name], so you're using the medial approach today, are you?', and it was as if somebody switched a switch on in his brain. You could see him almost like come awake and go: 'no, I think I will go in laterally'. But he couldn't say to me, you know: 'thanks for that, I was going to make a mistake' – we both had to play the game – this whole thing about hierarchies!

1000 Lives+ national programme team member (041); transcription 7:07

Consideration of the underlying contextual strata at the interpersonal and individual levels further reveals the impact of this cultural fault-line and exposes the deeply held belief systems anchored to such discordant professional logics. Different cultural stances could lead some individuals to pay little attention to the RSC and WHOSSC. For instance, it was reported that some consultant surgeons did not believe the WHOSSC to be necessary and, thus, viewed it as little more than a management weapon to exert control (transcriptions 7:08 and 7:09). As succinctly expressed in an excerpt from transcription 7:10, below, the institutionalisation of the WHOSSC was dependent on flattening the professional role-based hierarchy in the theatre department.

Our theory on it is if people get the briefings right – where they develop a real team by flattening the hierarchy – and there's respect for everyone in the theatre, the whole checklist sails through! People start to understand – they're not worried about challenging a surgeon – they see the value of it!

1000 Lives+ national programme team member (041); transcription 7:10

First-order emergents for key actors central to the institutionalisation of the World Health Organization Surgical Safety Checklist

A distinctive set of structural and cultural emergent properties shaped the context in which individuals who were central to the institutionalisation of the WHOSSC found themselves and conditioned their ensuing actions. Deeply entrenched professional role-positions orchestrated the operation of the theatre departments, and we asked theatre managers, consultant surgeons and anaesthetists, and theatre nurses to reflect on their placement, their vested interests and the perceived opportunity costs associated with various courses of action to determine how this shaped their activities.

Theatre managers

In case sites A–D, theatre managers' placement shaped their vested interests towards ensuring the successful implementation of the 1000 Lives+ national programme's RSC and WHOSSC initiatives. They operated under a professional logic aligned to health-care management and, for hybrid professional staff, the nursing profession. Given the need to succeed, their activity centred on the brokerage of support resource to leverage the RSC and WHOSSC via the emotions of pride and shame. To achieve this they drew on the core resources of the 1000 Lives+ programme's team, the MI-PDSA approach and the aligned Transforming Theatre team (transcriptions 7:11 and 7:12, below, and transcription 7:14).

We did have problems with the WHO checklist but they were picked up by 1000 Lives+ team, and they were followed through via the Transforming Theatre Team. They did their own audits and glitch lists. They'd go to each and every health and safety briefing and they would name and shame – which theatre was doing well, which ones weren't; which surgeons were turning up, which ones weren't – that caused huge amounts of conversation! But I think you can say it was nothing but positive because, even when they were arguing, they did start improving because they did not like seeing their poor results. That really helped get our WHO checklist and safety briefings on track. So we used both 1000 Lives+ and Transforming Theatre.

Theatre manager, case site A, (008); transcription 7:11

To begin with we had difficulty with the PDSA approach. Yes, we had difficulty with that! We had difficulty in getting our heads around it – we thought we'd mastered it but we hadn't – but we did eventually get through it! We worked with the 1000 Lives+ team and the Transforming Theatre team and looked at what we could improve. With the PDSA, well, we didn't understand it very well: we couldn't get our heads around it! At times we thought we'd mastered it but then they'd say: 'no, that's not right', and we thought: 'oh God, you know, somebody please give us a simple explanation so we can just get it right'. We'd sort of grasped it but we were trying to do it in sort of one hit and not doing small things – small rapid cycles of change – and then sort of escalating it gradually.

Theatre manager, case site B, (005); transcription 7:12

Consultant surgeons and anaesthetists

The behaviour of the consultant surgeons and anaesthetists interviewed during our study was markedly influenced by the nature of their engagement with the 1000 Lives+ national programme. For those who were simply participants, lacking the burden of professional and managerial accountability for the programme's implementation, the RSC and WHOSSC were viewed with a degree of disdain. In case site A, surgeons were perceived to be in a position of security, given NHS Wales' assumed reluctance to 'play heavy handed'. In response, surgeons tended to ignore the medical director's efforts at control (transcription 7:15, below).

If you want to play heavy handed then what you need to do is – which is what they've done in many trusts in England – is they sack people. It happens, that's what NHS England does. But we don't do that in Wales. Surgeons are in a position where we have security and the stick that the medical director can wield is just not big enough.

Consultant surgeon, case site A, (063); transcription 7:15

Such disengagement rendered the implementation of the RSC and WHOSSC into 'quite an interesting shambles', with senior medical professionals deciding to ignore the initiative (transcription 7:16, below). Thus actors' vested interests lay in maintaining their professional role-positional power, as there appeared to be no sanctions associated with their disengagement. The dominant logic of the bureaucratic state and aligned professional health-care management logic were, therefore, countervailed by professional medical logic.

One surgeon didn't want to play, he thought: 'why should I introduce myself to the anaesthetist? I'm busy writing up my previous case, so I'm not going to. . .' Also, the WHO checklist was all done, sort of, at the wrong time – you know, the end of the case bit, well it was done sort of retrospectively rather than live! [Laughs] It was all quite an interesting shambles actually. The senior people decided that they were above it all basically.

Consultant anaesthetist, case site A₁ (064); transcription 7:16

In contrast, in case site B, the theatre manager was able to broker wider medical participation through effective leadership of the implementation (transcription 7:17, below).

We have a really proactive Theatre manager, who is really good at working with the doctors and surgeons, so I think the WHO checklist was a breeze! I am assured that it is fully implemented because I have spot-checked them. I spoke to [Name, Theatre manager] when I first came into the organisation and I saw that we were 100% compliant. So, yeah, we seem to be rocking with the WHO checklist!

Consultant surgeon, case site B₁ (062); transcription 7:17

However, this overtly positive perspective was diluted by a respondent who pointed out that, despite apparent use of WHOSSC, mistakes had not been entirely eliminated, and suggested that not everyone at site B was enthusiastic about the initiative (transcription 7:18, below).

I gather, here, it's got its enthusiasts and it's got its detractors. But across NHS Wales we've had disasters even with the checklist being used: wrong site surgery, instruments left in, etcetera. [Even though the WHO Surgical Safety Checklist is being used?] Yes! In other words it's not being used properly. It will never cure all problems but you do wonder whether it's being used properly or whether people just pretend it's being used.

Consultant anaesthetist, case site B₁ (059); transcription 7:18

In contrast, for those chosen and tasked with the implementation of the 1000 Lives+ national programme, the RSC and the WHOSSC met with approval. In case sites C and D, such actors' vested interests lay in brokering participation with the WHOSSC with their professional colleagues to ensure that the checklist did not merely function as a 'tick-box exercise'. Their agency was directed to managing the tension promoted by the countervailing stance of professional medical logic (transcriptions 7:19 and 7:20, below).

When I first started in the health board, I got asked to assist with the implementation of the WHO checklist. I think – I'm not quite sure if I had an official title as such – but I was responsible for some of the surgical aspects. [Did you encounter any resistance towards the WHO checklist?] Ah yes . . . [Long pause] . . . that was an old chestnut, we had to deal with it at the time. I think with a lot of these projects where people are looking to try and implement change the difficulty is the people who volunteer to do them, of course, they're the believers! And the people who don't volunteer are not the believers. So, there's always a sort of a clash of culture, I guess, between the two. But clinicians like to see themselves as being very independent. Surgeons probably more than most! They have a certain arrogance and belief in themselves that they need in order to survive their day-to-day job. So, yes, you're right, there were a lot of, I don't know, issues. There were lots of little teething problems. One of which was how you actually record that you've done it!

Consultant surgeon, case site D₁ (083); transcription 7:20

This contested terrain is expressed in transcription 7:21, below. It reveals that other facets of the RSC, essentially the easy, less controversial ones that did not impugn surgical ability, were adopted first as readily achievable 'quick wins'.

When you think about the WHO checklist . . . [long pause] . . . Well you can understand why theatre nurses are going to choose to do normothermia! [Another component of the 1000 Lives+ RSC intervention] It's simple! You take a temperature, you make sure they're kept warm – the intervention is easy and there's no controversy – everyone knows normothermia is good; everyone knows good glycaemic control matters. Safe hair removal, it's fine, we just ban razors and go to clippers! We just stop procuring them, problem sorted. Done! So in some of the RSC interventions, all of those people are able to go: 'look, we are a success, and we've done it quickly'. So they've had the quick win. But the message is people choose the path of least resistance. The WHO checklist is more complex and so it's harder to achieve.

Medical Director, case site D, (117); transcription 7:21

Theatre nurses

Theatre nurses in case sites A–D, though their vested interests were aligned to the implementation of the RSC and the WHOSSC, varied in their perception of the degree to which their roles allowed them freedom to act according to its precepts. In case site A, engagement of all staff was promoted by a surgical consultant who, from personal experience of a surgical 'never event', was committed to the WHOSSC. However, others who showed only ambivalent adherence diluted such clear strategic surgical leadership (transcription 7:22, below).

We have one surgeon who was doing the WHO checklist before it was even implemented here – they had their own sort of version of it – and that because . . . [long pause] . . . they had had an incident happen, I think it was here, a wrong site surgery. From that moment on, they now make sure that everybody stops, everybody agrees, so that they get it right. They're the biggest convert! But most of them are ambivalent about it and just realise that they've got to do it.

Theatre nurse, case site A, (024); transcription 7:22

Theatre nurses in case site B, however, perceived that their role in the implementation of the RSC and especially of the WHOSSC was facilitated by the professional role-position of scrub nurse. The expertise and knowledge enacted through this role-position helped to level the entrenched professional hierarchy of the theatre department, particularly for surgeons in training, ensuring that they 'learn to listen' (transcription 7:23). This empowered and emancipated stance set the strategic direction for other theatre nurses to follow, aiding the normalisation of the WHOSSC in daily practice.

In case site C, rudimentary contextual constraints, such as a surgeon's family commitments preventing his attendance at the eight o'clock briefing, posed formidable barriers to engagement which nurses lacked the role-positional means to counter (transcription 7:24), while in case site D, the placement of one theatre nurse tasked with the implementation of the RSC and WHOSSC was devoid of resource support and expertise. This rendered the nurse ill equipped and isolated, limiting the extent to which she was able to promote the implementation (transcription 7:25, below).

I was seconded, part-time, to theatres. From my perspective, I was brought in late. It [1000 Lives+ RSC focal intervention] had already started, and the staff, which were heading it up for [name, health board], had already gone and had their briefing session. So I felt I was brought in blind. I didn't really understand it at the start to be honest. But we were given drivers of things that we needed to address – improvements that we needed to achieve; change in practice and audit really – and told to gather data to see if we were meeting the drivers and the standards. It was my job to tell the staff about what the standards and the drivers were, and how we were going to identify how we were going to change practice in line with what they were saying we needed to do. I had to gather all the data, put it into a graph, and then present that on a monthly basis. But I was isolated. I did the PDSA

cycles – I tried to involve people, I tried my hardest, I even had champions – but I was doing the PDSA cycles, writing them up, because they wanted written evidence that they were being done. It's embarrassing when you're presenting data that you haven't got – so I was doing it to make sure I had data to present – so that I wasn't going to be standing there saying: 'well sorry, I haven't got anything'. When theatre staff are working clinically they've got the pressure of patients coming through – and they come first – this is [WHO checklist] just a bit of paper that doesn't do anything.

Theatre nurse, case site D₁ (028); transcription 7:25

Second-order emergents and situational logic

In case sites A–D, the interplay of structural, cultural and agential emergent properties impacted on the three groups of actors central to the institutionalisation of the 1000 Lives+ national programme, the RSC and the WHOSSC, enabling or frustrating the position they adopted and their role in implementation.

Where structure was concerned, the RSC and WHOSSC emerged into a context moulded by internal and necessary linkages that reflected both complementarities and contradictions. However, as illustrated in the transcriptions above, culturally there was deep discord as the key actors were confronted by the constraining contradictions (necessary incompatibilities) between the dominant logic of the bureaucratic state with its aligned professional health-care management logic versus that of professional medical logic. This led to development of a situational logic of correction/compromise, where those tasked with the implementation of the WHOSSC confronted a context fraught with the power play of different professional groups and had to act in a manner that sought to ameliorate this sociocultural constraint.

Sociocultural interaction: agency and strategic negotiation

At each case site, the situational logic of correction/compromise motivated an essentially concessionary negotiating stance among the key actors. Below, we elaborate two features in depth to highlight this complex interplay across multiple case sites.

Power-induced compliance and political sanction

To examine the adoption of power-induced compliance and political sanction under a situational logic of correction/compromise, we considered individual actors' strategic negotiating stances across each case site. In transcription 7:26, below, the medical director admitted using reference to the Mid Staffordshire scandal and threats of losing their jobs to coerce colleagues into compliance with new practices.

With 1000 Lives+, the WHO checklist, whatever, resistance to that sort of change has to be managed in an open and transparent way, and it has to be managed in terms of saying a number of things – different drivers – if you like.

I haven't yet used the F word, but we'll use it now – Francis [Report of the public inquiry into Mid Staffordshire NHS Foundation Trust] – Francis will act as an important driver. Francis is ground breaking. So, I will use Francis, as a lever, to say: 'If you are not...'. But revalidation is another important lever; so we've got two levers. The third is: 'Well, the Welsh Government expects this of you...', and I don't like using that as a lever but why not chuck it in! [It causes more resistance...]
Yes, it does.

But where I need to get to as a medical director is to have a culture where I go to a consultant and say: 'Oh dear, I hear your complication rates are a bit high', to which I get an open answer in which they say: 'Yes they are, and do you know what, I'm doing an audit to check whether...', as opposed to 'No, I'm fine'. So, I think, that we want to develop is that candour culture that Francis wants.

With revalidation everybody has to reflect now – I've just revalidated all the medical directors, so I'm reflected out! – but now you have to reflect on everything! This is good; but they're going to have to do that. So, now, if they say to me: 'No, everything's fine', then they won't revalidate.

So that is how I will be moving forward, in terms of driving openness and transparency, and saying: 'You have no choice but to engage in this because otherwise those mechanisms will see to it that you are removed'.

Medical director, case site D₁ (117); transcription 7:26

However, some argued that such compliance was only token, with checklists being completed casually and inaccurately (transcriptions 7:27 and 7:28, below).

The WHO checklist should be 100% compliant: end of story! But drilling down through our data for that in more detail revealed problems. We do the safety briefings but what we were finding was it was a tick-box exercise – they were being done – but they were being done without the presence of the key members of the team, such as the consultant; they were being done a little bit flippantly, not necessarily with the real information that we needed for patients on the list; there were assumptions. They were very much nurse-led. . . [Long pause]. Look, I'm not confident that the data is accurate. I couldn't actually find evidence as to who was not doing it but whether or not it's 100% reliable I'm not sure. But the trend that we're setting is that we're 98–100% compliant.

Theatre manager, case site A₁ (008); transcription 7:27

I get the monthly reports from the computer system on the checklist compliance and it's always about 99 something per cent! I don't suppose that's true for a moment because people are just ticking the box on the computer. [You don't think that's a representative value?] No, I don't believe it: 99% every month, no way! My problem with all this is it's quantitative data being collected about a qualitative process. Take the incident that happened back last year. Somebody sat there in front of me, after it had all happened, and said: 'well, I did do the checklist', and I said: 'well, how do you account for the fact that they nearly did the wrong operation?', 'I don't know, perhaps the surgeon didn't hear me'. So they ticked the boxes on the checklist but they didn't do the checklist if you know what I mean.

Theatre nurse, case site D₁ (029); transcription 7:28

Observation of practice revealed computer-based systems that recorded completion of the WHOSSC via a simple yes-or-no option with progress through subsequent screens being prohibited by a no response, thus completely negating the purpose of the checklist and decoupling it from the physical enactment of the WHOSSC. Thus, under a situational logic of correction/compromise, the contested institutionalisation of the WHOSSC corrupted and was decoupled from meaningful governance processes. However, such subversions of the purpose of the checklist were felt likely to be exposed by growing public awareness of the WHOSSC, and the possibility of subsequent legal challenge in the face of surgical adverse or never event was perceived to be a latent generative mechanism for change and one that would be a 'very, very quick way to get it up to speed' (transcription 7:29).

Reciprocal exchange and harmonisation of desires

In case site B, the actions of the nurse theatre manager in ensuring that the WHOSSC was completed facilitated detailed examination of the use of strategic negotiation via reciprocal exchange and resource control. In this context, the manner of negotiation that held sway bordered on the coercive and the bureaucratic policy mandate for the RSC and the WHOSSC was employed to manifest effect. The role of nurse empowerment, in aiding normalisation, was also evident, with the manager and other nursing staff having sufficient confidence to insist that the checklist was completed. This illustrated both coherence of purpose and commitment to the WHOSSC as a practice (transcription 7:30, below).

[How did you get surgeons to participate in the WHO checklist?] Well, they didn't have a choice! [Laughs] Don't tape that! We said to them: 'you know, we've got to do the WHO checklist' – it is a mandatory patient safety check – 'so we haven't got a choice, you've got to be part of it, and we'll do it with the patient, and you, in here [Theatre], so you're going to have to listen'. Basically, we came to an agreement with the surgeons. We agreed that the scrub nurse would not start helping the surgeon until the WHO checklist was completed. So they had to be part of it! In the end, I think, they

came to the conclusion that they hadn't a choice really. It was a bit of a battle at the very beginning because they started arguing with us, and we just said: 'no, we don't want to argue about this, we haven't got a choice, we've got to do it'. We took the same approach with visiting consultants. [How did you manage them?] Well, actually, that was the easy bit. What I said was: 'if you're doing it in the [name, alternative hospital theatre site in health board], well then it doesn't bother you to do it here, does it?'

Theatre manager, case site B₁ (005); transcription 7:30

Such processes were enabled by the dominance of the professional role-position of theatre manager, manifesting through their long-honed expertise and social capital within the relational structure of the theatre department. Under such orchestration the situational logic of correction/compromise resulted in the progressive institutionalisation of the RSC and the WHOSSC.

In case site D, the situational logic of correction/compromise that held sway was attributable to five key individuals: an associate director with strategic oversight for the theatre department; the theatre manager tasked with the strategic oversight of its implementation; the consultant surgeon leading the clinical implementation of the WHOSSC; and two theatre nurses (transcriptions 7:31 to 7:35).

As illustrated in the excerpt from transcription 7:31, below, difficulties in brokering change, due to the entrenched schism between the managerial logic aligned to the nursing profession and the counterpoised stance aligned to surgeons and their medical colleagues, were acknowledged with the setting up of a multiprofessional team to support the implementation of the RSC and the WHOSSC.

Before the WHO checklist came out we were trying to introduce safety briefings in theatres. That was generally, sort of, well we tried, tried to be led by a nurse – a nurse-led approach – but there was a lot of challenge and resistance because the general thinking was that: 'we already do this, it's a waste of time, and how dare other people come in and try to tell us what to do!' But then there was a great team set up with one of our senior anaesthetists who worked with a nurse practice educator in operating theatres and we had even had a consultant surgeon! So, really, the three of them worked together and put their own house in order to set the example.

Associate Director, case site D₁ (049); transcription 7:31

Despite this apparently successful implementation, it was clear that the normalisation of the RSC and the WHOSSC remained contested, with some staff treating the WHOSSC in a cavalier manner, undermining it as a meaningful practice and eroding its value to that of a joke. Such disruptive institutional work diminished the legitimacy and moral foundation of the practice. It also served to limit the requisite remoulding of underlying belief systems to aid cognitive participation, collective action and reflexive monitoring during the implementation of the RSC and the WHOSSC (transcription 7:32, below).

I've had students come and tell me: 'Oh, the surgeon introduced themselves, they did the checklist' – so the tick on the box said: 'yes, we did it' – but then they tell me: 'they introduced themselves as Mickey Mouse', so they weren't taking it seriously. When you question them on that, they will say, quite rightly: 'we've worked together for 5 years, we all know each other'. We have even had: 'I am Spartacus, no I'm Spartacus!' when they go round introducing themselves. About 99% of our audit data is saying they're doing it, and yes, they might. But they're probably not doing it that often and, even when they are doing it, it might not be as fully comprehensive as it should be.

Theatre manager, case site D₁ (068); transcription 7:32

In the excerpt from transcription 7:33, below, the strategic negotiation led by the consultant surgeon exposes the reasons given by some surgical colleagues for their reluctance to adopt the WHOSSC.

... When we started we also went to people, individually, and spoke with them and gauged their resistance to it – you have to negotiate that with the individuals – a lot of it was, you know, a lot of people were fairly positive; but as I said they were the believers in the first place. Some people said: ‘well OK, well it won’t do any harm, so I might as well just do it just to please you’, which isn’t particularly positive but they did it.

Now, there are always going to be a group of people that will simply refuse and we basically ignored them – that was too big a fish to fry – because they were worried about other issues of their job of which the WHO checklist was a very small part. I mean colleagues would say, in as many words: ‘why would I worry about doing the WHO checklist at the beginning of the list when I can’t even guarantee that all of my patients get into hospital!’, which is understandable and real problem and it’s something we all grapple with. So it’s very difficult to say to them: ‘OK, well this is only a small change that you’re going to make and I can’t help you with your patients’ access’ as some will just say: ‘well, OK, I’ll help you out’ but others will say: ‘sort out my issues first, then I’ll help you!’. One way or the other, they’re sort of trying to get leverage.

Consultant surgeon, case site D₁ (083); transcription 7:33

Transcription 7:34, and transcription 7:35, below, illustrate the nuanced negotiation that is demanded under a situational logic of correction/compromise and the creative institutional work involved in reconstructing the social rules impacting on each operating theatre team, despite the lingering barriers of professional power and legitimacy.

We can only persuade people that it’s what they need to do. I can do very little – I have no authority over any of the medical staff – I have some power to tell staff what to do. But I think all along we’ve taken the approach that we’re trying to get people on our side, to understand the importance of the WHO checklist because what I’m asking people to do is – before you hand the knife over to the surgeon, after you’ve prepped and draped the patient, and it’s all ready to go, the anaesthetist is ready to go – is that you stop and get everybody’s attention and there is a point where you have that opportunity. But they have that power because they’ve got the knife. If they don’t hand it over and say: ‘right, we’re going to do the time out, we don’t start operating’ because if you give them the knife then they’re away, and they’re doing it. But it’s the constant sort of having to nag – it needs quite a strident person to be able to stand there, an empowered person – to stand there and say: ‘you’re not starting until you’ve done this’.

Theatre nurse, case site D₁ (029); transcription 7:35

Structural elaboration or reproduction in the Welsh health-care field

In examining the contested institutionalisation of the WHOSSC under a situational logic of correction/compromise we sought to gauge key actors’ perceptions of emergent outcomes. Structural change, wrought through the introduction of the WHOSSC and its integration into governance processes, was viewed to have been achieved. However, some interviewees openly acknowledged decoupling from governance processes and the diminishing of the RSC and WHOSSC to a ‘tick-box exercise’ (transcriptions 7:36 and 7:37, below).

As far as the WHO checklist [long pause]. I think it’s disappointing that the figures that are sent in to the centre about compliance bear no resemblance to what’s actually going on out in the service. I just worry that people at the top may be comfortable in the fact that everyone’s having a WHO checklist done and that’s not – that’s not – the case.

Theatre manager, case site C₁ (006); transcription 7:36

I think they saw the benefit but the time constraints get in the way – it became a tick-box exercise – and they weren't being filled in properly. I remember going round to pick up the form, and seeing someone quickly take it off the stand and tick it, so that data was not really true. The worth wasn't seen immediately.

Theatre nurse, case site D₁ (113); transcription 7:37

Yet other interviewees, who viewed the institutionalisation of the RSC and WHOSSC pragmatically, perceived structural progress, albeit blended with residual gaps due to professional cultural contradictions. Transcription 7:38, below, captured a cautionary viewpoint that acknowledged that discrete aspects of the WHOSSC had indeed failed to fully embed into daily practice. This reveals an important issue to be addressed when seeking to attain such cultural change: the act of brokering alignment between discordant professional logics demands ongoing creative institutional work to promote the desired alignment and unification at the cultural-system level.

The WHO checklist does work now, generally, but there are gaps. The things that didn't really take off were things like the theatre briefings before the meetings – they keep being revisited but they keep failing – and they're trying to relaunch those in [name, different health board] too! They talk about these 'champion theatres' of course but nobody knows what champion theatres are! If you ask anyone who's not in the know – who isn't a believer – then they won't have a clue! It's then very difficult to say: 'look, the guys in Theatre 3 are doing really good work, can you do the same?' And they say: 'well I don't know anything about it, why should I do that? What's in it for me?' It's compulsory! But even then it won't be taken care of.

Consultant surgeon, case site D₁ (083); transcription 7:38

In contrast, no pejorative stance muted the perceived success reported in transcriptions 7:39 and 7:40; although the respondent in transcription 7:40, below, was concerned about disparity in theatre department practice, this was mitigated by the belief that auditing such engagement would accommodate, though not reconcile, such variation.

The WHO checklist has been rolled-out across the organisation for some time now and it's used in each of our theatre suites. But how it's used is different, it's different: some of them will do their team debrief on the same day, others will do the WHO meetings all in the meeting, and then it's managed differently. But whatever they're doing it's audited. The activity around the WHO checklist is audited every month.

Associate Director, case site C₁ (119); transcription 7:40

Such varied responses underline the need for leadership and skilled strategic negotiation to broker compromise, contain discord and disregard among the disbelievers and deliver successful change to promote local patient safety practices.

1000 Lives+ institutionalisation: RSC – local implementation of the focal intervention and contribution to the I-CMAO configuration spanning the Welsh health-care field

We now seek to further our understanding of the local implementation of RSC-WHOSSC in theatre departments, and to define its contribution to the 1000 Lives+ programmes' I-CMAO configuration spanning the Welsh health-care field.

As illustrated in *Figure 20* and *Tables 22–26*, the RSC and WHOSSC were a mandatory part of the 1000 Lives+ programme, signalling systemic legitimisation and promoting negotiation across those staff tasked with the implementation of the intervention. This ensured that formalisation and the co-optation of others occurred. It also promoted the deinstitutionalisation of redundant theatre practices and fostered the preinstitutionalisation of the WHOSSC, together with other less controversial practices.

Tables 25 and *26* illustrate the type of information made publicly available as part of the new emphasis on transparency in relation to patient safety. They relate to the incidence of so-called 'never events' in surgery that the WHOSSC was designed to prevent.

Across each case site, the situated context was essentially comparable and overtly coercive; however, relational structures – the ties that bind social actors – were different. In each health board, innovation emerged from the MI-PDSA approach. Though this led to the identification of problems and systematic failings, thereby catalysing knowledge mobilisation and the validation of practices, the broader moral and pragmatic legitimisation of the WHOSSC remained contested.

To forward our I-CMAO configuration we turn to the findings of our realist analysis. First, in *Figure 20*, we consider the overall scheme of the intervention across the different structural contexts. Following this, in *Tables 25–27*, respectively, we show I-CMAO configurations illustrating the infrastructural system of the Welsh Government, the institutional setting of NHS Wales and its constituent health boards, and interpersonal relationships within the institutional settings.

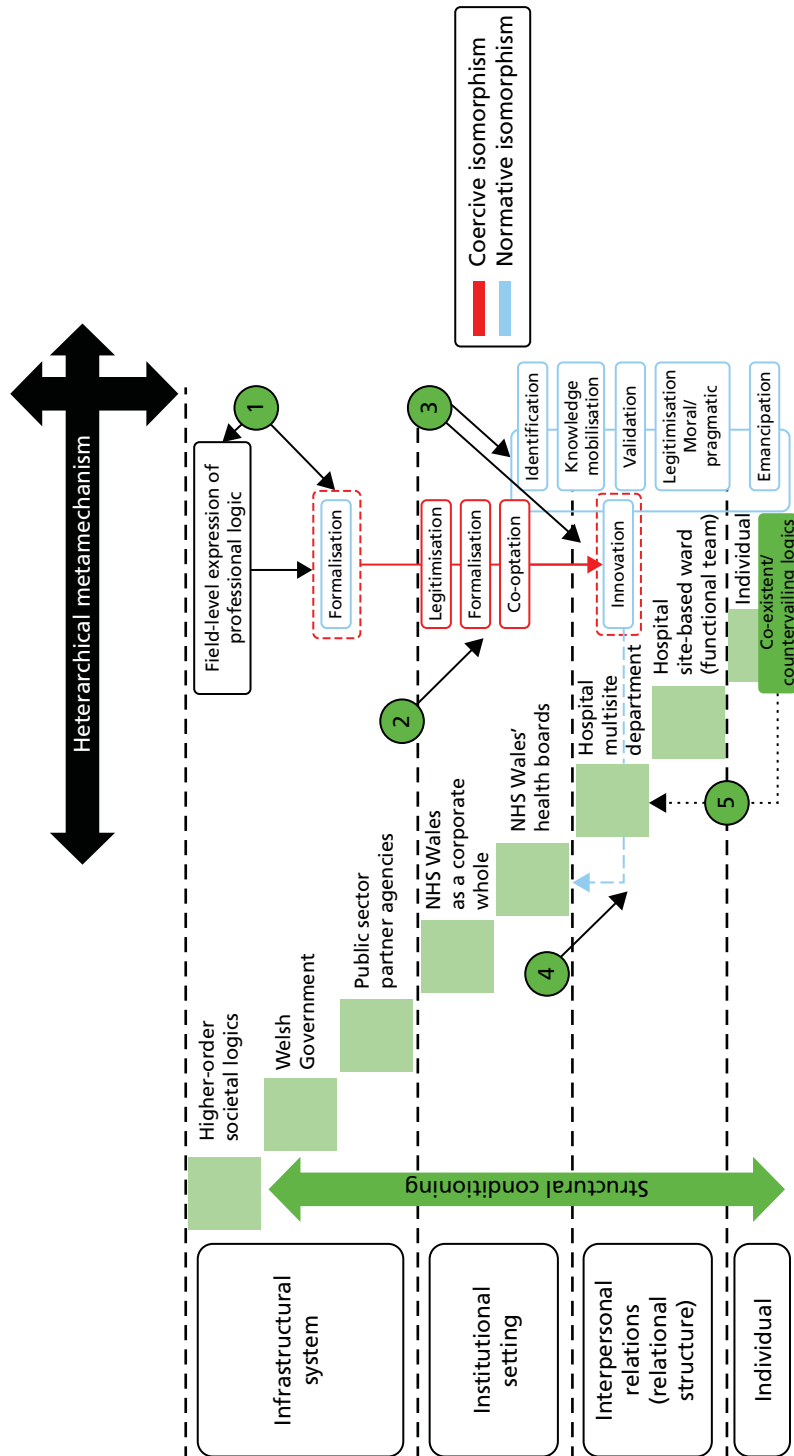


FIGURE 20 Reducing Surgical Complications: heterarchical metamechanism operating across contextual strata.

Figure 20: key point summary

In *Figure 20* we depict the implementation of the WHOSSC component of the RSC focal intervention.

In point 1 we draw attention to the formalisation of this process via professional guidelines and Welsh Government policy, thereby mandating engagement by all health boards and relevant theatre department staff.

In point 2, such structural constraint impacts at the level of the theatre department, fostering the co-optation of others, primarily surgical, anaesthetic, nursing and operation department practitioner staff, to support the implementation of the WHOSSC.

In point 3 such mandated engagement drives the innovation cycle in the situated context, so that new practices associated with the WHOSSC are enacted.

In point 4 we depict feedback through the multisite department to the health board as the operationalisation of the WHOSSC component of the RSC focal intervention gradually systematises across NHS Wales.

In point 5 we depict co-existent and countervailing logics, which, though muted by structural constraint, nonetheless impact at the level of the multisite department.

TABLE 22 Reducing Surgical Complications I-CMAO configuration: infrastructural system – Welsh Government

Intervention	1000 Lives+ national programme	
Component	RSC and WHOSSC	
Context	Welsh Government	
Mechanisms	<ul style="list-style-type: none"> ● Institutional isomorphism – coercive, mimetic and normative ● Coherence, cognitive participation and reflexive monitoring 	
Agency and institutional work	Normalisation: coupling to 1000 Lives+ and WHOSSC <ul style="list-style-type: none"> ● Agency – formalisation ● Institutional work – creation ● Leadership: distributed across policy and professional domains ● Team work: policy leads and professional engagement across aligned organisations ● Encultured values: centred on defining RSC and WHOSSC as mandated evidence-based practices 	Habituation: decoupling to 1000 Lives+ and WHOSSC <ul style="list-style-type: none"> ● Decoupling limited by structural and cultural constraints within infrastructural system
Outcome	1000 Lives+ national programme, RSC and WHOSSC institutionalised into policy processes	
	Exemplar transcriptions <ul style="list-style-type: none"> ● Agency – formalisation ● Institutional work – creation ● 7:01 (T146) – Coupling ● 7:02 (T083) – Coupling ● 7:03 (T005) – Coupling 	

TABLE 23 Reducing Surgical Complications I-CMAO configuration: institutional setting – NHS Wales and constituent health boards

Intervention	1000 Lives+ national programme	
Component	RSC and WHOSSC	
Context	NHS Wales as a corporate whole/NHS Wales' health boards	
Mechanisms	<ul style="list-style-type: none"> • Institutional isomorphism – coercive, mimetic and normative • Coherence, cognitive participation and reflexive monitoring 	
Agency and institutional work	<p>Normalisation: coupling to 1000 Lives+ and WHOSSC</p> <ul style="list-style-type: none"> • Agency – negotiation under a situational logic of correction/compromise • Institutional work – creation • Leadership: typically, consultant surgeon-led participative negotiation of the brokerage of change • Team work: harnesses multiprofessional leadership to foster adoption of the WHOSSC, augmented by heterarchical relational structure across theatre micro-work system • Encultured values: centred on 'believers' to embed WHOSSC and associated practices across the theatre micro-work system to address perceived problems • Agency – legitimisation • Institutional work – creation • Leadership: distributed, augmented by local champions • Team work: centred on MI-PDSA approach to change. • Encultured values: 'trying to get people on our side' to broker meaningful engagement • Agency – formalisation • Institutional work – creation • Leadership: medical director-led, formalised through revalidation/ relicensure process • Team work: centred on medical professional networks • Encultured values: drive for cultural change aligned to demands of Francis Report • Agency – co-optation • Institutional work – creation • Leadership: distributed, augmented by local champions, and supported by 1000 Lives' team • Team work: 'flattened' hierarchy, with heightened scope for nurse leadership of change • Encultured values: acceptance of challenge across theatre micro-work system 	<p>Habituation: decoupling to 1000 Lives+ and WHOSSC</p> <ul style="list-style-type: none"> • Agency – negotiation under a situational logic of correction/compromise • Institutional work – maintenance • Leadership: consultant surgeon-led, status a profound barrier to the participative negotiation of the brokerage of change • Team work: surgical professional role-position practices dominate with hierarchical relational structure of the theatre micro-work system • Encultured values: WHOSSC poses challenge to traditional surgical professional role-position practices and is a management means of control • Decoupling limited by structural and cultural constraints within institutional setting • Decoupling limited by structural and cultural constraints within institutional setting • Agency – co-optation • Institutional work – creation • Leadership: 'isolated', nurse led, ill equipped to broker change • Team work: fragmented and unsupportive of the change • Encultured values: WHOSSC is 'just a bit of paper that does not do anything'

continued

TABLE 23 Reducing Surgical Complications I-CMAO configuration: institutional setting – NHS Wales and constituent health boards (*continued*)

Outcome	<ul style="list-style-type: none"> Coupling 1000 Lives+ national programme and WHOSSC approach embraced and absorbed into extant management, internal governance and audit processes 	<ul style="list-style-type: none"> Decoupling 1000 Lives+ national programme and WHOSSC approach resisted and adsorbed onto extant management, internal governance and audit processes 								
	<p>Exemplar transcriptions</p> <table border="0"> <tr> <td> <ul style="list-style-type: none"> Agency – negotiation under a situational logic of correction/compromise Institutional work – creation </td> <td> <ul style="list-style-type: none"> 7:06 (T063) – Decoupling 7:07 (T117) – Decoupling 7:20 (T083) – Decoupling/coupling 7:21 (T117) – Decoupling 7:33 (T083) – Decoupling/coupling </td> </tr> <tr> <td> <ul style="list-style-type: none"> Agency – legitimisation Institutional work – creation </td> <td> <ul style="list-style-type: none"> 7:34 (T028) – Coupling 7:35 (T029) – Coupling </td> </tr> <tr> <td> <ul style="list-style-type: none"> Agency – formalisation Institutional work – creation </td> <td> <ul style="list-style-type: none"> 7:26 (T062) – Coupling </td> </tr> <tr> <td> <ul style="list-style-type: none"> Agency – co-optation Institutional work – creation </td> <td> <ul style="list-style-type: none"> 7:10 (T041) – Coupling 7:17 (T062) – Coupling 7:25 (T117) – Decoupling 7:30 (T005) – Coupling </td> </tr> </table>		<ul style="list-style-type: none"> Agency – negotiation under a situational logic of correction/compromise Institutional work – creation 	<ul style="list-style-type: none"> 7:06 (T063) – Decoupling 7:07 (T117) – Decoupling 7:20 (T083) – Decoupling/coupling 7:21 (T117) – Decoupling 7:33 (T083) – Decoupling/coupling 	<ul style="list-style-type: none"> Agency – legitimisation Institutional work – creation 	<ul style="list-style-type: none"> 7:34 (T028) – Coupling 7:35 (T029) – Coupling 	<ul style="list-style-type: none"> Agency – formalisation Institutional work – creation 	<ul style="list-style-type: none"> 7:26 (T062) – Coupling 	<ul style="list-style-type: none"> Agency – co-optation Institutional work – creation 	<ul style="list-style-type: none"> 7:10 (T041) – Coupling 7:17 (T062) – Coupling 7:25 (T117) – Decoupling 7:30 (T005) – Coupling
<ul style="list-style-type: none"> Agency – negotiation under a situational logic of correction/compromise Institutional work – creation 	<ul style="list-style-type: none"> 7:06 (T063) – Decoupling 7:07 (T117) – Decoupling 7:20 (T083) – Decoupling/coupling 7:21 (T117) – Decoupling 7:33 (T083) – Decoupling/coupling 									
<ul style="list-style-type: none"> Agency – legitimisation Institutional work – creation 	<ul style="list-style-type: none"> 7:34 (T028) – Coupling 7:35 (T029) – Coupling 									
<ul style="list-style-type: none"> Agency – formalisation Institutional work – creation 	<ul style="list-style-type: none"> 7:26 (T062) – Coupling 									
<ul style="list-style-type: none"> Agency – co-optation Institutional work – creation 	<ul style="list-style-type: none"> 7:10 (T041) – Coupling 7:17 (T062) – Coupling 7:25 (T117) – Decoupling 7:30 (T005) – Coupling 									

TABLE 24 Reducing Surgical Complications I-CMAO configuration: institutional setting – interpersonal relations

Intervention	1000 Lives+ national programme	
Component	RSC and WHOSSC	
Context	Hospital multisite department/hospital site-based ward (functional team)	
Mechanisms	<ul style="list-style-type: none"> Institutional isomorphism – coercive, mimetic and normative Coherence, cognitive participation and reflexive monitoring 	
Agency and institutional work	<p>Normalisation: coupling to 1000 Lives+ and WHOSSC</p> <ul style="list-style-type: none"> Agency – innovation Institutional work – creation Leadership: nurse-led practice-based focus Team work: nurse-led practice-based focus Encultured values: MI-PDSA central to practice-based change <ul style="list-style-type: none"> Agency – identification Institutional work – creation Leadership: distributed Team work: multiprofessional engagement with WHOSSC Encultured values: exposure of non-adherence to WHOSSC to limit decoupling 	<p>Habituation: decoupling to 1000 Lives+ and WHOSSC</p> <ul style="list-style-type: none"> Agency – innovation Institutional work – maintenance Leadership: surgeon led Team work: fragmented and unsupportive of the change Encultured values: WHOSSC poses challenge to traditional surgical professional role-position practices and is a management means of control <ul style="list-style-type: none"> Agency – identification Institutional work – maintenance/disruption Leadership: disengaged Team work: limited identification of errors, compounded by weak audit practices Encultured values: WHOSSC ‘tick-box’ exercise with acceptance of poor and overt malpractice normalised with failure to identify errors. Expanded in <i>Tables 28</i> and <i>29</i>

TABLE 24 Reducing Surgical Complications I-CMAO configuration: institutional setting – interpersonal relations (*continued*)

Agency and institutional work	<ul style="list-style-type: none"> ● Agency – knowledge mobilisation ● Institutional work – creation ● Leadership: distributed ● Team work: multisite enabled knowledge mobilisation supported via 1000 Lives+ networking events ● Encultured values: acceptance of challenge to foster innovation and change across theatre micro-work system ● Agency – validation ● Institutional work – creation ● Leadership: theatre manager-led governance and audit processes established ● Team work: multidisciplinary participation in governance and audit processes ● Encultured values: monitoring and measurement of patient safety ● Agency – legitimisation (moral/pragmatic) ● Institutional work – creation ● Leadership: distributed ● Team work: multiprofessional participation in WHOSSC ● Encultured values: WHOSSC accepted as ‘routine’ theatre practice ● Agency – emancipation ● Institutional work – disruptive ● Leadership: centred on role-position practices which erode traditional medical power base ● Team work: negotiated engagement with WHOSSC ● Encultured values: acceptance of challenge across multidisciplinary team 	<ul style="list-style-type: none"> ● Agency – knowledge mobilisation ● Institutional work – creation ● Leadership: disengaged ● Team work: limited identification of errors, compounded by weak audit practices ● Encultured values: WHOSSC ‘tick-box’ exercise with acceptance of poor and overt malpractice normalised ● Agency – validation ● Institutional work – maintenance ● Leadership: theatre manager-led processes established ● Team work: multidisciplinary participation on governance processes contested ● Encultured values: WHOSSC ‘tick-box’ exercise with acceptance of poor and overt malpractice normalised ● Agency – legitimisation (moral/pragmatic) ● Institutional work – creation ● Leadership: disengaged, especially by consultant surgical staff ● Team work: contested participation in WHOSSC ● Encultured values: WHOSSC ‘tick-box’ exercise with acceptance of poor and overt malpractice normalised ● Agency – emancipation ● Institutional work – maintenance ● Leadership: ‘isolated’, nurse led, ill equipped to broker change ● Team work: fragmented and unsupportive of the change ● Encultured values: WHOSSC is ‘just a bit of paper that doesn’t do anything’
Outcome	<ul style="list-style-type: none"> ● Coupling 1000 Lives+ national programme and WHOSSC approach embraced and absorbed into daily practice 	<ul style="list-style-type: none"> ● Decoupling 1000 Lives+ national programme and WHOSSC approach resisted and only lip service given to outward form of practice

continued

TABLE 24 Reducing Surgical Complications I-CMAO configuration: institutional setting – interpersonal relations (*continued*)

Exemplar transcriptions	
<ul style="list-style-type: none"> Agency – innovation Institutional work – creation 	<ul style="list-style-type: none"> 7:13 (T006) – Coupling 7:14 (T068) – Coupling 7:15 (T063) – Decoupling
<ul style="list-style-type: none"> Agency – identification Institutional work – creation 	<ul style="list-style-type: none"> 7:11 (T008) – Coupling 7:18 (T059) – Decoupling 7:27 (T008) – Decoupling 7:31 (T049) – Coupling 7:36 (T006) – Decoupling 7:40 (T119) – Coupling
<ul style="list-style-type: none"> Agency – knowledge mobilisation Institutional work – creation 	<ul style="list-style-type: none"> 7:14 (T068) – Coupling 7:24 (T112) – Decoupling
<ul style="list-style-type: none"> Agency – validation Institutional work – maintenance 	<ul style="list-style-type: none"> 7:28 (T029) – Decoupling 7:36 (T006) – Decoupling 7:37 (T113) – Decoupling 7:38 (T083) – Coupling/Decoupling 7:40 (T119) – Coupling
<ul style="list-style-type: none"> Agency – legitimisation (moral/pragmatic) Institutional work – creation 	<ul style="list-style-type: none"> 7:08 (T029) – Decoupling 7:15 (T063) – Decoupling 7:16 (T064) – Decoupling 7:19 (T061) – Decoupling 7:22 (T024) – Coupling 7:32 (T068) – Decoupling 7:39 (T005) – Coupling
<ul style="list-style-type: none"> Agency – emancipation Institutional work – disruptive 	<ul style="list-style-type: none"> 7:25 (T028) – Decoupling 7:30 (T005) – Coupling

TABLE 25 Reducing Surgical Complications: local implementation – ‘never events’ across NHS Wales’ health boards: 1 April 2012 to 31 March 2013

Health board	Type of surgical ‘never events’	Details
Abertawe Bro Morgannwg University Health Board	<ul style="list-style-type: none"> Retained instrument Wrong implant/prosthesis Retained foreign object post operation 	<ul style="list-style-type: none"> Retained swab Right implant into left knee Retained swab
Aneurin Bevan University Health Board	<ul style="list-style-type: none"> Wrong implant/prosthesis 	<ul style="list-style-type: none"> Wrong size lens
Betsi Cadwaladr University Health Board	<ul style="list-style-type: none"> Retained foreign object post operation Wrong-site surgery 	<ul style="list-style-type: none"> Retained swab Wrong tooth removed
Cardiff and Vale University Health Board	<ul style="list-style-type: none"> Misplaced naso or orogastric tube Retained foreign object post operation 	<ul style="list-style-type: none"> Misplaced nasogastric tube Silicone object
Cwm Taf Health Board	None recorded	None recorded
Hywel Dda Health Board	<ul style="list-style-type: none"> Retained instrument 	<ul style="list-style-type: none"> Retained swab
Powys (Teaching) Health Board	None recorded	None recorded

Data accessed via Patient Safety Wales: www.patientsafety.wales.nhs.uk/never-events.

TABLE 26 Reducing Surgical Complications: local implementation – ‘never events’ across NHS Wales’ health boards, 1 April 2013 to 31 March 2014

Health board	Type of surgical ‘never events’	Details
Abertawe Bro Morgannwg University Health Board	<ul style="list-style-type: none"> Retained foreign object post operation Misplaced naso or orogastric tube Wrong-site surgery 	<ul style="list-style-type: none"> Retained swab Misplaced nasogastric tube Wrong toe incised
Aneurin Bevan University Health Board	<ul style="list-style-type: none"> Retained foreign object post operation Retained foreign object post operation Retained foreign object post operation 	<ul style="list-style-type: none"> Retained swab Retained foreign object Retained tip of needle identified postoperatively
Betsi Cadwaladr University Health Board	<ul style="list-style-type: none"> Misidentification of patient Wrong-site surgery Maladministration of insulin Maladministration of insulin Wrong gas administered Wrong-site surgery 	<ul style="list-style-type: none"> Wrong patient had exploratory procedure Wrong part of organ identified: rectified during procedure No wristband in place: misidentification of patient Maladministration of insulin Seal not removed on oxygen cylinder Left side prosthesis implanted instead of right
Cardiff and Vale University Health Board	<ul style="list-style-type: none"> Wrong-site surgery Wrong-site surgery Air embolism 	<ul style="list-style-type: none"> Wrong scar site identified for procedure Initial skin incision incorrectly made: rectified during procedure Intraoperative air embolism
Cwm Taf Health Board	<ul style="list-style-type: none"> Misplaced naso- or orogastric tube 	<ul style="list-style-type: none"> Misplaced nasogastric tube
Hywel Dda Health Board	<ul style="list-style-type: none"> Misidentification of patient 	<ul style="list-style-type: none"> Relates to histopathology specimens
Powys (Teaching) Health Board	None recorded	None recorded

Data accessed via Patient Safety Wales: www.patientsafety.wales.nhs.uk/never-events.

TABLE 27 Reducing Surgical Complications: realist analysis – signposting how the empirical data connect to I-CMAO

Intervention	RSC
Component	WHOSSC
Context	Structural conditioning of the institutional setting: NHS Wales health boards’ implementation of 1000 Lives+ national programme’s RSC
Structural emergent properties	<ul style="list-style-type: none"> Structural constraints and enablements shaped by the bureaucratic processes of formalisation emergent from the infrastructural system of the Department of Health and Social Care impact 1000 Lives+, RSC and WHOSSC The dominant structural emergent property impacting the RSC and associated WHOSSC was the overarching policy mandate of the 1000 Lives+ national programme. The policy and professional compulsion to undertake the WHOSSC, therefore, created a sense of structural force majeure

continued

TABLE 27 Reducing Surgical Complications: realist analysis – signposting how the empirical data connect to I-CMAO (continued)

Cultural emergent properties	<ul style="list-style-type: none"> The dominant cultural emergent properties, which moulded the institutionalisation of the 1000 Lives+ RSC and WHOSSC, arose from the institutional system emblematic of the theatre departments, namely its sense of separation from the health board, compounded by distinctive functional and professional cultures
Social actors	<ul style="list-style-type: none"> Consultant surgeons tasked with the implementation of the WHOSSC: the focal intervention WHOSSC is targeted to all theatre department staff
Social position	<ul style="list-style-type: none"> Elite power role with high social position, professional standing and widespread networks
Role-position practices	<ul style="list-style-type: none"> Professional role-position practices centred on professional leadership of surgical staff and close liaison with theatre manager and theatre nursing staff and operating department practitioners
Mechanism	Mediation of structural conditioning to core actors and their reflexive theorisation
Institutional logics and type of alignment between core actors	Consultant surgeons tasked with the implementation of the WHOSSC operated under a professional logic that was aligned to the dominant logic of the bureaucratic state and professional health-care management logic. However, their actions were directed to managing the tension promoted by the countervailing stance adopted by other surgeons
First-order emergents	The vested interests of consultant surgeons, tasked with the implementation of the RSC and WHOSSC, lay primarily in the successful brokerage of theatre staff engagement with the WHOSSC
Second-order emergents	Constraining contradictions (necessary incompatibilities) between the dominant logic of the bureaucratic state and aligned professional health-care management logic vs. that of professional medical logic held by surgeons opposed to the introduction of the WHOSSC
Situational logic	Correction/compromise
Reflexive theorisation	<p>For consultant surgeons tasked with the implementation of the WHOSSC, their logic is shaped by alignment between the dominant logic of the bureaucratic state, aligned professional health-care management logic, and that of their professional medical logic. This therefore fosters coherence, cognitive participation and reflexive monitoring focused towards addressing the constraining contradictions, which arise as a result of the countervailing professional medical logic held by surgeons opposed to the introduction of the WHOSSC, and who remain disengaged</p> <p>The reflexive theorisation of consultant surgeons tasked with the implementation of the WHOSSC is, therefore, directed towards the discernment of issues impairing such logical alignment, the deliberation of their importance, and dedication of ensuing agency to broker compromise to correct and counteract the opposing stance thereby normalising the WHOSSC into daily practice</p>
Agency and institutional work	Agency, the unfolding strategic negotiation of change, and the mode of institutional work enacted
Agential emergent properties	Agency was directed to managing the tension promoted by the countervailing stance of professional medical logic
Strategic negotiation	<ul style="list-style-type: none"> Power-induced compliance and political sanction Reciprocal exchange and harmonisation of desires
Institutional work	Multimodal

- Exemplar transcriptions: 7:02, 7:09, 7:15, 7:16
- Exemplar transcriptions: 7:06, 7:17, 7:19, 7:20

TABLE 27 Reducing Surgical Complications: realist analysis – signposting how the empirical data connect to I-CMAO (*continued*)

Agency and institutional work	Agency, the unfolding strategic negotiation of change, and the mode of institutional work enacted
Outcome	Social elaboration, reproduction or invariance
Structural	Structural change, wrought through the introduction of the WHOSSC and its integration into governance processes, was achieved. However, the openly acknowledged decoupling from governance processes distorted coherence and commitment to the RSC and WHOSSC by diminishing it to a tick-box exercise
Cultural	Cultural change limited as harmonising discordant professional logics demands prolonged creative institutional work to promote the desired coalescence and unification at the cultural system level
Agential	Invariant

Finally, in *Table 27*, and focusing, for expediency, primarily on the generative mechanisms and ensuing agency attributed to consultant staff tasked with the implementation of the RSC and WHOSSC, we present our realist analysis linking the empirical data to I-CMAO.

As alluded to above, a sense of structural force majeure was evident, but its influence was reduced by theatre departments' feeling of relative separation from the parent health board and wider health-care institutional field. Consultant staff, tasked with the implementation of the RSC and the WHOSSC, were confronted by the contradictions between the dominant logic of the bureaucratic state and aligned professional health-care management logic and that of professional medical logic. In such circumstances a situational logic of correction/compromise arose that was open to the power play of different professional groups, each seeking to turn such sociocultural constraint to their advantage.

As set out in *Table 27*, the reflexive theorisation of consultant staff tasked with the implementation of the RSC and the WHOSSC focused on addressing the concerns of surgeons opposed to the introduction of the WHOSSC. Their thinking and actions were, therefore, directed towards seeking the reasons for such opposition and seeking ways of finding compromise positions and/or solutions which would be acceptable to the dissidents and enable the WHOSSC to be normalised into daily practice.

The structural elaboration evident across each case site was shaped by the integration of the WHOSSC into governance processes. However, the openly acknowledged decoupling of the insulated surgical theatre world from such governance processes distorted coherence and commitment to the RSC and the WHOSSC by diminishing it to a tick-box exercise. Indeed, the large number of 'never events' (serious patient safety violations) which occurred in NHS Wales' health boards during the period 1 April 2012 to 30 September 2013 (see *Tables 28* and *29*), while unable to necessarily be directly attributed in part or in whole to failure to implement the WHOSSC, serve only to underscore such decoupling.

This contested institutional change highlights the time required to negotiate alignment between discordant professional logics and stresses the complexity of the creative institutional work required.

Summary

In *Chapter 7*, we furthered our understanding of the local implementation of the focal intervention, RSC, centred on the WHOSSC, and defined its contribution to the 1000 Lives+ programmes' I-CMAO configuration spanning the Welsh health-care field.

Chapter 8 Reducing Health-care-Associated Infection

Overview

In this chapter we examine RHA1, the final focal intervention drawn from the 1000 Lives+ programme. Our attention was directed to two aspects of this patient safety intervention: (1) hand hygiene and (2) the appropriate use of antimicrobial drugs. Importantly, in contrast to the other focal interventions selected from the 1000 Lives+ national programme, set out in *Chapters 6 and 7*, such interventions do not represent practice innovations. Instead, they represent the consolidation of established best practice. We begin with a brief overview of the RHA1, defining its multicomponent structure, aim and drivers. This we augment with a review of health-care-associated IPAC, highlighting key issues and the challenges that confront developed health-care systems.

Second, we undertake a realist analysis of the institutionalisation of RHA1 in Wales, as illustrated by our comparative case study of sites A, B, C and D. We explain the structural conditioning, sociocultural interaction and structural elaboration or reproduction fostered through the actions of three groups of key actors: consultant microbiologists, IPAC nurses and pharmacists specialising in antibiotics medicines management. We concentrate on these three groups because they are directly involved in the operation of RHA1 under the 1000 Lives+ programme, but we also include in our analysis the perceptions of a wide range of health-care professionals. Finally, informed by the findings of our realist analysis, we set out our understanding of the RHA1 I-CMAO configuration.

Focal intervention, aim and drivers

Reducing Health-care-Associated Infection, the last of the three focal interventions considered in this study, aims to support health-care staff to reduce the overall burden of nosocomial (hospital-acquired) infection in NHS Wales. As illustrated in *Figure 21*, RHA1 comprises four interventions to prevent the transmission of infection, two of which are aligned to promote the effective treatment of infection, and a further three interventions to facilitate patient involvement in their care. During the period of this study RHA1 was augmented with further advice on the appropriate and timely use of invasive devices, specifically guidance aimed to reduce peripheral venous cannula (PVC) and catheter-associated urinary tract infections (CAUTI). This extension was beyond the scope of our research protocol and ethics submissions, and so our research focused on standard precautions for hand hygiene to prevent the transmission of infection and the appropriate use of antimicrobial drugs to ensure the effective prevention and treatment of infection. Nonetheless, the publicity surrounding the launch and implementation of the PVC and CAUTI interventions impacted on the context of care.

Health-care-associated infection, prevention and control

Health-care-associated infection (HCAI), prevention and control is an issue that impacts on developed and developing health-care systems.^{572–574} It is a source of concern for politicians, health-care professionals, patients and the public alike.^{575,576} Addressing the human costs in terms of morbidity and mortality is paramount,^{577,578} but there is also a need to minimise the cost burden incurred through protracted treatment and extended lengths of stay.^{577,579–582} A range of patient safety interventions have been designed to improve this problem.^{181,583–590} Such interventions typically encompass (i) mandatory reporting and surveillance programmes;^{591–594} (ii) ensuing targets, standards and performance indicators for IPAC,^{595–620} especially for high-risk clinical practices^{600–602} and vulnerable patient groups;^{603–606} and (iii) heightened control over the use of antimicrobial drugs in the face of

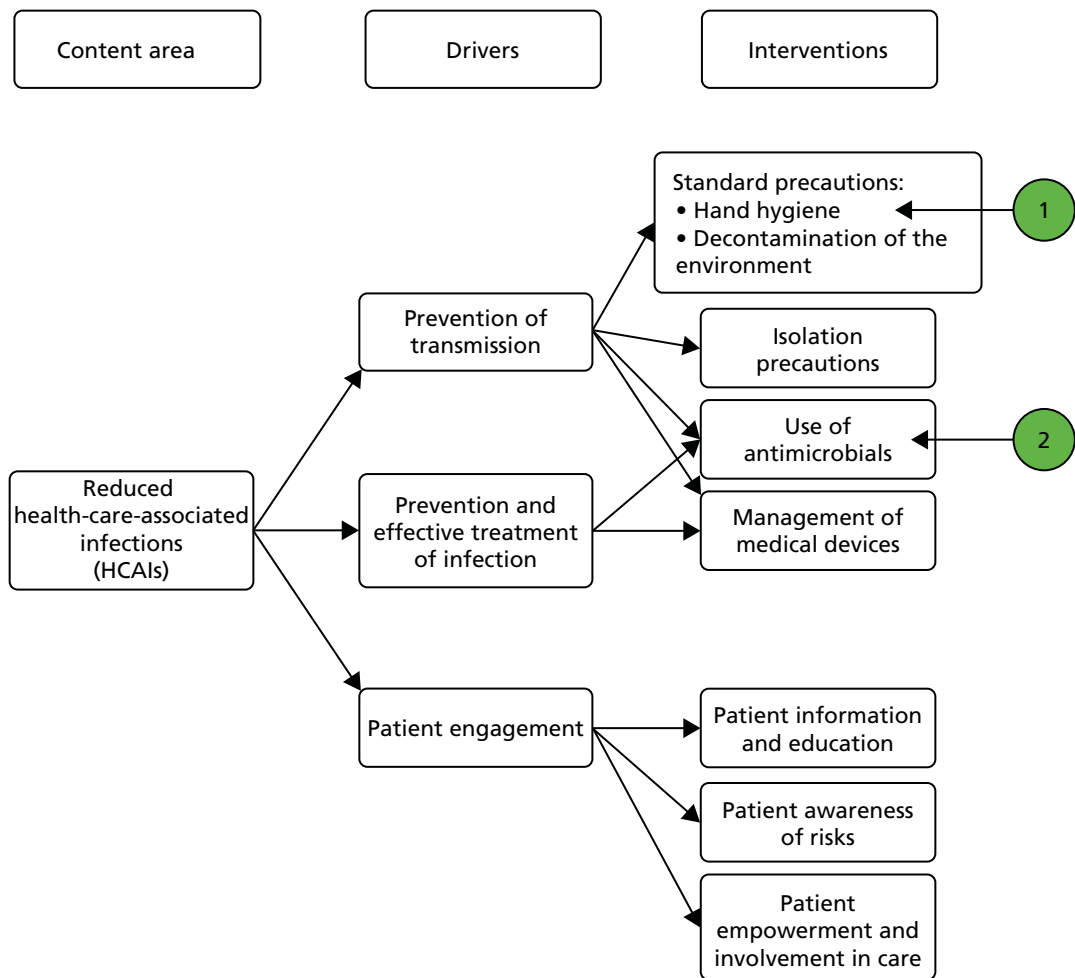


FIGURE 21 Driver diagram: RHAIs.

Figure 21: key point summary

Figure 21 depicts the driver diagram for the focal intervention: RHAIs. Attention is directed to two of the four aspects of this patient safety intervention which are focused at clinical and other staff, as defined below:

- point 1, standard precautions for hand hygiene to prevent the transmission of infection and
- point 2, appropriate use of antimicrobial drugs to ensure the effective prevention and treatment of infection.

To aid our understanding of the interplay of context and mechanism in the operationalisation of this focal intervention, the perspectives of consultant microbiologists, IPAC nurses and pharmacists specialising in antibiotics medicines management, each directly involved in the operationalisation of the RHAIs under the auspices of the 1000 Lives+ national programme, enrich our analysis.

In contrast to the other focal interventions selected from the 1000 Lives+ national programme, standard precautions for hand hygiene and the appropriate use of antimicrobial drugs do not represent practice innovations but are merely the consolidation of established best practice.

the changing epidemiology of HCAs,^{589,607–610} exemplified by the rise of MRSA and extended-spectrum beta-lactamase (ESBL)-producing strains of *Escherichia coli* and *Klebsiella pneumoniae*.^{609,611–619}

In the NHS, following major outbreaks of hospital-acquired (nosocomial) infection,⁶²⁰ national targets for the reduction of MRSA bacteremias (blood infections) and *C. difficile* (gastrointestinal) infection are supported by enhanced mandatory surveillance. Oversight rests with the Health Protection Agency in England and Scotland,^{592,597,621} and, in Wales, the WHAIP led by Public Health Wales. In this manner, IPAC is placed at the centre of clinical and corporate governance.⁶²² Indeed, the Health Act 2006 Code of Practice mandates adherence to national and local policies and protocols.⁶²³ Zero tolerance of HCAs^{624,625} is a primary policy goal.

Core to success is the enactment of good hand hygiene across health-care practitioners, support workers^{626–630} and patients.^{631–635} This standard precaution, perceived to be fundamental to safe health-care practice,⁶³⁶ is captured through the WHO's 'five moments of hand hygiene'.⁶³⁷ These guidelines harness a substantial evidence base in support of hand antisepsis to limit the incidence of HCAs.⁵⁸⁷ However, such education requires regular updating^{638–640} to promote the adoption of, and continued adherence to, evidence-based improvements,^{641,642} and monitoring systems are necessary to audit compliance.^{595,596,643–645}

Although existing studies highlight success in limiting HCAs^{48,181} through hand hygiene^{195,639,646–648} and wider reaching educational programmes,^{649–653} a high level of non-compliance with basic infection control measures persists among health-care professionals.⁶⁵⁴ Indeed, junior medical and nursing staff copy the aberrant behaviour of their superiors,^{655–657} which results in the entrenchment of non-compliance across successive generations.^{655–660} IPAC teams, therefore, have a central role to play in active staff engagement,⁶⁶¹ support for peer-to-peer education,⁶⁶² and the monitoring of HCAs to reduce the burden of avoidable harm to patients and its associated untoward costs.^{581,663–689}

The changing epidemiology of HCAs^{607,608,611,612,617,666–694} also places demands on medical microbiologists and clinical pharmacists specialising in antibiotic medicines management.^{57,671} Collectively, their active stewardship of antibiotic prescribing is acknowledged to limit overprescribing⁶⁷² and improve adherence to guidelines.^{673–676} However, their oversight of surgical prophylaxis is constrained by the charting and timing of the administration of such drugs within the theatre environment.^{677–679}

There are many other ways in which patients may acquire infections while in hospital. These include the use of invasive medical devices such as ventilators,^{48,680–710} intravenous and arterial cannulae^{605,687–690} and various sorts of catheter.^{691–695} However, these sources of infection and the precautions taken to avoid them are not considered in this study.

Realist analysis and comparative case study

We now undertake a critical realist analysis of the institutionalisation of the 1000 Lives+ programme's RHA. Again, our case study considers sites A, B, C and D. Our analysis focuses on three groups of key actors: consultant microbiologists, IPAC nurses and pharmacists specialising in antibiotics medicines management. Each is directly involved in the operation of RHA under the auspices of the 1000 Lives+ national programme. However, as HCAs are an issue for all to address, we include the perceptions of a wide range of health-care professionals in our analysis.

As in the two previous chapters, we consider the focal intervention in context and explore the dominant structural and cultural emergent properties impacting key actors involved in the operation of the RHA. Next, to reveal the generative mechanisms in play, we examine mediation via first- and second-order emergents and the resultant situational logic. Then, to examine the initiation of change, we explore the unfolding strategic negotiation of change and the mode of institutional work enacted. Finally, we reflect on the nature of any sustained outcome, be that elaborative or reproductive, that occurred following the

implementation of RHA1. This analysis forms the foundation of our refinement of the I-CMAO configuration spanning the Welsh health-care field in 1000 Lives+ *institutionalisation: RHA1 – local implementation of the focal intervention and contribution to I-CMAO configuration spanning the Welsh health-care field.*

Structural conditioning: structural and cultural emergent properties in the Welsh health-care field

In contrast to the other focal interventions selected from the 1000 Lives+ programme and analysed in Chapters 6 and 7, the discrete interventions selected from RHA1 – standard precautions for hand hygiene to prevent the transmission of infection and the use of antimicrobial drugs to ensure the effective prevention and treatment of infection – did not represent practice innovations. The dominant structural emergent properties impacting the RHA1 were, therefore, the complex array of established alternative frameworks and the ongoing surveillance of their effectiveness via the WHAIP (transcription 8:01, below).

The question for me is, how do we untangle 1000 Lives+ from all of the other elements in play – it's complicated, confounded – because what's happening is happening between 1000 Lives+, all of the other frameworks and antimicrobial guidelines that are out there, and mandatory surveillance reporting and feedback via WHAIP.

So, it's through one or a combination of all of those things that the higher echelons, if you like, of hospital management are now faced with infection control, and its importance, much more so than they were 10 years or so ago, or even less than that. So I think, whether it's due to 1000 Lives+, other frameworks, or the surveillance processes in place, I think it's achieving something – because they have to be aware and address HCAI due to WHAIP reporting to the Welsh Government – my impression is that they are aware of it and they feel accountability.

Now when you have accountability in the higher levels of management, the way that they effect that accountability, quite rightly, is through delegation and spreading the message in terms of what needs doing. The previous medical director here, who was spectacularly engaged, even before 1000 Lives+, with the idea of infection control provided a real sense of leadership, and had an awful lot of insight. I don't know why that was, perhaps he just saw it as part of his role, I don't know, but he did it very well. But now, now that we're a lot bigger, and we have a wider range of – I don't want to use that term 'lower' – some of the next tier down levels of management, like director level and their associates or assistants, that message is dissipated.

Consultant microbiologist, case site C, (034); transcription 8:01

Other structural issues also surfaced during discussions with respondents, notably the compounding impact of the reconfiguration of NHS Wales on framework alignment, and the need for the co-ordination and consolidation of different guidelines under a health-board-wide and emergent all-Wales remit (transcriptions 8:02 and 8:03, below).

The reconfiguration of NHS Wales, the formation of health boards that's occurred during the roll-out of the original 1000 Lives campaign and 1000 Lives+, I think this has created issues which are problematic. I think that the creation of much larger health boards has created barriers to the roll-out of 1000 Lives and 1000 Lives+. So, for example, something that's seen to be an incredibly high priority within this health board, quite rightly, is the fact that before we were [number] Trusts, and we all had, I imagine, a pretty good spread of infection control policies that were broadly in line, and in their own way ticked the boxes for national recommendations. But they were not the same. Now a priority, here, is that we have harmonised consistent policies. So, you know, we all have workable policies

that we could just leave alone to would work on each site; but no, we are required to have single harmonised policies that we all agree to. Now the differences that existed were there for a reason. But now we've got to try and overcome those differences, agree amongst ourselves, and then get wider agreement across the consultants. And the point being that that's a job of work that takes time and is outside the time requirements that might be put into 1000 Lives.*

Consultant microbiologist, case site A₁ (035); transcription 8:02

Working with consultant microbiologists, we produce and review the antibiotic policies used across the health board. There're planning to have all Wales antibiotic policy guidelines. [Have they been produced and published?] No, no way: it's still at a very early stage of discussion, about 6 months in, and I think it will take years to agree: there's so much disagreement about what to use, when, and some doctors simply refuse to follow any guidelines, no matter who produces them: 'where's the evidence; the evidence is disputed; it's not that clear cut; it's my freedom to prescribe how I see fit for my patient'. We get that same old argument, from some of them, all the time.

So, we produce the health board's antibiotic guidelines and monitor them through audit cycles across each ward or base hospital; we do the education associated with antibiotic usage for the junior doctors, nurses, and other staff, including other pharmacists; and we do antibiotic ward rounds with consultant microbiologists – this is a small hospital, so consultant microbiologists don't have junior doctors attached to them, so, in a way, we act like their juniors – this involves antibiotic prescribing and follow-up, checking that the drug and indication are appropriate, that the dose, route, are all correct, that sort of stuff. I don't think of the context outside so much, I suppose; for me, it's about the people I talk to and work with each day.

Pharmacist, Antibiotics Medicines Management, case site B₂ (001); transcription 8:03

In addition to the structural constraints arising from various existing guidelines, a previous patient safety improvement programme, the Safer Patients Initiative, had a legacy effect which resonated strongly with some IPAC nurses interviewed as part of this study (transcription 8:04, below, and transcription 8:05).

If I'm honest with you, when it [1000 Lives] came out originally, it was a bit of a spin-off from the SPI [Safer Patients Initiative], you know, the IHI approach, wasn't it?

It came out at the time when we were reorganising the health service in Wales. So, I think, a lot of the correspondence went to people whose positions have changed and so on and so forth. They started off at a very high level but there was a lot going on in the organisations and it didn't really filter down – the leadership was a little bit fragmented at that time – I think in the last 2 years we've sort of taken hold of it.

We were a little bit at odds with the priorities of the RHA1 programme initially because we had done our own prevalence survey, internally, and we hadn't identified problems with catheter-associated UTIs [urinary tract infections]. We did an incident survey over a period of 1 month in wards in the organisation and there were no issues with catheter-associated infections at that point in time. However, we identified problems with peripheral venous cannulas during our point prevalence survey. But the campaign was mandating a focus on short-term urinary catheters, whereas our priority at that time was more to do with peripheral lines. So it was a little bit of, it was a little bit, you know, sort of didactic I guess: 'this is a priority, and this is what you must do', and I was thinking, well, in our organisation, this is our priority and we will do that, at the moment we need to focus on that.

Senior nurse, IPAC, case site A₂ (076); transcription 8:04

Such structural constraints were interwoven with the current financial challenge; as one respondent commented, 'the biscuits are gone!' (transcriptions 8:06 and 8:07).

The cultural emergent properties impacting staff involved with infection control arose from their different but interlocking roles. It was clear that there was close liaison between each professional group (transcriptions 8:08 and 8:09, below).

I'm aware that there are different models, if you like, with the consultant leading, consultant microbiologist, the infection control doctor leading the service. Here it's a flat model – a flat model between the lead infection control nurse and the lead infection control doctor – and it is something that I feel not only works well but is appropriate because we bring different skills to the mix, and I'm not sure that any set of skills is more important than the other.

Consultant microbiologist, case site C₁ (T034); transcription 8:08

Well, predominantly, in infection control, our role is for support and advice to staff. That's our role. But we're also involved in conducting audits – particularly things like hand hygiene audits, commode audits, environmental audits, and those kind of things – and those are fed back to ward staff, the results and an required action. But we also carry out things like surveillance, so we'll monitor our alert organisms [for WHAIP]. If there's any kind of change – an indication that there's an increase in health-care-associated infections, or an increase in any of our WHAIP alert organism, such as MRSA, MSSA [meticillin-sensitive S. aureus], C. diff, Group A strep [Group A Streptococcus], E. coli, any of the alert organisms, we'll go and find out, and liaise with the consultant microbiologist.

Senior nurse, IPAC, case site D₂ (017); transcription 8:09

Such liaison also gave rise to professional networks which enabled processes of interprofessional knowledge mobilisation that were perceived to be operating at a more challenging level than those of 1000 Lives+ (transcription 8:10, below).

If I'm facing something that new, a bit different to what I've handled before, I would first contact other antibiotic specialist pharmacists – there's a network across Wales – so that would be one source of information and advice. The others, naturally, are the consultant microbiologists and IPAC nurses. Also, there's a formal meeting twice a year of the Antibiotic Stewardship Forum, which consists of medical microbiologists, pharmacists, and some specialist nurses. They don't meet that often but they're a great source of information, and an opportunity to share learning and development.

[Are there any other groups that you would contact for advice or support?] Yes, the UK CPA [UK Clinical Pharmacy Association] is another source of information. They have an infection management group – they're more advanced in England – there's a good web site, support materials, that sort of stuff which is very helpful. In England, they have developed the consultant pharmacists role – we don't have those in Wales yet; but I think one is due to be developed in Renal Pharmacy, which is an incredibly complex field. So that sort of recognition, legitimacy almost, is absent in Wales. Another group is the British Society for Antimicrobial Chemotherapy. They've got a useful website, and they run all Wales study days, which, in terms of the evidence and focus, are pitched at a far higher level than 1000 Lives+. I feel like I'm learning something new when I attend these, not just being told to wash my hands before I go onto a ward, or to make sure that a course of antibiotics has a defined stop date! Another is the Welsh Microbiological Association and again, they run study days, really focused on education, and this is linked into Public Health Wales. So this is all at a level above 1000 Lives+.

Pharmacist, Antibiotics Medicines Management, case site B₂ (001); transcription 8:10

First-order emergents for key actors central to the institutionalisation of Reducing Health-care Associated Infection

Such structural and cultural emergent properties shaped the context in which key actors, central to the institutionalisation of the RHAi now found themselves and conditioned their ensuing actions. We therefore asked consultant microbiologists, nurses specialising in IPAC and pharmacists specialising in the management of antibiotic medicines to reflect on their placement, their vested interests and the perceived opportunity costs associated with various courses of action, to determine how this shaped their activities.

Consultant microbiologists

The vested interests of consultant microbiologists lay in the day-to-day operational management of IPAC, centred on the provision of their expert advice, and the ongoing demands which arose from WHAIP surveillance (transcriptions 8:11 to 8:13). The 1000 Lives+ national programme and RHAi, though aligned to such tasks, were a secondary consideration (transcription 8:12, below).

Well, of course, a lot of the mandatory reporting used to be done manually by microbiologists – that used to take up our time, particularly statistics for bacteraemia – but that’s all done centrally now. So all that information is sucked out of the data store in Wales.

In terms of mandatory requirements, there’s, in theory, there’s less for us to do. But I strongly suspect that – I’m not alone here, in fact I guarantee you that all microbiologists who used to do it, still do it – because there is an expectation that, a requirement for us, when reports are generated centrally through WHAIP before those reports come out as you know the raw data is circulated back to us to check if we think it’s correct but we would only know that if we were doing the same data collection that we ever did!

But we would want to do it anyway – not just to check the accuracy of WHAIP reports, bearing in mind that some of those reports are somewhat retrospective – because if we relied on them to find out if we were having an out of the ordinary rise in numbers of C. diff in a given area or MRSA bacteraemia associated with line use in a certain area, we’d miss the boat and problems would have deteriorated. So we have, we need to do these things, relatively, real time. So that’s one form of reporting pressure if you like. I mean we see it as part of our work – as our normal role – and that’s why I’m fairly confident that it doesn’t matter who you ask in Wales they’ll probably give you that exact same answer. But nonetheless it’s a time pressure that needs, a role that needs to be fulfilled.

On top of that you’ve then got two other pressures. So, one is the one I’ve just mentioned, whereby you’re noticing your own local priorities with these figures that you’re generating for WHAIP, so that we can focus our attention and look at the interventions that should be being made, and audit whether they are being made, and how well they’re being done and that kind of thing. But at the same time we might be receiving instructions that we should be looking at other areas – and it’s not that those areas aren’t important – but then our time is split because there’s the thing that we see, that we feel we have an immediate need, and then there’s the requirement to fit in with 1000 Lives+ I suppose.

Consultant microbiologist, case site B₁ (036); transcription 8:12

In focusing on the broader remit of IPAC, as opposed to the progressive institutionalisation of RHAi, consultant microbiologists operated under a professional (medical) logic co-existent with and complementary to professional (health-care management) and bureaucratic state logics. Thus, the RHAi was absorbed and integrated into existing and culturally entrenched monitoring processes. This aided its adoption and reproduction across NHS Wales’ health boards.

Infection prevention and control nurses

The vested interests of IPAC nurses at each case site, captured in transcriptions 8:14 to 8:21, again reflected the impact of their traditional role jurisdictions. These overshadowed and pre-dated the 1000 Lives+ national programme and RHA1 (transcriptions 8:14 and 8:15, below).

We do all the audits – environmental audits, hand hygiene audits – ward-based teaching, like the session that you’re going to see this afternoon, and just general support for the wards, and where we find a problem, we like to go back and offer a solution and support the staff to eradicate hospital-acquired infections.

Nurse, IPAC, case site A₂ (003); transcription 8:14

We were doing all this before 1000 Lives and 1000 Lives+ – including looking at urinary catheter-associated infections and peripheral and central line infections – so the interventions 1000 Lives+ promotes are already integrated into our monitoring systems, and it would be the same for all health boards.

Senior nurse, IPAC, case site A₂ (002); transcription 8:15

In addition, some aspects of infection control lay far beyond the scope of RHA1 (transcription 8:17, below).

It is unacceptable to have a case of Clostridium difficile, and if you have two within a 28-day period, a formal meeting is called. [What do you do if you have a persistent problem with Clostridium difficile?] If there was a continuing problem, then we’d look to Bioquel the ward – bio-bomb it with hydrogen peroxide – they go in, in their decontamination suits, and close the doors. They do it one section at a time, they vapour blast it with hydrogen peroxide, they leave all the equipment in there, all the beds, everything stays in there, so there’s no risk of us missing something really. After that the domestic staff will go in and just clean – soap and water, detergent – and then we put the patients back in the ward. So far, that seems to be very effective. But we’ll only do that if we have real hotspots.

Nurse, IPAC, case site B₁ (131); transcription 8:17

The newer 1000 Lives+ interventions associated with RHA1, though beyond the scope of this study, were an extension of established practice. However, owing to medical resistance, some specified changes were a source of concern (transcription 8:18, below).

The new 1000 Lives+ intervention was launched nationally last year, and we’ve been rolling out the PVC bundle but we have the catheter bundle in place for about 4 years now. The PVC bundle has proved a little more difficult to implement really, in that there’s been a change to practice, there’s also been a lot of medical opposition. [Why?] Because they’ve got to do stuff! What they’re saying is: ‘where’s the evidence to say that they’re not doing things properly, and that we’ve got a high rate of infection? Why should I change my practice without the evidence that there’s a problem in the first place?’ [They don’t perceive a problem in their current practice or the rates of infection?] Because they don’t believe they’ve got a problem. They don’t believe that by changing practice, or being forced to evidence that they’re doing what they should be doing, that that will make any difference. And, in one respect, you could sort of see their point, in that there is a low rate of peripheral venous infections. But we do get catheter-related bloodstream infections and the incidence of MSSAs [meticillin-sensitive S. aureus] within the health board has been increasing. But what we asking them to do, due to 1000 Lives+, well, for them, it just takes too long.

Nurse, IPAC, case site C₁ (132); transcription 8:18

In regards to 1000 Lives+, I’d say the introduction of the bundles and the STOP campaign is probably all the infection control team have been involved with and some of that just involved minor changes to our practice.

Nurse, IPAC, case site D₂ (019); transcription 8:21

In focusing their agential activity on the broader remit of IPAC, in addition to the institutionalisation of the RHA, specialist nurses operated under a professional (nursing) logic that was complementary to professional (health-care management) and bureaucratic state logics.

Antibiotic medicines management pharmacists

Transcriptions 8:22 to 8:29 suggest that the vested interests of pharmacists with expertise in antibiotic medicines management were poorly aligned to RHA, which they saw as irrelevant given their level of expertise (transcriptions 8:24 and 8:25, below).

[When you think about the knowledge and information that you use within your role, do you draw on the 1000 Lives+ resources?] No, I don't use them. There's little information in them that relevant to me; I mean, it's just so basic – really bottom-end stuff, basic, mundane – if you don't know it, you shouldn't be working as a clinical pharmacist.

1000 Lives+ is, it's too basic, directed at lower-level nurses. For me, it offers little. [Do you use the driver diagrams?] No, they're not relevant: they're basic. I do a ward round with a consultant microbiologist each day and there's more to that than hand washing! The diagrams aren't education. I mean, we are using the key points in our stickers, developed as part of the antibiotic care bundle, but it's our system. [Do you use the PDSA cycle?] No, we have ongoing audit cycles, which, I guess, serve the same function but they're part of the health board's audit regimen and not informed by the 1000 Lives+ programme.

Pharmacist, Antibiotics Medicines Management, case site B₂ (001); transcription 8:24

[When you think of 1000 Lives+, what does it mean to you?] That's a good question. What does it mean to me? I'd say it's pretty much invisible. I guess it's one of a number of elements that we take into account on a day-to-day basis. It's tricky because you're undertaking CPD [continuous professional development] all the time. It's probably not recorded as CPD but every article you read in the PJ [Pharmaceutical Journal] is all CPD. For example, I'm going to have a lunchtime teaching session, and there could be two or three things in that that I will take away, and then use in my day-to-day practice. But as a consequence there are things that I will probably drop out by day-to-day practice because they're become superseded by something else more important. 1000 Lives+ is just one element. There are lots of other things you're taking in and trying to maintain as current all the time.

Pharmacy manager, case site B₂ (016); transcription 8:25

Such disregard was augmented by the notion that, for pharmacists, aspects of 1000 Lives+ have not been 'translated to pharmacy-speak' (transcription 8.26). Hence, for this professional group, the resources offered by RHA were not considered to be a worthwhile innovation in practice (transcription 8:28, below).

If you look the 1000 Lives+, although I think this might have existed with 1000 Lives as well, but I mean, with 1000 Lives+ – I forget what the terminology is but the project theme or something for health-care-associated infection – you have the key intervention areas, if I remember correctly, you've got things like standard precautions, hand hygiene and decontamination; isolation precautions, that would be another, and antimicrobial stewardship and so on and so on. But all of these are in the strategies we've had in Wales for years! So they, they're not new and they're not separate are they?

Pharmacist, Antibiotics Medicines Management, case site D₂ (020); transcription 8:28

Second-order emergents and situational logic

In case sites A–D, the interplay of structural, cultural and agential emergent properties impacted on the three groups of actors directly involved in the operationalisation of RHA1. First, in structural terms, RHA1 was integrated into the social system-level but was overshadowed by existing systems. Second, in cultural terms, though internal and necessary complementarities could be seen between the RHA1 and the array of professional logics in play, this was not considered to add much to already existing principles and procedures and was largely disregarded. RHA1, therefore, operated under a situational logic of protection that was primarily directed towards the pre-existing structural and cultural system-level, and thus to sociocultural interaction aligned with long-established practices.

Sociocultural interaction: agency and strategic negotiation

As discussed in *Chapter 6*, a situational logic of protection is typically associated with a defensive negotiating stance. However, for RHA1, prior systems of HCAI surveillance and developed IPAC practices overshadowed the intervention. The progressive institutionalisation of the 1000 Lives+ national programme and RHA1, therefore, unfolded in a terrain marred by a degree of disdain. We highlight this complex interplay in both a discrete case site and across multiple case sites, again drawing out different degrees of bureaucratisation and normalisation to help enrich our understanding of the institutional work complementary to the interplay of the focal intervention, context and mechanism.

Power-induced compliance and political sanction

To examine the issues of power-induced compliance and political sanction, we considered individual actors' strategic negotiating stances across different case sites and professional roles.

It was clear that the IPAC team, in the broader sense, were connected to the managerial core (transcription 8:30). However, they were also intermittently connected to ward-based functional health-care teams, though IPAC nurses and pharmacists undertook regular ward visits as part of their practice. This created a context in which such roles, while offering advice and expertise, also functioned as part of the ward-based governance of IPAC.

However, this oversight role was compromised. Poor practice was adapted in the presence of IPAC nurses, changing so that it demonstrated, while observed, close adherence to the hand washing guidelines of RHA1 (transcriptions 8:31 and 8:32, below). This finding was corroborated by our observation of practice at each case site.

There's some wards you go to and, you know, 1000 Lives+ is just an aside, an extra element of work. For example, you ask them about commode cleaning and they say: 'well, we don't have to clean it after every patient', and then we say: 'but you've got to, that is part of the task, it's part of the commode bundle', and they roll their eyes and argue: 'well, we haven't got the time'.

I think, wow, if you haven't got time to just clean a commode, what else have you not got time for? It's almost as if everything on some wards is seen as on top of what they're trying to do, you know, because they're so run ragged, which is understandable, but that's when it's harder, then, to implement something new: when they can't even be doing the things that they should be, you know?

[Can you mandate adherence to these guidelines?] Yes, we tell them, and we audit them, but because we are all known to staff, the minute we walk onto a ward their practice changes. [So they adopt the expected behaviour when you are present?] Yes.

Nurse, IPAC, case site D₂ (019); transcription 8:31

About 90% of the staff in ITU [intensive therapy unit] are familiar with me. So, they all know me, and they all know what my job is. When I walk in twice a year, even if they don't know my name, they know who I am – that sounds really self-important, and that not the issue, but they know me and it's a problem – and people often will come up, and they'll stand and chat to me and wash their hands, and I know perfectly well that they've done absolutely nothing – they haven't been near a patient – it's just that conscious effort to demonstrate hand washing. They'll walk into ITU, they'll have a squirt of alcohol gel, and they'll be watching me, looking at me, to check I'm watching them. So now I sent up [name_a] and [name_b], both IPAC as most of the staff don't know them. So, they went up, on the pretext of looking through patients' notes, and the hand hygiene practice was not acceptable. But, as soon as they realised that they were being audited, their practice changed immediately. They were like washing their hands, alcohol gel, everything changed.

Nurse, IPAC, case site B₁ (137); transcription 8:32

The IPAC staff demonstrated the professional role-positional power to challenge poor practice within extant bureaucratic governance processes. However, confronted by normalised malpractice and decoupling from pre-existing and repacked RHA1 standards, their institutional work was predominantly corrective.

Similar corrective institutional work was also demonstrated in the ward-based actions of pharmacists with expertise in antibiotic medicines management (transcriptions 8:34 and 8:35, below).

We don't get all doctors following the antibiotic prescribing guidelines. Some do, some don't. So it's a core part of the role for pharmacists to challenge and change that when they do their ward rounds.

Pharmacy manager, case site D₁ (021); transcription 8:34

[What happens if a doctor prescribes off guidelines within the health board?] We challenge them. I had one, a few days ago, who I challenged because he had prescribed two drugs, and only one was needed for the patient's indication; but all he said was: 'so what's the problem, it's not illegal is it?' But it's a waste of money, medicine, and more of a risk and inconvenience for the patient. I think that a lot of my role is really about education and changing the culture in the health board. [But is that refusal to follow the guidelines reported to anyone?] Yes, all the audits go to the medical director. But it's anonymised data: ward level, not prescriber level. One of my colleagues in [name, health board] has done this per consultant team, and they've had good results in changing prescribing because the data is ranked. Everyone knows who's playing ball, and more importantly, who's not, so to speak.

Pharmacist, Antibiotics Medicines Management, case site B₂ (001); transcription 8:35

In this example, though such staff demonstrated the professional role-positional power to challenge poor practice and enacted corrective institutional work, the lack of transparency and feedback at this site, compared with the respondent's example of another site, where 'everyone knows who's playing ball, and more importantly, who's not, so to speak', only served to erode the goals of RHA1.

Reciprocal exchange and harmonisation of desires

Gaining widespread support and agreement for a harmonised approach to IPAC, and thus RHA1, proved difficult due, in part, to individual prescribing preferences and ensuing practices. Indeed, this issue was a consistent theme at each case site and across professional groups (transcriptions 8:36 and 8:37, below).

Getting agreement between the all of the consultant microbiologists in the health board is quite demanding but that pales into insignificance when we have to start telling other medical consultants or surgeons what they are supposed to prescribed for a given indication. You know this as much as me! They're all got their preferred drugs, ones that they have used for years, new ones that offer more, and cost more, it's that debate that difficult, and it's one we are having to address due to the formation of the health board.

Consultant microbiologist, case site B₁ (036); transcription 8:36

I don't know if they'll all agree to a health board-wide antibiotic policy. I mean, we'll get agreement on the overarching health-care-associated issues – say C. diff management because that's changing, and it's our area per se: they don't want to claim that for themselves – but it's harder to negotiate with respiratory physicians, orthopaedics, all the rest, as they've got their preferred drugs. So changing their prescribing practice is difficult. Our policy is monitored by pharmacists, and IPAC nurses, as they work at ward level, so they are at the sharp end.

Consultant microbiologist, case site C, (034); transcription 8:37

The comment from a respondent that 'To change something – whether you're talking about the 1000 Lives+ work, adherence to current policy guidelines, or the development of new guidelines across the health board, you've got to know the people involved in the system' (transcription 8:38) highlights the critical role of contextual relational structure and social interaction in the brokerage of such contested change. Leadership and the use of co-opted medical power were also seen as central to the negotiating stance employed (transcriptions 8:39 and 8:40, below).

On the wards, well, you've got issues, other things, you know, if you've got high sickness rates on a ward as well, motivation is often low, so when you're trying to introduce 1000 Lives+ guided change that's going to impact more on their workload, often that's seen as a negative. The key issues then is, how do you really sell that to them because it's no good us saying: 'this is all the new paperwork, go on, use this', the wards have got to see the benefits of that, and own it, and want it, for it to work. I think that's where good leadership comes in because it's sort of, you know, if they sell it, if the ward manager sells it as this is a positive thing: 'if we do this we can reduce our rates', the staff will be on board.

Lead nurse, IPAC, case site A, (037); transcription 8:39

We're having problems with the PVC insertion bundles because we went on the sticker route for the insertion bundles, whereby you put the sticker on the prescription chart, on the PRN [as required medication] side of the prescription chart. Well, every time they went to change a cannula they would just need to sign the prescription chart to say that they'd changed it, and the sticker will have things like hand hygiene, personal protective equipment, and the right dressing on it, you know. But doctors insert venflons and doctors don't like to document that they've inserted something! So when we spoke with the associate medical director at the time, he suggested that we approached clinical champions to try and embed that a little bit further. So with the audit work and the regular feedback, and identifying clinical champions, we'll begin to see an improvement in compliance, you know, if we don't, we'll feed it back to them.

Nurse, IPAC, case site B1 (131); transcription 8:40

Although these IPAC nursing staff demonstrated the professional role-positional power to challenge poor practice, their corrective institutional work, buttressed by the power of others, was directed towards the maintenance of best practice and its evolution through RHA1.

Structural elaboration or reproduction in the Welsh health-care field

In examining the progressive institutionalisation of the 1000 Lives+ national programme's RHA1 we sought to gauge key actors' perceptions of the structural elaboration or reproduction that had manifested under a situational logic of protection. For consultant microbiologists, attributing improved outcomes in HCAs to 1000 Lives+ or RHA1s was considered to be very challenging, owing to the interplay and collective impact of multiple IPAC policies on WHAIP's robust epidemiological modelling (transcription 8:41, below).

If you're looking at say, catheter care policy, now, looking for it to reduce catheter-associated UTIs [urinary tract infections] then that's going to be a small subset. So, it's very, very difficult to be able to draw and demonstrate a reduction. It's technically possible, if you have a big enough study population. However, practices in hospital are not static, things change, for the better, for the worse, for a whole host of reasons, and controlling any one aspect through 1000 Lives+ policy, or something

of that nature, that may have one impact but there may be contrary aspects that the main path is working on. So, it can be, I think, very challenging, and very difficult to really show a reduction and improvement in outcomes.

Consultant microbiologist, case site A₁ (035); transcription 8:41

Structural change was apportioned to the ward-based functional health-care team. In enacting RHA1 and other IPAC guidelines, such staff not only delivered change (transcription 8:42, below), but were continually motivated to do so through fear of exposure of failings (transcriptions 8:43 and 8:44).

Our C. difficile rates have actually gone down, a reduction again on last year. So it's good. But, you know, that's where our support and advice has come in. But at the end of the day, in infection control, we're not there on the coalface, if you like, it's the staff who put that into practice, into place, you know, they carry on with what we advise. So, you know, a lot of the hard work is down to them.

Nurse, IPAC, case site D₂ (019); transcription 8:42

Cultural change, by contrast, was perceived to be far more marked, with a professional logic of zero tolerance of HCAs emerging across NHS Wales, although it remained far removed from the reality of day-to-day health-care practice (transcription 8:45, below).

I think the culture is changing, I mean, I've seen it in the short time I've been in infection control, the ownership at ward level for infection control has shifted. Whereas, you know, if there was a problem on the ward, often the wards wouldn't call us, so we would find out by our surveillance!

But now wards are contacting us to say: 'I think we've got a problem', so there's the acceptance of their role in infection prevention and control. Before, for Clostridium difficile, it was accepted that it's just a consequence of being in hospital – the attitude was: 'what do you expect, you're going to have antibiotics, you're elderly, you're bound to get it' – but that is changing now. Now people are saying: 'no, they shouldn't be getting a health-care-associated infection, it's just not good enough'. There should be zero tolerance on infection, health-care-associated infection. [But they still happen, don't they? And patients still die as a consequence, don't they?] Yes. [Long pause] But I think at ward level staff now are not accepting that patients should acquire an infection as a result of being in hospital.

Nurse, IPAC, case site B₁ (131); transcription 8:45

In addition, though tangential to RHA1, the normalisation of the 1000 Lives+ MI-PDSA approach was evident (transcriptions 8:46 and 8:47). However, the crux of such cultural change lay in the education of staff (transcription 8:48, below, and transcriptions 8:49 and 8:50).

Education is key, too, not just education for the sake of antibiotic education but to change the culture. But, again, we face a huge problem here as the attitude is: 'well, what's the problem; why do we need to change how we do things; the evidence is weak', it's always the same.

I don't want to sound cynical, I don't. I love my job. But getting people to change is difficult, especially doctors, though they do know that I know what I'm on about. But we go through the same issues with each junior doctor rotation – I feel that I have to re-prove myself to them because they prescribe, wrongly – I know what they should be prescribing better than they do. So, a large part of what I do is education, and not just about drugs.

[Do you think that the junior doctors respect the work you do?] If they're arrogant, and think they know it all, probably not; but they're the most dangerous. Once you're stopped them from killing a patient, once or twice; once they've realised how fallible they're, and how, within the NHS, you're lucky if you got a good team around you, who all know their own profession and offer different expertise, they start to listen. They're not all like it, thankfully. Some are really good, and with more joint training early on in health-care professional careers, I think the issue of professional respect is

getting better. But the best doctors are those that listen, and, more importantly, they ask for information and advice, they're keen to learn, and you know they're going to be good because they work constructively within the team. But with some with doctors, we often just get point blank refusal to co-operate.

[What are the consequences of this? How does the audit cycle, and associated governance processes intervene to feedback in such circumstances?] Well, the pharmacy audit will be sent to the medical director but, with the lack of prescriber identification, and data aggregation, it gets blunted.

Pharmacist, Antibiotics Medicines Management, case site C, (013); transcription 8:48

1000 Lives+ institutionalisation: RHAI – local implementation of the focal intervention and contribution to the I-CMAO configuration spanning the Welsh health-care field

Our efforts to understand the local implementation of RHAI, and define its contribution to the 1000 Lives+ programmes' I-CMAO configuration spanning the Welsh health-care field, were limited, as there was a profound sense of it being overshadowed by the complex array of established alternative frameworks and the ongoing surveillance of their effectiveness via the WHAIP. Indeed, RHAI was found to be, in some respects, a leftover theme from the predecessor 1000 Lives campaign. Furthermore, for some staff, the legacy effect of the Safer Patients Initiative was more pertinent. Consequently, though the institutional change inherent to formalisation shaped the situated context of action for all, the impetus of RHAI, nonetheless, dissipated.

Turning now to the findings of our realist analysis, we first consider, in *Figure 22*, the overall scheme of the intervention across the different structural contexts, focusing, for simplicity, on only one of the two processes researched in this part of the study, namely the appropriate use of antimicrobial drugs to ensure the effective prevention and treatment of infection.

In *Tables 28–30* we show, respectively, I-CMAO configurations for the implementation of RHAI, illustrating the infrastructural system of the Welsh Government, the institutional setting of NHS Wales and its constituent health boards, and interpersonal relationships within the institutional settings.

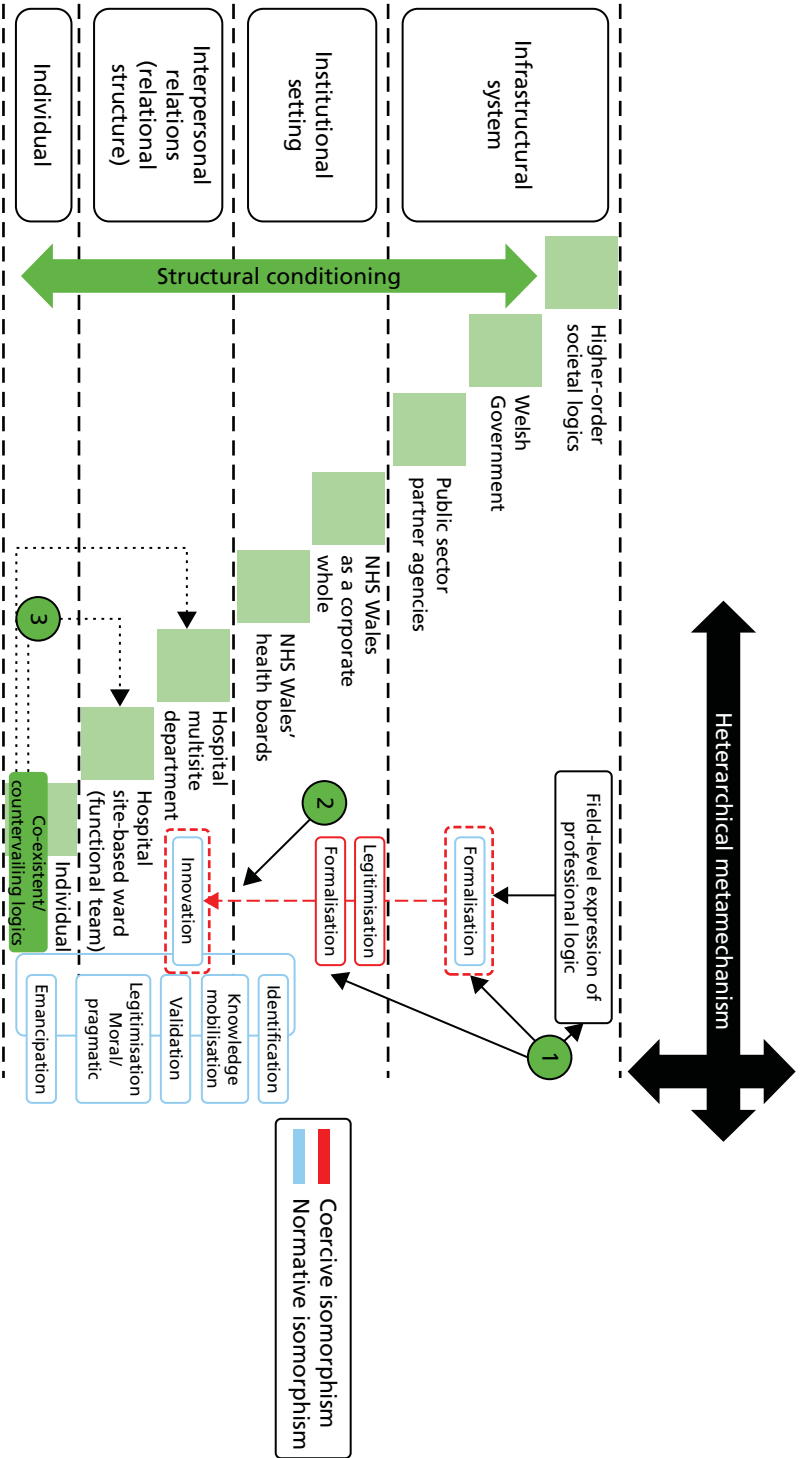


FIGURE 22 Reducing health-care-associated infection: heterarchical metamechanism operating across contextual strata – management of antibiotic drugs.

Figure 22: key point summary

In *Figure 22* we depict the implementation of local antibiotic guidelines in association with the RHAf focal intervention.

At point 1 we draw attention to the formalisation of this process via professional guidelines and Welsh Government policy, thereby mandating engagement by all health boards, health-care staff with prescribing privileges and pharmacists with expertise in antibiotics medicines management.

In point 2 we highlight that, although such practices are legitimate and formalised, under the 1000 Lives+ national programme they represent established practices which do not represent or drive innovation.

Point 3 highlights illustrates that such mandated engagement may be opposed across the micro-work system.

TABLE 28 Reducing health-care-associated infection I-CMAO configuration: infrastructural system – Welsh Government

Intervention	1000 Lives+ national programme	
Component	RHAf	
Context	Welsh Government	
Mechanisms	<ul style="list-style-type: none"> • Institutional isomorphism – coercive, mimetic and normative • Coherence, cognitive participation and reflexive monitoring 	
Agency and institutional work	Normalisation: coupling to 1000 Lives+ and RHAf <ul style="list-style-type: none"> • Agency – formalisation • Institutional work – maintenance • Leadership: distributed across policy and professional domains • Team work: policy leads and professional engagement across aligned organisations • Encultured values: centred on defining RHAf and WHAIP as mandated evidence-based practices 	Habituation: decoupling to 1000 Lives+ and RHAf <ul style="list-style-type: none"> • Decoupling limited by structural and cultural constraints within infrastructural system, specifically pre-existing mandated WHAIP monitoring
Outcome	1000 Lives+ national programme and RHAf institutionalised into policy processes via WHAIP	
	Exemplar transcriptions <ul style="list-style-type: none"> • Agency – formalisation • Institutional work – creation • 8:01 (T034) – Coupling • 8:02 (T035) – Decoupling • 8:28 (T020) – Decoupling 	

TABLE 29 Reducing health-care-associated infection I-CMAO configuration: institutional setting – NHS Wales and constituent health boards

Intervention	1000 Lives+ national programme	
Component	RHAi	
Context	NHS Wales/NHS Wales' health boards	
Mechanisms	<ul style="list-style-type: none"> • Institutional isomorphism – coercive, mimetic and normative • Coherence, cognitive participation and reflexive monitoring 	
Agency and institutional work	<p>Normalisation: coupling to 1000 Lives+ and RHAi</p> <ul style="list-style-type: none"> • Agency – negotiation under a situational logic of protection (status quo ante) • Institutional work – creation/maintenance • Leadership: distributed across IPAC clinical micro-work system but contested by others outside relational structure • Team work: harnesses multiprofessional leadership to foster adoption of the RHAi centred on maintenance of extant IPAC guidelines, greater alignment at health board-level and gradual progression to all Wales standards • Encultured values: mandated adherence via WHAIP monitoring <ul style="list-style-type: none"> • Agency – legitimisation • Institutional work – creation • Leadership: distributed across IPAC clinical micro-work system • Team work: dependent on relational structure of IPAC clinical micro-work system • Encultured values: mandated adherence via WHAIP monitoring <ul style="list-style-type: none"> • Agency – formalisation • Institutional work – creation • Leadership: distributed across IPAC clinical micro-work system • Team work: centred on IPAC clinical networks • Encultured values: mandated adherence via WHAIP monitoring <ul style="list-style-type: none"> • Agency – co-optation • Institutional work – creation • Leadership: bound by IPAC clinical micro-work system • Team work: centred on IPAC clinical networks, integrated knowledge and skills • Encultured values: mandated adherence via WHAIP monitoring 	<p>Habituation: decoupling to 1000 Lives+ and RHAi</p> <ul style="list-style-type: none"> • Agency – negotiation under a situational logic of protection (status quo ante) • Institutional work – maintenance • Leadership: distributed across IPAC clinical micro-work system but contested by others outside relational structure • Team work: contested due to extant practices within each health board hospital site • Encultured values: 1000 Lives+ and RHAi subsumed by site-specific routine IPAC clinical practices <ul style="list-style-type: none"> • Agency – legitimisation • Institutional work – creation • Leadership: distributed across IPAC clinical micro-work system but contested by others outside relational structure • Team work: dependent on relational structure of IPAC clinical micro-work system • Encultured values: mandated adherence via WHAIP monitoring <ul style="list-style-type: none"> • Decoupling limited by structural and cultural constraints within infrastructural system, specifically pre-existing mandated WHAIP monitoring <ul style="list-style-type: none"> • Agency – co-optation • Institutional work – creation • Leadership: distributed across IPAC clinical micro-work system but contested by others outside relational structure • Team work: vulnerable to staff absence and recruitment limitations • Encultured values: IPAC practices entrenched within clinical micro-work system

continued

TABLE 29 Reducing health-care-associated infection I-CMAO configuration: institutional setting – NHS Wales and constituent health boards (*continued*)

Outcome	<ul style="list-style-type: none"> Coupling 1000 Lives+ national programme and RHAi approach embraced and absorbed as part of mandated WHAIP monitoring 	<ul style="list-style-type: none"> Decoupling 1000 Lives+ national programme and RHAi approach resisted and adsorbed onto daily practice as part of mandated WHAIP monitoring 								
	<p>Exemplar transcriptions</p> <table border="0"> <tr> <td style="vertical-align: top;"> <ul style="list-style-type: none"> Agency – negotiation under a situational logic of protection (<i>status quo ante</i>) Institutional work – creation </td> <td style="vertical-align: top;"> <ul style="list-style-type: none"> 8:03 (T001) – Decoupling 8:31 (T019) – Decoupling 8:36 (T036) – Decoupling 8:37 (T034) – Decoupling 8:38 (T019) – Coupling </td> </tr> <tr> <td style="vertical-align: top;"> <ul style="list-style-type: none"> Agency – legitimisation Institutional work – creation </td> <td style="vertical-align: top;"> <ul style="list-style-type: none"> 8:04 (T076) – Decoupling 8:05 (T002) – Decoupling 8:06 (T013) – Decoupling </td> </tr> <tr> <td style="vertical-align: top;"> <ul style="list-style-type: none"> Agency – formalisation Institutional work – creation </td> <td style="vertical-align: top;"> <ul style="list-style-type: none"> 8:11 (T035) – Coupling 8:43 (T130) – Coupling </td> </tr> <tr> <td style="vertical-align: top;"> <ul style="list-style-type: none"> Agency – co-optation Institutional work – creation </td> <td style="vertical-align: top;"> <ul style="list-style-type: none"> 8:08 (T034) – Coupling 8:23 (T015) – Decoupling 8:27 (T017) – Decoupling 8:45 (T131) – Coupling </td> </tr> </table>		<ul style="list-style-type: none"> Agency – negotiation under a situational logic of protection (<i>status quo ante</i>) Institutional work – creation 	<ul style="list-style-type: none"> 8:03 (T001) – Decoupling 8:31 (T019) – Decoupling 8:36 (T036) – Decoupling 8:37 (T034) – Decoupling 8:38 (T019) – Coupling 	<ul style="list-style-type: none"> Agency – legitimisation Institutional work – creation 	<ul style="list-style-type: none"> 8:04 (T076) – Decoupling 8:05 (T002) – Decoupling 8:06 (T013) – Decoupling 	<ul style="list-style-type: none"> Agency – formalisation Institutional work – creation 	<ul style="list-style-type: none"> 8:11 (T035) – Coupling 8:43 (T130) – Coupling 	<ul style="list-style-type: none"> Agency – co-optation Institutional work – creation 	<ul style="list-style-type: none"> 8:08 (T034) – Coupling 8:23 (T015) – Decoupling 8:27 (T017) – Decoupling 8:45 (T131) – Coupling
<ul style="list-style-type: none"> Agency – negotiation under a situational logic of protection (<i>status quo ante</i>) Institutional work – creation 	<ul style="list-style-type: none"> 8:03 (T001) – Decoupling 8:31 (T019) – Decoupling 8:36 (T036) – Decoupling 8:37 (T034) – Decoupling 8:38 (T019) – Coupling 									
<ul style="list-style-type: none"> Agency – legitimisation Institutional work – creation 	<ul style="list-style-type: none"> 8:04 (T076) – Decoupling 8:05 (T002) – Decoupling 8:06 (T013) – Decoupling 									
<ul style="list-style-type: none"> Agency – formalisation Institutional work – creation 	<ul style="list-style-type: none"> 8:11 (T035) – Coupling 8:43 (T130) – Coupling 									
<ul style="list-style-type: none"> Agency – co-optation Institutional work – creation 	<ul style="list-style-type: none"> 8:08 (T034) – Coupling 8:23 (T015) – Decoupling 8:27 (T017) – Decoupling 8:45 (T131) – Coupling 									

TABLE 30 Reducing health-care-associated infection I-CMAO configuration: institutional setting – interpersonal relations

Intervention	1000 Lives+ national programme	
Component	RHAi	
Context	Hospital multisite department/hospital site-based ward (functional team)	
Mechanisms	<ul style="list-style-type: none"> Institutional isomorphism – coercive, mimetic and normative Coherence, cognitive participation and reflexive monitoring 	
Agency and institutional work	<p>Normalisation: coupling to 1000 Lives+ and RHAi</p> <ul style="list-style-type: none"> Focal interventions selected from the RHAi do not represent evidence-based practice innovations 	<p>Habituation: decoupling to 1000 Lives+ and RHAi</p> <ul style="list-style-type: none"> Agency – innovation Institutional work – maintenance Leadership: distributed across IPAC clinical micro-work system but contested by others outside relational structure Team work: contested owing to extant practices within each health board hospital site Encultured values: 1000 Lives+ and RHAi subsumed by site-specific routine IPAC clinical practices
	<ul style="list-style-type: none"> Agency – identification Institutional work – creation Leadership: distributed across IPAC clinical micro-work system Team work: centred on IPAC clinical networks with heightened participation from ward-based staff Encultured values: mandated adherence via WHAIP monitoring and extant audit processes 	<ul style="list-style-type: none"> Decoupling limited by structural and cultural constraints within infrastructural system, specifically pre-existing mandated WHAIP monitoring

TABLE 30 Reducing health-care-associated infection I-CMAO configuration: institutional setting – interpersonal relations (*continued*)

Agency and institutional work	<ul style="list-style-type: none"> • Agency – knowledge mobilisation • Institutional work – creation • Leadership: distributed across IPAC clinical micro-work system • Team work: centred on IPAC clinical networks with heightened participation from ward-based staff • Encultured values: heightened awareness of IPAC practices 	<ul style="list-style-type: none"> • Agency – knowledge mobilisation • Institutional work – creation • Leadership: profession-specific knowledge led • Team work: fragmented • Encultured values: 1000 Lives+ and RHAIP subsumed by site-specific routine IPAC clinical practices
	<ul style="list-style-type: none"> • Agency – validation • Institutional work – creation • Leadership: distributed across IPAC clinical micro-work system, supporting extant governance and audit processes • Team work: multidisciplinary participation in governance and audit processes • Encultured values: monitoring and measurement of RHAIP to enhance patient safety 	<ul style="list-style-type: none"> • Decoupling limited by structural and cultural constraints within infrastructural system, specifically pre-existing mandated WHAIP monitoring
	<ul style="list-style-type: none"> • Agency – legitimisation (moral/pragmatic) • Institutional work – creation • Leadership: distributed across IPAC clinical micro-work system • Team work: multiprofessional participation in RHAIP • Encultured values: RHAIP accepted as part of pre-existing mandated WHAIP monitoring 	<ul style="list-style-type: none"> • Agency – legitimisation (moral/pragmatic) • Institutional work – creation • Leadership: distributed across IPAC clinical micro-work system but contested by others outside relational structure • Team work: multiprofessional participation in RHAIP eroded by profession-specific knowledge and associated standards • Encultured values: 1000 Lives+ and RHAIP subsumed by site-specific routine IPAC clinical practices
	<ul style="list-style-type: none"> • Agency – emancipation • Institutional work – disruptive • Leadership: centred on role-position practices which erode traditional IPAC power base • Team work: centred on IPAC clinical networks with heightened participation from ward-based staff • Encultured values: ‘everyone believing the same thing and working towards improving patient care’ legitimising challenge 	<ul style="list-style-type: none"> • Agency – emancipation • Institutional work – maintenance • Leadership: role position-practices profession specific • Team work: fragmented • Encultured values: 1000 Lives+ and RHAIP subsumed by site-specific routine IPAC clinical practices
Outcome	<ul style="list-style-type: none"> • Coupling 1000 Lives+ national programme and RHAIP approach embraced and absorbed into daily practice 	<ul style="list-style-type: none"> • Decoupling 1000 Lives+ national programme and RHAIP approach resisted and adsorbed onto daily practice

continued

TABLE 30 Reducing health-care-associated infection I-CMAO configuration: institutional setting – interpersonal relations (*continued*)

Exemplar transcriptions	
<ul style="list-style-type: none"> Agency – innovation Institutional work – creation 	<ul style="list-style-type: none"> 8:15 (T002) – Decoupling 8:26 (T013) – Decoupling
<ul style="list-style-type: none"> Agency – identification Institutional work – creation 	<ul style="list-style-type: none"> 8:09 (T017) – Coupling 8:12 (T036) – Decoupling 8:13 (T034) – Coupling 8:14 (T003) – Coupling 8:20 (T018) – Decoupling 8:34 (T021) – Coupling 8:35 (T001) – Decoupling
<ul style="list-style-type: none"> Agency – knowledge mobilisation Institutional work – creation 	<ul style="list-style-type: none"> 8:10 (T001) – Decoupling 8:21 (T019) – Decoupling 8:22 (T031) – Decoupling 8:24 (T001) – Decoupling 8:40 (T131) – Coupling 8:42 (T019) – Coupling
<ul style="list-style-type: none"> Agency – validation Institutional work – maintenance 	<ul style="list-style-type: none"> 8:32 (T137) – Coupling
<ul style="list-style-type: none"> Agency – legitimisation (moral/pragmatic) Institutional work – creation 	<ul style="list-style-type: none"> 8:18 (T132) – Decoupling 8:19 (T133) – Coupling 8:25 (T016) – Decoupling 8:30 (T034) – Coupling 8:41 (T035) – Decoupling 8:48 (T013) – Decoupling
<ul style="list-style-type: none"> Agency – emancipation Institutional work – disruptive 	<ul style="list-style-type: none"> 8:44 (T099) – Coupling

Tables 31 and 32 report data relating to the incidence of two types of hospital-acquired infection made publicly available as part of the new emphasis on transparency in relation to patient safety.

Finally, in Table 33, we present our realist analysis linking the empirical data to I-CMAO.

In this context, deinstitutionalisation did not occur. After all, no appreciable change to practice was required. As illustrated in Tables 31–33, RHA1 placed emphasis on well-established health-care practices, each supported by a wealth of tacit knowledge and a burgeoning evidence base, which were institutionalised in NHS Wales. Hence the information offered by the discrete components of this intervention was neither new nor challenging to extant practice. Instead, these components were merely the continuation of standard precautions for hand hygiene, together with the ongoing debate on appropriate antimicrobial prescribing and the merger of guidelines that was required following the reconfiguration of NHS Wales.

In addition, the transcriptions set out in Tables 28–30 depict high levels of decoupling. This finding is supported by the wider literature. For example, it is known that hand hygiene benefits from entrenched ideas about its meaning and broader social utility.³⁵² This most basic of practices, therefore, constitutes a cognitive and behavioural ensemble that demands little by way of organised competencies.^{595,626} However, in order to be effective, hand hygiene must be enacted as a conscious activity.⁶³⁰ But its broader social utility positions this practice as routine and somewhat mindless⁶⁹⁶ and habitual,⁶⁹⁷ which limits the individual’s reflexive monitoring and appraisal of the practice.

Moreover, as RHA1 did not demand change, theorisation was not triggered, so that established factors inhibiting actors’ meaningful participation^{629,645,658} persisted. Compounded by environmental contamination,⁶⁹⁸ these factors encouraged the spread of nosocomial infection.

TABLE 31 Reducing health-care-associated infection: local implementation – WHAIP. Data are rates of MRSA bloodstream infections per 100,000 bed-days

Health board	Monitoring period				
	1 April 2012 to 31 March 2013	1 April 2011 to 31 March 2012	1 April 2010 to 31 March 2011	1 April 2009 to 31 March 2010	1 April 2008 to 31 March 2009
Abertawe Bro Morgannwg University	4	4	6	5	8
Aneurin Bevan University	4	5	4	5	8
Betsi Cadwaladr University	7	8	8	7	No comparable WHAIP data
Cardiff and Vale University	4	6	7	10	12
Cwm Taf University	5	4	4	9	8
Hywel Dda	4	6	5	7	8
Powys (Teaching)	0	0	No comparable WHAIP data	No comparable WHAIP data	No comparable WHAIP data

Data accessed via WHAIP: www.wales.nhs.uk/sites3/page.cfm?orgId=379&pid=23913.

TABLE 32 Reducing health-care-associated infection: local implementation – WHAIP. Data are rates of *S. aureus* bloodstream infections per 100,000 bed-days

Health board	Monitoring period				
	1 April 2012 to 31 March 2013	1 April 2011 to 31 March 2012	1 April 2010 to 31 March 2011	1 April 2009 to 31 March 2010	1 April 2008 to 31 March 2009
Abertawe Bro Morgannwg University	26	24	21	24	22
Aneurin Bevan University	23	23	23	25	26
Betsi Cadwaladr University	23	26	26	25	No comparable WHAIP data
Cardiff and Vale University	27	26	30	29	32
Cwm Taf University	20	15	15	24	23
Hywel Dda	30	25	26	28	26
Powys (Teaching)	1	1	No comparable WHAIP data	No comparable WHAIP data	No comparable WHAIP data

Data accessed via WHAIP: www.wales.nhs.uk/sites3/page.cfm?orgId=379&pid=23913.

TABLE 33 Reducing health-care-associated infection: realist analysis – signposting how the empirical data connect to I-CMAO

Intervention	RHAI
Component	Antibiotics medicines management
Context	Structural conditioning of the institutional setting: NHS Wales health boards' implementation of 1000 Lives+ national programme's RHAI
Structural emergent properties	<ul style="list-style-type: none"> • Structural constraints and enablements shaped by the bureaucratic processes of formalisation emergent from the infrastructural system of the Department of Health and Social Care impact 1000 Lives+ and RHAI • The dominant structural emergent properties impacting the RHAI were the complex array of established alternative frameworks and the on-going surveillance of their effectiveness via the WHAIP
Cultural emergent properties	<ul style="list-style-type: none"> • The cultural emergent properties arose from the close liaison between each professional group and their different but interlocking professional roles in IPAC
Social actors	<ul style="list-style-type: none"> • Pharmacists with expertise in antibiotics medicines management
Social position	<ul style="list-style-type: none"> • Expert professional role and widespread networks
Role-position practices	<ul style="list-style-type: none"> • Professional role-position practices centred on promoting and monitoring the appropriate prescribing of drugs used in the treatment of infection
Mechanism	Mediation of structural conditioning to core actors and their reflexive theorisation
Institutional logics and nature of alignment between core actors	For this professional group, their agential activity therefore manifested under a professional (pharmacy) logic that, though co-existent to others in the field, express disregard for the RHAI
First-order emergents	The vested interests of pharmacists with expertise in antibiotic medicines management was poorly aligned to the RHAI as it was perceived to lack relevance
Second-order emergents	The RHAI emerged into a context moulded by internal and necessary linkages of a complementary nature to extant structures. The RHAI was integrated into the social system-level but, in so doing, it was overshadowed. Though internal and necessary complementarities manifested between the RHAI and the array of professional logics in play, this was tainted by disregard
Situational logic	Protection (of status quo ante)
Reflexive theorisation	Although the RHAI emerged into a context moulded by internal and necessary linkages of a complementary nature to extant structures – thereby in alignment to the dominant logic of the bureaucratic state, and collaborative logic, and professional (pharmacy) logic – the reflexive theorisation that manifested was, as indicated above, not considered to add much to already existing principles and procedures and largely disregarded. Coherence, cognitive participation and reflexive monitoring were, therefore, anchored to the past, such that the discernment of issues, deliberation of their importance, and dedication of ensuing agency in alignment to the goals of the RHAI were superficial as, for these actors, little had changed
Agency and institutional work	Agency, the unfolding strategic negotiation of change, and the mode of institutional work enacted
Agential emergent properties	Agency was directed to the maintenance of practice
Strategic negotiation	<ul style="list-style-type: none"> • Power-induced compliance and political sanction • Reciprocal exchange and harmonisation of desires <div style="background-color: #c6e0b4; padding: 5px; margin-top: 5px;"> <ul style="list-style-type: none"> • Exemplar transcriptions: 8:06, 8:07 • Exemplar transcriptions: 8:03, 8:10 </div>
Institutional work	Primarily maintenance
Outcome	Social elaboration or reproduction
Structural	Reproduction
Cultural	Reproduction
Agential	Invariant

As illustrated in *Table 33*, and supported by the explanatory schematic *Figure 22*, our realist analysis adds insight. Centred on pharmacists with expertise in antibiotic medicines management, sociocultural interaction through the wide range of activities depicted in this study, though undertaken in logical alignment to the RHAi, were marred by the lack of appreciable change demanded. Indeed, only the new interventions, focused on the appropriate and timely use of invasive devices – specifically guidance aimed to reduce PVC and CAUTI – prompted cognitive participation and collective action to deliver change. Accordingly, little structural elaboration was displayed across each case site, compounded by the view expressed by some pharmacists that RHAi did not offer any substantive enhancement of their practice.

Summary

In *Chapter 8*, we furthered our understanding of the local implementation of the focal intervention RHAi and defined its contribution to the 1000 Lives+ programmes' I-CMAO configuration spanning the Welsh health-care field.

Chapter 9 Discussion and conclusion

Overview

In this chapter we present the discussion and conclusion of our study. Here, the explicit intention is to move beyond simple iteration. We therefore present our closing argument in four main parts.

First, we return to the original research questions posed in the aim and objectives of this study and address them guided by our empirical findings. In this manner, we forward our conceptualisation of context, mechanism, agency and ensuing outcome, and develop insights from the local implementation of the three focal interventions selected from the 1000 Lives+ national programme: ILQI, RSC and RHA1. Second, we acknowledge the limitations of our study and set out our stance regarding the generalisability of our findings. Next, we consider the contribution of this study to the study of patient safety, outline the future outputs from this project and suggest areas for future research. Finally, we consider the implications of the research for health-care practice and patient safety.

Which contextual factors matter: how, why and for whom?

In this study, we sought to ascertain which contextual factors matter, how, why and for whom, in order that processes and outcomes of future patient safety programmes may be improved. Our study therefore deviated, quite markedly, from the traditional focus of realist inquiry, and the newly established RAMESES publication standards for realist syntheses (www.ramesesproject.org). Most significantly, our unit of analysis was the process of local implementation of the 1000 Lives+ programme, as opposed to the evaluation of the 1000 Lives+ programme per se.

Before we could begin to address this issue, the notion of context demanded clarification. As Bate⁶⁹⁹ has recently commented, context is everything. However, there has been very limited systematic and independent analysis of the relationship between organisational factors, which shape the local context of health care, and the outcomes of patient safety interventions.^{124,216–223} In this study, guided by the established approach to realist inquiry,^{228,241,242,247} we specified four main levels of contextual hierarchy: infrastructural system, institutional setting, interpersonal relations and individual. All levels except the individual are divided into substrata (see *Figure 5*). Through this depiction we sought to capture and convey the accumulated sense of contextual constraints and enablements, structural and cultural, which impact differently positioned actors within the Welsh health-care field to shape their scope and perceived discretion to act. Context was, therefore, conceptualised as 'situated'. By this we mean that context is stratified, conditioned, relational and temporally dynamic.

Importantly, our view of context was reflected in our findings. At the level of the functional team, context was perceived to be distinct from that of the wider organisation. Indeed, it resonated with that of a bounded health-care managerial or clinical micro-work system.^{163,164,166,700–704} Accordingly, we suggest that this finding challenges the use of the health-care organisation as a unit of analysis for patient safety programmes, as adopted in this study and as advocated in the 'four high-priority' features of organisational context.^{5,223,705} Indeed, our use of a comparative case-study design across major, district general and small community hospital sites within each participant health board was somewhat confounded.

In phase 1 of our analysis, despite the bureaucratic mandate to engage with the 1000 Lives+ programme that was evident at the field level of analysis (see *Chapter 4*), our examination of the normalisation of 1000 Lives+ at the suborganisational level (see *Chapter 5*) surfaced a complex pattern. At this level, discrete pockets of high adherence sat alongside areas of enforced but somewhat disengaged adoption.

As such, even within case sites, it was not uncommon to find disparity between adjacent wards. In essence, two polarised types of situated context emerged. In the first type, 1000 Lives+ was normalised and absorbed into daily practice, becoming integral to care. In the second type of situated context, engagement with 1000 Lives+ was merely adsorbed (attached to but not fully integrated with) onto daily practice. It was then perceived to be an additional burden above and beyond the routine demands of health-care provision. The local implementation of the 1000 Lives+ programme was, therefore, positioned across a spectrum between these polarised stances. This highlights the transitional and fragile state of its progressive institutionalisation across NHS Wales. We therefore contend that focus directed at the level of the 'micro-work system'^{163-170,706-711} may offer greater insight into the impact of patient safety improvement programmes at the point of patient-centred care. Indeed, this may even help to challenge Pawson's iron law of evaluation: the expected value of any net impact assessment of any large-scale social program is zero.²⁴¹

Contextual organisational factors pertinent to the health outcomes of hospital patient safety interventions

In this section we build on our conceptualisation of a situated context. Informed by our realist analysis of the local implementation of the 1000 Lives+ programme's three focal interventions – ILQI, RSC and RHA – we identify and analyse the supraorganisational and organisational factors in the Welsh health-care field which are pertinent to the health outcomes of these hospital patient safety interventions.

What supraorganisational factors matter: how, why and for whom?

In this study, we have drawn on the long-held view that multiple institutional logics co-exist.³³¹ As illustrated in *Figures 8 and 9*, at the higher-order societal level, the balance between these logics shapes what is expected and accepted behaviour for broader society. Moreover, at the level of the Welsh health-care institutional field, their expression orchestrates the rituals, routines and practices constituting day-to-day professional work.³⁸ The interplay between logics and their inherent tensions give rise to the institutional complexity that all health-care practitioners confront.⁷¹² Consequently, each individual – whether positioned as a policy lead in the Welsh Government, a health board chief executive or board-level director, or a hospital doctor, nurse or other aligned professional group – has to negotiate individually, and as part of a functional team, the consequences of countervailing, co-existent and complementary logics. Existence within such a system demands nuanced institutional work. This is typically executed through role and professional position-based power to attain a state of force majeure, or to broker a workable sense of reconciliation and compromise.⁷¹³

Our findings indicate that the precise balance of the institutional logics moulding the Welsh health-care institutional field impacts patient safety in a particular way. First, the paradigmatic logic of bureaucratic command and control, which fosters mandated engagement with 1000 Lives+ via coercive institutional isomorphism, structures the health-care policy context for elite individuals such as policy leads, members of public sector partner agencies tasked with the strategic oversight of patient safety and board-level personnel in NHS Wales' seven health boards.

Although this logic was dominant at the level of the infrastructural system, as illustrated in *Figures 8 and 9*, professional logic was found to dominate contextual strata at sub-board organisational levels across each health board. This gave rise to conflict between logics. In the example of the mandated completion of the WHO checklist, cited in *Chapter 7*, while the moral and pragmatic legitimacy of the 1000 Lives+ programme was promoted by the logic of policy leads and health-care managers, it was challenged by the logic of some groups of health-care clinical professionals. Importantly, it was not the central issue of patient care that promoted such contestation, but the means through which it was imposed. Mandated engagement was perceived in a pejorative light as a means of management control that eroded professional autonomy: a core component of professional logic.^{335,336} This created tensions that provoked decoupling from the goals and practices advocated by the 1000 Lives+ programme.

What organisational factors matter: how, why and for whom?

Our findings set out in *Chapter 4* illustrated that the paradigmatic logic of bureaucratic command and control inculcated a pervasive performance measurement and management ethos across the Welsh health-care field. Mandated engagement with 1000 Lives+ was, therefore, legitimised as a core policy lever for health-care transformation. This clearly impacted on board-level actors in NHS Wales' seven health boards. Specifically, it caused their actions to be directed to the (i) co-optation, negotiation and legitimisation of the distributed leadership of change across the relational structure of their personal managerial and professional networks; and (ii) the formalisation of patient safety governance processes, specifically the statutory Quality and Safety Committee, aligned to the Welsh National Quality and Safety Forum.

Such mandated engagement was, however, hindered by the challenges posed by the structural reconfiguration of NHS Wales. Indeed, our findings highlight that the emergence of health boards has (i) added management tiers, which now distort communication channels formerly shaped by proximity and close relational ties for health-care managers and health-care clinical professionals alike; and (ii) disrupted the relational structures of clinical micro-work systems due to clinical service reconfiguration across formerly distinct organisations. Furthermore, the profound challenges posed by the economic downturn impact patient safety and NHS Wales' organisations engaged with 1000 Lives+ have to do 'more with less'.

Reflecting on such issues at the level of the functional team added further insight into the nature of situated context. For example, the organisational factors impacting the focal intervention ILQI, set out in *Chapter 6*, were found to be closely integrated with the 1000 Lives+ programme's position as a legitimised core policy lever for health-care transformation across NHS Wales. Formalised through the Welsh Government's tier 1 targets, this structural constraint drove board-level engagement and severely limited the scope for decoupling. Moreover, it was compounded by demands for heightened transparency with respect to the publication of health board and discrete hospital site RAMI data (see *Tables 14–20*) and board papers conveying the use of patient stories.

In addition, in the aftermath of the Francis Report,⁷¹⁴ cultural constraints and enablements centred on heightening awareness of systemic failings and the need to foster a culture of high-quality compassionate care. This gave rise to the institutionalised division of delegated strategic oversight of patient safety – and thus 1000 Lives+ and ILQI – to the directors of medicine, nursing, and therapies and health science. Given the board-level status and professional role-positions of such actors, the inherent change agenda overarching the 1000 Lives+ programme and, thus, the ILQI were executed from a position of high negotiating strength.

Structural elaboration was, therefore, displayed across each case site. Indeed, an objective outcome of the ILQI was the normalisation of the three practices examined in *Chapter 6*. In addition, the relational structure at each site had evolved, promoting the diffusion of the ILQI, and thus the 1000 Lives+ programme, while engendering a culture of organisational learning. However, cultural change was restricted by medical disengagement – notably via challenge to the moral and pragmatic legitimacy of some components of the 1000 Lives+ programme. The two key issues we identified were the burden of documentation and weak feedback from boards to wards.

The organisational factors impacting at the level of the functional team for the focal intervention RSC and the associated WHOSSC, set out in *Chapter 7*, were, once again, shaped by the bureaucratic processes of formalisation emergent from the infrastructural system of the Welsh Government's Department of Health and Social Care. However, in this regard, the overarching policy mandate of the 1000 Lives+ programme was augmented by the compulsion to undertake the WHOSSC forwarded by professional Royal Colleges.

Cultural constraints and enablements centred on the institutional system emblematic of the theatre departments. Two critical features surfaced in this study were a sense of separation from the broader health board that was compounded by distinctive functional and dominant professional cultures.

In essence, the local implementation of the RSC and the WHOSSC demanded skilful brokerage of institutional change across two groups of theatre department staff. The first group were consultant surgeons who lacked the burden of managerial accountability for the implementation of the RSC and WHOSSC, and who, therefore, were, quite simply, participants in its local operationalisation. This group of actors viewed the change with a degree of disdain: 'It was all quite an interesting shambles actually. The senior people decided that they were above it all basically'. The second group were consultant surgeons, supported by theatre managers, who were explicitly tasked with the strategic oversight of the local implementation of the RSC and the WHOSSC. Given the professional role-positions of such theatre department actors and the inherent change agenda overarching the 1000 Lives+ programme, the RSC and the WHOSSC were executed through negotiated compromise through multimodal institutional work.

Once again, as set out in *Chapter 7*, structural elaboration was evident across each case site. This was illustrated by the integration of the WHOSSC into governance processes. However, the openly acknowledged decoupling from such governance processes distorted coherence and commitment to the RSC and the WHOSSC by diminishing it to a tick-box exercise. Such a contested change highlights the time demanded to bring discordant professional logics into alignment. It also underscores the complexity of the prolonged period of creative institutional work required to promote the desired coalescence and unification at the cultural system level.

In contrast, the organisational factors impacting the focal intervention RHA1 centred on the complex array of established alternative frameworks and ongoing surveillance of their effectiveness via the WHAIP. This was compounded by different but interlocking professional roles across the local IPAC team. Accordingly, in such a situated context, no appreciable change to practice was required and deinstitutionalisation did not occur. The 1000 Lives+ programme and RHA1 were, therefore, blunted through adherence to alternative frameworks of perceived heightened professional legitimacy via institutional maintenance work.

Mechanisms that interact with contextual organisational factors to generate the health outcomes of hospital patient safety interventions

In this section, first, we reflect on the notion of a mechanism. Then we set out how our findings have identified critical mechanism substructures which impact the local implementation of the 1000 Lives+ programme.

From mechanism to causal configuration

In realist inquiry, mechanisms are considered to be the engines of explanation embodied in an agent's reasoning and their selective attention to the disparate resources offered through a social programme.^{228,241,242} However, consideration of social actors' contextually situated reflexive reasoning remains underdeveloped.²⁵⁶ One reason for this arises from the inherent problems associated with unpacking and conceptualising reasoning, specifically as justifications for choices may operate within different, and often contradictory, stances.³²¹

The notion of 'a mechanism', in the sense of a unitary phenomenon, obscures its inherent structure and operation within a broader causal configuration. Hence, in this study, mechanism, while centred on agents' reasoning, is theorised as part of a causal configuration emergent from a cluster of contextual factors and organisational components. These typically encompass a complex array of social structures, practices, relations, rules and resources. Yet, collectively, it is these factors which possess the powers, capacities and potentials to do certain things when operating in a spatio-temporal relationship with other objects.^{306,309,310} Conceptualised in this manner, mechanisms, and their attendant causal I-CMAO (CMO) configurations, may be embedded in another or configured in a series, so that the outcome of one configuration becomes the context for the next in the chain of implementation steps.³⁰⁷ This aspect of realist inquiry remains underdeveloped, as it demands the formulation of I-CMAO configurations, which pervade and connect contextual strata, in the form of bidirectional (top-down and bottom-up) nested causal cascades or metamechanisms.³¹⁶⁻³¹⁸

In this study, our aim was to contribute to these conceptual challenges by examining the nuanced demarcation between context and mechanism across defined yet linked contextual strata, each involved in the operationalisation of the 1000 Lives+ programme within the Welsh health-care field. Hence, to examine the process of the local implementation of this complex and ambitious patient safety programme, we drew on two fundamental institutional processes – bureaucratisation and normalisation – which, we argue, operate as sociocultural and organisational metamechanisms. Bureaucratisation and normalisation, therefore, act as the underpinning carriers³⁴⁷ of the processes of health-care institutional change and ensuing practice-based change advocated by 1000 Lives+. In essence, it is through successful embedding within these fundamental metamechanisms that the patient safety programme becomes institutionalised.

Our findings from *Chapters 4–8* illustrated three mechanism substructures, which collectively compose core components of the causal configuration for the local implementation of the 1000 Lives+ programme and further enrich our appreciation of the complex interplay of context and mechanism.

Mechanism substructure I: institutional isomorphism – mimetic, coercive and normative – coupling and decoupling

Institutional theory has arguably become the dominant approach for the study of macro-organisational phenomena.⁷¹⁵ Indeed, in institutionally informed health-care research it is acknowledged that institutions are primary and mould the context in which the varied health-care actors' interests operate.⁷¹⁶ Dominant institutional logics are, therefore, a critical field-level mechanism⁷¹⁷ that focus attention on the manner through which the attendant 'culture'⁷¹⁸ influences lower-level organisational change.⁷¹⁹

As set out in *Chapter 4*, our findings indicated that, within the Welsh health-care field, institutionally prescribed values were orchestrated at field level and echoed at the organisational level of the Welsh Government and NHS Wales, though they manifested in a distinctive manner in functional subgroups. This stance has been identified in other complex, institutionally dense organisations.⁷²⁰ However, it was the discrete professions embedded within this institutional field that operated as the 'pre-eminent institutional agents', enacting isomorphic institutionalism through mimetic, coercive or normative means.^{404,721} Furthermore, our findings highlight that such institutional work engendered legitimacy which impacted strategy and culture as well as associated structures and processes, in part, due to the statutory accountabilities and governance structures enmeshed with patient safety practices across NHS Wales.

Voronov *et al.*⁷²² have identified the important role of 'glocalisation' – fidelity to global norms with aligned adaptation to local conditions – in institutional maturation and change. In our study, this effect was apparent in the transmission of the IHI patient safety practices via mimetic isomorphic forces, driven by the dominance of the IHI's position and their acceptance by elite institutional actors with close professional ties to policy leads within the Welsh Government. Indeed, our data highlighted that for social actors embedded within the policy domain of the Welsh Government, mimetic isomorphic forces drove acts of imitative entrepreneurship even for those who expressed questions over the legitimacy of the 1000 Lives+ programme. Mimetic isomorphism also arose through the institutional work of 'believers' in the 1000 Lives+ programme's ethos and values, thereby catalysing co-optation and engagement of others. Yet despite the salience and assumed core values enshrined in the notion of patient safety, this institutional mechanism, as previously illustrated by Van Wijk *et al.*,⁷²³ was marred by the disruptive distributed brokerage of change.

Coercive institutionalism was apparent throughout our study. It emerged from dominating organisational structures tied to health-care policy, health board performance and the 'legitimising rhetoric'⁷²⁴ of governance – external and internal – of patient safety. Yet this, too, was challenged by professional, predominantly medical, power-based structures of membership and specialism identity.⁷²⁵

In addition, isomorphic institutionalism through normative means was apparent in some long-established interventions, which had previously operated under the banner of the 1000 Lives campaign and, indeed, the Safer Patients Initiative, together with others associated with the 1000 Lives+ programme. However, as illustrated in *Chapter 5*, such normalisation was fragmented and isolated in discrete pockets.

Normalisation of the 1000 Lives+ programme was also associated with clear leadership of change, internal health-care practice maturation emergent from the MI-PDSA approach, and complex 'boundary brokerage'^{34,91,726} to signal an identity for the programme, its adherents and associated health-care practices. The creative institutional work required to change beliefs, values and, through time, associated norms of practice was frequently displayed by actors occupying hybrid professional roles, including nurse-managers, associate directors with dual management and clinical portfolios, and board-level clinical practitioners. This finding parallels that of Reay *et al.*^{222,408}

Our findings illustrated that, while the local implementation of the 1000 Lives+ programme fostered strong institutional coupling that was moulded by the institutional isomorphism inherent to its bureaucratisation and normalisation, the operationalisation of 1000 Lives+ in everyday practice was distorted by adaptive and maladaptive decoupling.

Adaptive decoupling arose in the focal intervention RHA1, as already established alternative IPAC guidelines and the ongoing surveillance of their effectiveness via the WHAIP were perceived to offer more rigor and, thus, heightened legitimacy across the core professional groups examined in our study. Hence given the embedded nature of such alternatives, and their aligned clinical practices, the 1000 Lives+ programme was simply circumvented.

In contrast, maladaptive decoupling was apparent in the local implementation of the focal intervention RSC, centred on the WHOSSC. Given the Welsh health-care policy commitment to this practice, as well as its world-wide professional advocacy,^{439,565,727} it is worth considering the means through which such maladaptive decoupling manifested, that is, the simple and common failure to identify the members of the theatre team in the checklist. This practice reduced the possibility of individuals being blamed for any failures, undermining belief in the WHOSSC as a meaningful practice. Indeed, such disruptive institutional work diminished the legitimacy and moral foundation of the practice and hindered the remoulding of underlying belief systems. Perceived as a threat to the entrenched professional dominance of surgeons, the resistance rendered the WHOSSC down to a tick-box exercise which was interpreted by respondents to demonstrate that it was having little effect on reducing error '...across NHS Wales we've had disasters even with the checklist being used: wrong site surgery, instruments left in, etcetera ... In other words it's not being used properly'.

Mechanism substructure II: alignment of institutional logics – countervailing, co-existent and complementary – and ensuing coherence, cognitive participation and reflexive monitoring

At the level of the Welsh health-care institutional field, the nature of the alignment of institutional logics - be they complementary, co-existent or countervailing – impact patient safety. As discussed in *Contextual organisational factors pertinent to the health outcomes of hospital patient safety interventions, What supra-organisational factors matter: how, why and for whom?*, and as illustrated in *Figures 8 and 9*, this centred on the interplay of the logic of the bureaucratic state and professional logic. However, previous studies have illustrated that, within health care, professional logic does not manifest in unitary manner.^{37,38,222,373,728} Rather, different interprofessional logics and attendant institutions are displayed, each connected by some semblance of an overarching 'logic of care'.³⁷³

Our findings illustrated the dynamic and complex nature of this relationship. When a complementary alignment of professional logics arose, as in the case of the focal intervention ILQI, coherence, cognitive participation and reflexive monitoring of the health-care practices advocated by the 1000 Lives+ programme was fostered, thereby aiding its normalisation in daily practice. In contrast, a countervailing

alignment of logics, or their mere co-existence, was found to have stymied normalisation. Such varied permutations may be found both between different health-care professional groups, and within a discrete health-care professional group, and are typically dependent on two factors. The first is variation in individual practitioners' reflexive theorisation, encompassing their discernment of the patient safety practice in question, deliberation over the issues and dedication to a chosen action guided by their situational logic. The second factor is variation in the situational logic apparent at the level of the functional team.

Normalisation, a pivotal stage of institutionalisation, was therefore found to be dependent on the actions of those who were the 'believers': perceiving meaning in 1000 Lives+ due to alignment with the beliefs and values of their professional logics. When such coherence manifested, it promoted cognitive participation and reflexive theorisation in the individual and, importantly, at the level of the functional team, building commitment and co-ordinated engagement with the programme across the bounded clinical micro-work systems. Underscoring the fundamental role of leadership and effective teamwork to orchestrate the actions of the functional team, such processes were central to local innovation and adaptation of the health-care practices advocated by 1000 Lives+ and appeared to be a viable means of developing micro-competences across the functional team.

Mechanism substructure III: relational structure – role position-practices and profession – and the power to change health-care practice

Across *Chapters 4–8*, our findings highlight the role of the relational structure of the functional team in the local implementation of the 1000 Lives+ programme. This mechanism substructure places attention on the human relationships. By this we mean the ties that bind the functional team, its orchestrating situational logic, ethos and values, and the presence of hierarchical or distributed leadership.^{729,730} These factors collectively impact team-level performance and, in turn, patient safety. Hence relational structure is moulded by the interplay of role position-practices and profession within the multidisciplinary team, and the power to change health-care practices is aligned to leadership functions across managerial and clinical micro-work systems.

In *Chapters 4–8*, those in professional role-position practices shaped by high levels of social capital – typically board-level managers and consultant medical or surgical health-care practitioners – were found to have had a valued role to play in reconfiguring other actors' belief systems to support the local implementation of 1000 Lives+. Our findings therefore echo those that recognise the role of managerial, medical and nurse leadership in patient safety, especially in the brokerage of change across different functional teams.^{34,731,732} Despite this, there were some such actors who, as the following comment illustrates, overtly rejected the 1000 Lives+ programme: 'The 1000 Lives+ national programme and the campaign – it's command and control rather than a grass roots culture change – it hasn't been created by the people. It's not of the people. It's an imposition. It's control. It's from Cardiff. It's very much a Cardiff thing that is being pushed to everyone else because: "we know better". Outside Cardiff, it feels remote and distant and not part of us, it's something that we all recognise as important, clearly, but we don't necessarily own it'.

However, such demonstrable leadership was not the exclusive jurisdiction of high-status actors. Social actors across an array of managerial and clinical roles, who expressed their belief in the 1000 Lives+ programme and actively engaged in creative institutional work to imbue a similar sense of meaning in others, were undeniably central to the local implementation of 1000 Lives+ and the ongoing discourse of patient safety across NHS Wales. This was expressed in the view that 'Clinical leadership is key – credible clinical leadership – and that's all about empowerment of Band 7 nurses', underscoring the empowerment and emancipation of those in roles traditionally subordinate to the profession of medicine. Therefore, in supporting staff at all levels, an important outcome of the 1000 Lives+ programme was the progressive erosion of entrenched professional barriers that prohibit challenge and scope for health-care practice change.

Mediation and reflexive theorisation

In defining such mechanism substructures, our findings help to reveal how the structural constraints and enablements of context are mediated to social actors engaged in the local implementation of the 1000 Lives+ programme. As expanded in *Chapter 2*, these influences give rise to four potential second-order emergents, which foster the accompanying situational logics of protection, correction/compromise, opportunism and elimination, thereby guiding the generative mechanisms in play.

Our findings illustrated that the focal intervention ILQI drew professional logic into alignment with that of the bureaucratic state. This fostered the systematisation of 1000 Lives+ and ILQI across the cultural system level of NHS Wales and promoted the reproduction of such practices across each health board. Consequently, at board level, ILQI operated under a situational logic of protection that guided sociocultural interaction, agency, strategic negotiation and ensuing modes of institutional work.

The focal intervention RSC, centred on the local implementation of the WHOSSC, confronted a more contested terrain, with the coalescence and cohesion manifest between the views of theatre managers, consultant surgeons tasked with the implementation of the WHOSSC, and theatre nurses, stymied by the countervailing stance adopted by some surgeons. These constraining contradictions (necessary incompatibilities) between the dominant logic of the bureaucratic state and aligned professional health-care management logic versus that of professional medical logic held by surgeons opposed to the introduction of the WHOSSC therefore created a situational logic of correction/compromise. This logic guided sociocultural interaction, agency, strategic negotiation and ensuing modes of institutional work along its disrupted path.

The focal intervention RHA1 emerged into a context moulded by internal and necessary linkages of a complementary nature to existing structures. Nonetheless, a situational logic of protection of the status quo ante manifested. Reflexive monitoring was found to be anchored to the past, to preferred and more highly rated organisational and professional processes currently in use. Under these conditions, there was only superficial interest in and action to engage with RHA1.

Development and hypothesis testing of relationships between contextual organisational factors, mechanisms and the health outcomes of hospital patient safety interventions

In this study, we sought to develop and test hypothesis regarding the nature of the relationships between contextual organisational factors, mechanisms and the health outcomes of hospital patient safety interventions. Yet given the ontological commitment to critical realism, set out in *Chapter 2* (see *Addressing the challenges of realist enquiry, Realist social theory*) and *Chapter 3* (see *Comparative case study approach, Ontological and epistemological alignment to realist analysis*), such hypothesis testing was markedly different from that commonly adopted in positivistic studies. In essence, our approach centred on the progressive explanation and refinement of our understanding of the local implementation of the 1000 Lives+ programme, and the three focal interventions considered in more depth, all framed through our I-CMAO configurations.

Across *Chapters 4–8*, this approach revealed the nuanced relationships associated with the bureaucratisation and normalisation of the 1000 Lives+ programme, as illustrated in the explanatory schematics and accompanying data tables. What emerged from our data was the role of structural and cultural conditioning on the individual, embedded at the level of the functional team – managerial and clinical – and their ensuing disposition and scope to act to effect institutional change in support of patient safety. Such social structure, understood as the internal and necessary relations between social positions and positioned-practices, gave rise to emergent causal powers as the material cause of social activity.^{733–735} Perceived through our non-reductionist critical realist ontological stance, patient safety is, therefore, an emergent property of the micro-level organisation of health care.

In examining the bureaucratisation and normalisation of the 1000 Lives+ programme, together with the local implementation of the three focal interventions selected, the underpinning role of the MI-PDSA approach, depicted in *Figures 2–11*, was revealed. 1000 Lives+, together with this core resource, were found to have become ‘part of the patient safety language of NHS Wales’ . . . ‘PDSA cycles and all of that stuff it’s created a language that they like: it’s language that they all understand’. That, supported by the 1000 Lives+ dedicated website, and aligned resources from Improving Quality Together and Patient Safety Wales, now provide the means to spread such practices across NHS Wales.

However, although innovation through identifying failings and honing local knowledge and skills to change health-care practice was evident throughout our study, there were those who challenged the evidence that the programme was working: ‘The evidence-base for the 1000 Lives+ national programme has been systematically attacked by the other factions – for one side, it’s evidence and truth; for the other, it’s spin and fluff – and reality is caught in the middle’.

Limitations of the study

Although we contend that our realist analysis framework presents an innovative and suitable means to address the research questions posed, we must acknowledge inherent limitations. There are three main sets of limitations to this work: (1) those posed by the process of realist analysis itself, (2) those consequent on any qualitative social science research, and (3) those posed by a lack of the type of quantitative data which would have added further validity to our findings.

The most significant limitation in producing a narrative which is true to the tenets of critical realism is in the abstraction, abduction and retrodution inherent to the data analysis. Abstraction draws out the various components within the situated context, facilitating the conceptualisation of their interplay, through combination and interaction, so that the researcher may gain new insight.³¹⁰ Abduction involves the production of an elementary account of a basis process or mechanism.³⁶³ Retrodution builds on this analytical stage. The aim is to reconstruct the basic conditions for such phenomena to be what they are, so fostering knowledge of the transfactual conditions, structures and mechanisms in play.³⁶³ In this study, this process was aided by the hierarchical bureaucratisation of the Welsh health-care institutional field, which facilitated the explication of the internal and necessary relationships underpinning structural and cultural emergent properties.

To be adequate, as noted by Herepath,³⁴² this approach must abstract from particular conditions, excluding those which are believed to have no significant effect, in order to focus on those which do and identify relations of different types: ‘substantial’, ‘formal’, ‘external or contingent’ and ‘internal or necessary’.³¹⁰ Only once this step has been achieved may it be possible to combine or synthesise the various separate understandings into a unity that reconstitutes, or provides a better understanding of, the concrete.⁷³⁶ Thus, an explanatory structure is devised through a combination of theory and experimental observation.²²⁸

Inevitably, such analysis is open to the criticism that, as it must be influenced by the investigator’s perspective, beliefs and experience, the data represent only individual interpretation. To counter such criticism we made considerable efforts to ensure the data collected were as robust as possible. We achieved this triangulation of data collection by accessing documentary evidence and conducting on-site observation, as well as interviewing a large and varied number of individuals.

A further limitation of our study is our inability to derive detailed linkage of quantitative data to the qualitative data relating to each specific intervention studied. Paradoxically, given the engagement in the study of all seven of the health boards in NHS Wales, detailed linkage of quantitative data was prohibited as it would have proved impossible to ensure anonymisation at organisational, hospital case site and

individual level. The best we were able to do was to accommodate for this deficit by giving illustrative public source data for each health board, as set out in *Tables 14–20* (RAMI data), *Tables 25 and 26* ('never events' across NHS Wales' health boards) and *Tables 31 and 32* (MRSA per 100,000 bed-days and *S. aureus* per 100,000 bed-days).

Possible applications

As this study centred on the local implementation of the 1000 Lives+ national patient safety programme across NHS Wales, a substate nation with devolved oversight of health-care policy, it is pertinent to consider to what extent our findings may be applicable to other developed or developing health-care systems.

There is, of course, a global debate on patient safety, and patient safety programmes have been widely integrated into developed health-care systems on a world-wide scale. In that sense, some of the processes and practices seen in our study of the implementation of 1000 Lives+ in NHS Wales may well be identified in other settings and, therefore, offer insights into other similar processes and practices elsewhere. Nevertheless, the extent to which our findings may be directly transferable to other health-care systems implementing major programmatic changes is limited by a number of factors.

First, as presented in *Chapter 4*, NHS Wales is shaped by a distinctive health-care policy trajectory in which engagement with the 1000 Lives+ programme is mandated and monitored. This created a health-care institutional field moulded by coercive isomorphism in addition to the normative and mimetic modes more typical to studies of the diffusion of patient safety practices.³⁵⁸

Furthermore, the study period overlapped the period of transition following the reconfiguration of health services in Wales. As such, health boards, through the merger of other former NHS Wales' hospital trusts with primary care organisations, were newly established. Each organisation, therefore, confronted a strategic agenda burdened by the managerial demands of reconfiguration, including change to management cadres and clinical director roles, together with the politicised and public constraints fostered through the ongoing reconfiguration of hospital service provision across each territory. Though such circumstances are far from unique in developed health-care systems, they were distinctively shaped by the particular context of health care in Wales, and these factors do limit the degree to which the lessons learned from this study may be transferable to other settings.

Another limitation of applicability is that, although in our research protocol our case site selection criteria encompassed a major hospital, an intermediate hospital and a small local community hospital within each health board, to offer a desirable mix of different organisational features the strategic oversight of the 1000 Lives+ programme and its leadership was predominantly centred within the major hospital sites. Indeed, the 1000 Lives+ programme was, ostensibly, acute in its focus, with fewer interventions applicable to small case hospitals. This limited our scope to explore the implementation of each focal intervention across the range of organisations. Our findings are, therefore, more broadly applicable to large and intermediate hospital settings.

Case study participants were initially selected by the research team's local contact at each case site and, thus, a degree of bias must be acknowledged. However, we sought to mitigate this issue through our use of a snowball sampling strategy, as discussed in *Chapter 3*. As evidenced by the candid and occasionally very blunt comments embedded in *Chapters 4–8*, the research team is confident that the data collected accurately represented the views of those interviewed, although, as a degree of self-selection was involved, we cannot discount the possibility that others who were not interviewed might have held different views.

Despite these caveats, however, we would argue that, at the micro-level of functional teams in wards and departments, the processes and practices of implementation identified in this study may well mirror those to be found in similar circumstances in other health-care systems, and that our findings may thus have relevance and offer lessons to be learned elsewhere.

Contribution of the study to patient safety research

This study offers conceptual, methodological and empirical contributions to patient safety research. In conceptual terms, we developed a theoretically grounded and evidence-based realist model of which organisational factors matter, how they matter and why they matter. To do this, we introduced conceptual resources from sociological institutionalism and Archerian critical realism to address challenges associated with applying realist inquiry. Our model incorporates four elaborations of the established approach to realist inquiry.

First, so that we may understand precisely 'what' is working, for whom, how and in what circumstances, we include intervention as a separate analytical category in our realist analysis. Second, we forward a view of 'situated context' as stratified, conditioned, relational and temporally dynamic. This involves identifying the dominant structural and cultural emergent properties in play and separating context from its mediation. Third, we apportion mediation and reflexive theorisation to mechanism. In this manner, we distinguish the conceptual elements of mechanism from its ensuing outcomes, which include the agential emergent properties, expressed through the unfolding strategic negotiation of change, and the mode of institutional work enacted, to deliver sustainable outcomes, be they elaborative or reproductive. This fine-grained realist analysis therefore explicates the fundamental role of beliefs and values – institutional logics – on the propensity to act, to reveal the contested nature of institutional change, health-care practice evolution, and thus social elaboration or, indeed, reproduction. Finally, in our realist analysis framework, outcome is not perceived as a simple, single aspect of change, such as a defined health outcome. Rather, we reveal structural and ideational differentiation, together with the regrouping inherent to the power play of the diverse array of agents embroiled in the institutionalisation of a complex patient safety improvement programme.

In methodological terms, this is one of the first studies of patient safety to apply realist philosophy of social science across inception, design, fieldwork, analysis and writing. This has generated a number of features that may inform and challenge the field of patient safety research.

First, in contrast to the majority of health services research studies, this study has taken seriously, and explicated, realist epistemology and ontology. These foundations of our research conditioned its design, conduct and reporting. They helped shape our concern for ontological depth and contextual strata, and they directed us towards the identification and explanation of the underlying generative mechanisms which shape structure, agency, social relations and the ensuing practices that are reproduced and/or transformed. In terms of analysis, this is one of the first health services research studies to conduct abstraction, abduction and retroduction³⁶³ to devise an explanatory structure through a combination of theory and experimental observation. While we have earlier noted the challenges posed by this approach, we believe that this study has demonstrated the value of the analytical approach in helping to reconstruct the basic conditions for focal phenomena to be what they are, so fostering knowledge of the conditions, structures and mechanisms in play. In addition, the conclusions of our realist analysis are recognised to be both provisional and fallible.

In terms of empirical contribution, for each of the three focal interventions of 1000 Lives+ programme, this study offers a nuanced explanation of how local conditions relating to each level of our stratified model of context differentially combine with mechanisms (the engines of explanation embodied in people's reasoning) to derive outcomes in terms of structural and cultural reproduction or change. Reflecting social reality, these causal configurations are complex and nested. To aid our elucidation of these configurations we augment our textual description with a series of graphics. This approach to presentation of our findings allows us to clearly specify how particular configurations of factors across multiple layers of context (e.g. logics, power relations) combine with two metamechanisms (bureaucratisation and normalisation) and three submechanisms (isomorphism, logic alignment and relational structure) to generate outcomes that are variously viewed as more or less successful by multiple stakeholders.

We believe these findings will provide a valuable resource for policy-makers, managers and practitioners, locally, nationally and internationally, and will enable stakeholders to develop improvement interventions that are more likely to 'work' (for specified stakeholders) in their local contingent circumstances. They may also serve as a diagnostic tool to be used as a precursor to the design of more differentiated and context-sensitive interventions in future.

Future project outputs

This report addresses gaps in conceptual, methodological and empirical knowledge about the influence of context on the local implementation of patient safety programmes so that we may discern which contextual factors matter – how, why and for whom – in order that processes and outcomes of future improvement programmes may be improved. Future research outputs will seek to contribute to a broad range of academic and professional literatures.

Active dissemination of emergent findings to academic audiences has commenced via participation in relevant national and international conferences [Academy of Management (US); British Academy of Management; European Group for Organizational Studies; Health Services Research Network; International Organisational Behaviour in Healthcare; International Research Society for Public Management]. Dissemination will now continue through the submission of papers to leading academic journals. The first of such papers is currently under review.

As well as disseminating our findings to academic audiences, we intend to work with case site organisations in NHS Wales and, potentially, to reach out to a wider audience in NHS England, through a series of interactive seminars for health-care policy and professional audiences. These discussions will be disseminated through publications targeted specifically at NHS professional audiences including, for example, the *Health Service Journal*.

Future research

While the work conducted in this study could be developed in a number of ways, we believe that three options are most promising.

First, although this study adopted the organisation as the primary unit of analysis, we now consider that the micro-work system – managerial and clinical – could be a more fruitful unit of analysis from which to develop further insight into the implementation of patient safety programmes. Indeed, this offers the potential to examine the complexity inherent to the delivery of patient-centred care across discrete care pathways, thereby spanning organisational boundaries between primary, secondary and, potentially, tertiary-based functional teams. Such an approach, we believe, will help to explicate the true demands of leadership, followership, and empowered and emancipated team working, which underpin health-care practice innovation and commitment to the delivery of health care of the highest quality for all.

Second, this study has placed great significance on the role of, and interplay between, logics operating across the multiple strata of our model of context. In our case based in Wales, a critical dynamic occurs between the field level, where the paradigmatic logic of bureaucratic command and control shapes the activity of elite actors, while actors at sub-board organisational levels are influenced primarily by professional logics. It will, therefore, be important to compare the processes and outcomes from that context with (i) settings with similar institutional arrangements (possibly Scotland), and (ii) arenas with alternative arrays of dominant logics across contextual strata (possibly England, where the dominant paradigmatic logic is competition augmented by devolution and transparency).

Furthermore, given the mandated nature of engagement with the 1000 Lives+ programme in our study, and the tensions thereby fostered for some health-care clinical professionals, it will also be important to compare future patient safety interventions which emerge at the level of the functional team so that their insights may be effectively harnessed and their diffusion aided within, and across, health-care organisations.

Finally, this study has illustrated the complex interplay that lies behind the 1000 Lives+ programme's summary I-CMAO configuration. Indeed, it has exposed that distinctive 'cultures of care' emerged and operated throughout the local implementation of the 1000 Lives+ programme. These ranged from 'discrete pockets of high adherence' to situated contexts of 'enforced but somewhat disengaged adoption'. This finding demonstrates the time and institutional work needed to achieve change amid competing priorities, contested professional values and notions of control. Future research should address the relational dynamics of the functional team within a situated context to refine our understanding of high-performing micro-work systems and thus penetrate beyond the illusory notion of a cohesive culture of care.

Priorities for practice

Below, we set out the implications of our findings for realist informed research and the design and operationalisation of complex patient safety interventions.

Realist analysis

The realist analysis undertaken in this study is different from established approaches to realist inquiry. It is neither a realist evaluation of the success or failure of the 1000 Lives+ patient safety programme, nor a realist synthesis of extant data to inform the future redesign of the 1000 Lives+ patient safety programme and associated policy in NHS Wales. Rather, as set out in the introduction to this report, our approach to realist analysis defines an alternative means to analyse the complex interplay of this patient safety intervention within a specified 'situated' context. This creates challenges and opportunities for the field.

The challenges posed are primarily conceptual and methodological, and arise from the need to integrate distinct research traditions – realist inquiry, critical realism and institutional theory – with the information to be assimilated from aligned medical, health-care policy and health-care organisational and professional fields. However, we would argue that the opportunities offered by the adoption of our approach, and the generation of I-CMAO configurations within other studies, arise from the more nuanced understanding to be gained of the organisation and operation of developed health-care safety practices at the level of the functional team. This, we consider, possesses the potential to enrich our understanding of the emergence of patient safety as a dynamic capability within high-performing health-care teams, thereby informing the design of patient safety interventions.

Realist analysis: refinement of the concepts of context and mechanism

Our conceptual refinement of the situated context of care suggests that future patient safety research will need to consider context as more than a mere amorphous residual. While it may not be practicable for all research designs to actively embrace our stratified, conditioned, relational and temporally dynamic approach, a heightened awareness and account of context will foster cumulative insight and contribute to appreciation of the locus of change within complex health-care systems or discrete organisations.

Similarly, in future realist informed research, apportioning both the mediation of contextual forces and reflexive theorisation to mechanism will help to refine our understanding of what drives social agents – be they organisations, professions or individuals – to actively embrace and normalise a new patient safety practice or reject and retard such change. This will help to clarify the role of that such mechanisms play within larger and more complex causal configurations.

Realist analysis: refinement of agency and outcome

This study suggests that the combination of Archerian critical realism and institutional theory offers a robust means to examine mechanism across aligned or conflicted institutional logics in different organisational and professional jurisdictions. This feature of an I-CMAO configuration, therefore, helps to further inform our understanding of the operationalisation of patient safety practices, specifically by offering insight into the actions that unfold within and across functional teams. Accordingly, both patient safety research and the implementation of such interventions will benefit from an enhanced understanding of practice, centred on the unfolding strategic negotiation of change and mode of institutional work enacted to deliver sustainable outcomes.

Design of patient safety improvement programmes

This study demonstrates that complex patient safety interventions, though targeted at whole-systems or multisite health-care organisations, do not embed and normalise into practice in such a totalising manner. Rather, acceptance and adherence is piecemeal and fragmented. This suggests that their design may be more logically framed at the level of the functional team and associated discrete high-risk health-care practice. This has marked implications for the leadership of localised change and support provided, and the emancipation of front-line health-care professionals may further the development of innovative patient safety practices at the point of care.

Oversight of the implementation and operationalisation of patient safety improvement programmes

This study has demonstrated a significant cause for concern by capturing the ready acceptance of gaming,⁴⁰⁵ under a legitimacy façade, that obscures the failure to adhere to recommended patient safety practices. Such actions are diverse – ranging from hollow engagement with WalkRounds and disconnected recording of the WHOSSC in computer-based systems to the overt ‘performance’ of observed hand-washing – but they suggest the need for (i) clearly visible and meaningful leadership of patient safety and (ii) integration of the oversight of patient safety programmes into corporate governance and organisational development programmes, with ensuing accountability for performance and staff development. To this end, as outlined in *Chapter 5* (specifically in the sections *Putative mechanisms fostering and normalisation of 1000+ Lives*, *Cognitive participation* and *Collective action*), cognitive participation is an essential component of collective action to ensure that systemic and organisational factors giving rise to patient neglect are addressed, while knowledge sharing and trust are enhanced.

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Professor Justin Waring BA MSc PhD, coprincipal investigator, Professor of Organisational Sociology, Nottingham University Business School, University of Nottingham: participated in the advisory board, contributed to the academic development of the project and commented on the draft report.

Data sharing statement

Owing to the nature of the study and condition of ethics approvals, we are unable to share data related to this study.

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Appendix 1 Summary of case study organisations

Corporate parent	Abertawe Bro Morgannwg University Health Board	Aneurin Bevan University Health Board	Betsi Cadwaladr UHB University Health Board	Cardiff and Vale University Health Board	Cwm Taf University Health Board	Hywel Dda University Health Board	Powys (Teaching) Health Board
Geographical area	South	South	North	South	South	Mid	Mid
Population (000) (URL: www.wales.nhs.uk/sitesplus/922/home)	518	577	688	472	293	382	133
Major hospital with accident and emergency services	2	2	3	1	2	3	0
District general hospital with minor injuries unit	2	2	9	1	2	1	4
Small hospital/clinic without accident and emergency/ minor injuries unit	11	10	37	7	3	13	6

Health board hospital configuration accessed via www.wales.nhs.uk/nhswales/aboutus/structure.
For health board-specific information:
Abertawe Bro Morgannwg: www.wales.nhs.uk/sitesplus/863/directory/hospitals/.
Aneurin Bevan: www.wales.nhs.uk/sitesplus/866/directory/hospitals/.
Betsi Cadwaladr: www.wales.nhs.uk/sitesplus/861/directory/hospitals/.
Cardiff and Vale: www.cardiffandvaleuhb.wales.nhs.uk/directory/hospitals/.
Cwm Taf: www.cwmtafuhb.wales.nhs.uk/directory/hospitals/.
Hywel Dda: www.wales.nhs.uk/sitesplus/862/directory/hospitals/.
Powys: www.wales.nhs.uk/sitesplus/867/directory/hospitals/.

Appendix 2 Semistructured interview questionnaire

HOSPITAL PATIENT SAFETY: A REALIST ANALYSIS

[NIHR SDO 10-1007-06]

INTERVIEW QUESTIONNAIRE

Surname:

**First
name(s):**

Organisation:

Job title:

Date:

**FOR STUDY USE
ONLY**

Part 1

Information about the interviewee

This opening section of the interview aims to discuss the interviewee's role, professional background and management reporting relationships within the hospital case site.

1. What is your current role within the organisation?
 - i. How long have you worked in that role?
 - ii. What did you do before you took up your current role?
2. What is your professional background? [Asked if not explicit from comments above.]
3. Please will you tell me a little more about what your role involves on a day-to-day basis?
 - i. Who do you report to?
 - ii. Who reports to you?

Part 2

Awareness, understanding, and personal involvement in the 1000 Lives+ national programme and predecessor 1000 Lives campaign.

1. When and how did you first become aware of the 1000 Lives campaign or 1000 Lives+ national programme?
2. What does the 1000 Lives+ national programme mean to you?
3. How is the 1000 Lives+ national programme managed in your organisation?
 - i. Who is involved in the local leadership of the 1000 Lives+ national programme?
 - ii. How would you describe your involvement in the 1000 Lives+ national programme?

Part 3

Discussion of I-CMAO configurations for 1000 Lives+ national programme and relevant focal interventions.

Intervention

1. What patient safety interventions have been adopted?
2. Do you use any of the resources supported by the 1000 Lives+ national programme? [Ascertain awareness web site and support materials.]
3. Do you use the Model for Improvement, Plan-Do-Study-Act Cycle in your functional team?

Context

4. What do you consider to be the context in which you work: how would you describe it?
 - i. Awareness of Welsh health-care policy commitment to the 1000 Lives+ national programme.
 - ii. How is an ethos of patient safety advocated and developed?
 - iii. What organisational- or team-level governance processes are in place to measure and monitor the internal oversight of patient safety? [Assess visits via WalkRounds.]
 - iv. What external governance processes are in place to measure and monitor patient safety? [Assess inspection visits by Healthcare Inspectorate Wales, Community Health Councils, etc.]
 - v. What happens if you have a patient safety incident?
 - vi. Can you explain your complaints procedure?
5. How has the reconfiguration of NHS Wales/the health board impacted patient safety?

Mechanism

6. Do you think the 1000 Lives+ national programme improves patient safety?
7. Why/how do you believe it works?
8. What has helped or hindered the local implementation and ongoing operationalisation of the 1000 Lives+ national programme?

Outcome

9. How do you measure and monitor the impact of the 1000 Lives+ national programme on patient safety?
 - i. Awareness of monitoring processes for local targets, data collection, ownership, analysis and reporting.
 - ii. How is such data reported, to whom, formality and frequency?
 - iii. What changes in health-care practice have been encouraged by the 1000 Lives+ national programme?
10. If you could change *the 1000 Lives+ national* programme in any way, what would you do?

Appendix 3 Data search strategy

Databases	Research domain				
	Social science	Business	Health-care studies	Medicine	Nursing
ABI/INFORM Global (ProQuest)		✓			
AMED (Allied and Complementary Medicine) (via Ovid)			✓		✓
ASSIA (Applied Social Sciences Index and Abstracts)	✓		✓		
Biomed Central			✓		
British Humanities Index (via CSA)	✓				
British Nursing Index (via Ovid)			✓		✓
CINAHL (Cumulative Index to Nursing and Allied Health Literature)			✓		✓
COPAC	✓		✓		
EBSCOhost Business Source Premier		✓			
EMBASE (<i>Excerpta Medica</i>) (via Ovid)			✓	✓	✓
Emerald Library (via Emerald)		✓			
Ingenta Connect	✓	✓			
JSTOR	✓				
MEDLINE (via Ovid)			✓	✓	
MEDLINE In-Process & Other Non-Indexed Citations			✓	✓	
PsycINFO (via Ovid)	✓		✓	✓	✓
PubMed			✓	✓	✓
ScienceDirect – all subscribed content – V4 (Elsevier)	✓	✓			
SCOPUS – V4 (Elsevier)			✓	✓	✓
SwetsWise	✓	✓			
Web of Knowledge	✓	✓			
Zetoc			✓	✓	✓

Research themes and key author-based searches

Patient safety

- Harm.
- Health-care-associated infection.
- Health-care management.
- Health-care leadership and followership.
- MI-PDSA cycle.
- Mortality review and organisational performance
- Patient safety culture.
- Patient stories.
- Public inquiries.
- Shared decision-making.
- WalkRounds™.
- WHO Surgical Safety Checklist.

Health-care organisational analysis: key authors

- Allen D.
- Andrews R.
- Banaszak-Holl J.
- Barber N.
- Batalden P.
- Berwick D.
- Boyne G.
- Braithwaite J.
- Currie G.
- Dixon-Woods M.
- Dixon A.
- Dopson S.
- Exworthy M.
- Ferlie E.
- Finn R.
- Fitzgerald L.
- Franklin B.
- Fulop N.
- Greener I.
- Greenhalgh T.
- Ham C.
- Hyde P.
- Kirkpatrick I.
- Kitchener M.
- Le Grand J.
- Lilford R.
- Lockett A.
- Mannion R.
- Marshall M.
- McDonald R.
- McGivern G.
- McKee L.

- Ovretveit J.
- Pronovost P.
- Rycroft-Malone J.
- Schofield J.
- Shekelle P.
- Vincent C.
- Wachter R.
- Walshe K.
- Waring J.

Realist inquiry

- Critical realism.
- RAMESES publication standards (realist syntheses).
- Realist analysis.
- Realist evaluation.
- Realist review.
- Realist synthesis.

Realism: key authors

- Ackroyd S.
- Archer M.
- Bhaskar R.
- Cruickshank J.
- Danermark B.
- Edwards P.
- Elder-Vass D.
- Fleetwood S.
- Hartwig M.
- Mutch A.
- Outhwaite W.
- Pawson R.
- Potter G.
- Sayer A.
- Searle J.
- Smith C.
- Vincent S.

Institutional theory

- Bureaucratisation.
- Institutional change.
- Institutional creation.
- Institutional disruption.
- Institutional entrepreneurship.
- Institutional isomorphism (coercive, mimetic, normative).
- Institutional logics.
- Institutional maintenance.
- Institutional structure.
- Institutional work.
- Normalisation.

Institutional theory: key authors

- Battilana J.
- Boxenbaum E.
- Dacin T.
- Dcoupling.
- Dorado S.
- Goodrick E.
- Greenwood R.
- Hardy C.
- Hinings B.
- Lawrence T.
- Leca B.
- Lounsbury M.
- Meyer R.
- Ocasio W.
- Phillips N.
- Reay T.
- Scott W.
- Suddaby R.
- Thornton P.
- Tracey P.
- Ventresca M.
- Vermeulen P.
- Voronov M.
- Washington M.
- Zietsma C.
- Zilber T.

Appendix 4 Study invitation letter, information sheet and consent to be interviewed form

Dear [*Name to be inserted*],

RE: HOSPITAL PATIENT SAFETY—A REALIST ANALYSIS

I am writing to invite you to participate in a research study of hospital patient safety in Wales. *[This study is led by Professor Martin Kitchener, Associate Dean, and Director of Cardiff Healthcare Organisation and Policy Studies (CHOPS) at Cardiff Business School, Cardiff University. It is funded by the National Institute for Health Research Service Delivery and Organisation Programme (NIHR SDO)]

* Latterly revised to:

[This study is led by Professor Martin Kitchener, Dean, Cardiff Business School, Cardiff University. It is funded by the National Institute for Health Research Health Services and Delivery Research Programme (NIHR HS&DR)]

The study aims to examine the local implementation of three safety interventions—(i) *Improving Leadership for Quality Improvement*, (ii) *Reducing Surgical Complications*, and (iii) *Reducing Healthcare Associated Infections*—in NHS hospitals participating in the Welsh *1000 Lives*⁺ programme. In so doing, it will address the principal research objective to examine which organisational contextual factors matter, how they matter, and thus explain why they matter in order that the processes and outcomes of hospital patient safety interventions may be improved.

I hope that you wish to participate in this study, and help to promote improvements in patient safety and healthcare quality across NHS Wales. In that hope, I therefore enclose a Participant Information Sheet that sets out further information for your consideration.

Participation in this study will involve an interview (approximately one hour) to discuss your views of the local implementation of the three focal safety interventions selected from the Welsh *1000 Lives*⁺ programme, and the organisational factors which impact upon hospital patient safety. Furthermore, as the study progresses, participants will be invited to attend a feedback workshop to comment on its interim and end-stage results.

If you wish to participate in this study, or if you require further details, please do not hesitate to call me on [] or e-mail me at [].

Yours sincerely,

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Tel:

Web site: <http://www.cf.ac.uk/carbs/research/hospitalpatientsafety>

HOSPITAL PATIENT SAFETY: A REALIST ANALYSIS

[NIHR SDO 10-1007-06]

PARTICIPANT DETAILS

Surname:

**First
name(s):**

Organisation:

Job title:

Date:

**FOR STUDY USE
ONLY**

INTRODUCTION

This study aims to examine the local implementation of three safety interventions—(i) *Improving Leadership for Quality Improvement*, (ii) *Reducing Surgical Complications*, and (iii) *Reducing Healthcare Associated Infections*—in NHS hospitals participating in the Welsh *1000 Lives*⁺ programme.

In doing so, it will address the principal research objective to examine which organisational contextual factors matter, how they matter, and thus explain why they matter in order that the processes and outcomes of hospital patient safety interventions may be improved.

STUDY OBJECTIVES

The proposed study has five main research objectives.

1. To identify and analyse the organisational factors (e.g., structure, culture, and managerial priorities) pertinent to the health outcomes of hospital patient safety interventions.
2. To identify and analyse the contextual mechanisms (logics, or belief systems) that interact with organisational factors to generate the health outcomes of hospital patient safety interventions.
3. To develop and test hypotheses concerning relationships between organisational factors, mechanisms, and the health outcomes of hospital patient safety interventions.
4. To produce a theoretically-grounded and evidence-based model of which organisational 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.

THE ROLE OF PARTICIPANTS

Participation in this study will involve an interview (approximately one hour) to discuss your views of the local implementation of the three focal safety interventions selected from the Welsh *1000 Lives*⁺ programme, and organisational factors which impact upon hospital patient safety.

INVITATION TO PARTICIPATE IN THIS STUDY

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. **One of our team will go through the information sheet with you and answer any questions you have.** We suggest this should take at least 10 minutes.

Talk to others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear.

PART 1

WHAT IS THE PURPOSE OF THE STUDY?

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. Along with these human costs, safety incidents are a drain on devolved NHS resources, costing an estimated £3.5 billion a year in additional bed days and negligence claims.

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 numerous improvement programmes have been introduced. However, evidence that the outcomes of NHS patient safety improvement programmes vary across hospitals demonstrates that the organisational context of their implementation matters. Yet the relationships between features of organisational context (e.g., structure, culture, and managerial priorities) and the health outcomes of patient safety programmes are both under-theorized and poorly understood in empirical terms.

The study, **Hospital Patient Safety: A Realist Analysis**, is the first to 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 which organisational contextual factors matter, how they matter, and thus explain why they matter in order that the processes and outcomes of hospital patient safety interventions may be improved.

WHY HAVE I BEEN INVITED?

During this study, the research team will collect available documents containing organisational and clinical improvement data related to the local implementation of the three safety interventions selected from the Welsh *1000 Lives*⁺ programme: (i) *Improving Leadership for Quality Improvement*, (ii) *Reducing Surgical Complications*, and (iii) *Reducing Healthcare Associated Infections*. However, this information will be supplemented by extensive fieldwork at each participating Welsh NHS Hospital, including interviews with a broad range of hospital staff:

- (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).

In addition, this data 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.

In this study, we therefore seek your views of the local implementation of the three focal safety interventions selected from the Welsh *1000 Lives*⁺ programme, and your opinion of the organisational factors which impact upon hospital patient safety.

All data collected in this manner will be treated as confidential and anonymised (at the individual, site hospital and organisational level). The only person identifiable data collected during this study will be: (i) participant's names; (ii) their organisational role; and (iii) employing organisation. This data will be held within the proposed study's anonymisation record, which will be stored in a locked filing cabinet in Cardiff Business School. All hard copy archive and anonymised data will be stored in a locked filing cabinet in Cardiff Business School, and accessible only by the research team. All electronic raw data files will be password protected and accessible only by the research team.

DO I HAVE TO TAKE PART?

Your participation in this study is entirely voluntary and unpaid. You are free to withdraw at any time, without giving a reason.

It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

The Senior Research Fellow working in this study will contact you, via letter or e-mail, to arrange a suitable date and time for you to be interviewed. This one-hour interview will normally occur in your 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 undertake a follow-up interview.

As the study progresses, you will be invited to attend a feedback workshop to comment on its interim and end-stage results.

Throughout this study, contact may be maintained via the study's dedicated web site: [www.cf.ac.uk/carbs/research/hospitalpatientsafety], and a specific e-mail contact address [].

WHAT WILL I HAVE TO DO?

In this study, we are seeking your views of the local implementation of the three focal safety interventions selected from the Welsh *1000 Lives*⁺ programme, and your opinion of the organisational factors which impact upon hospital patient safety.

You will be asked to reflect upon our questions, and answer only those that you want to—*there are no right or wrong answers*. However, your opinion is very important to this study. All you have to do is express your beliefs and understanding of hospital patient safety.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

This study poses a very low risk, or burden, to potential research participants. However, participant will experience:

- (i) minimal intrusion during the process of seeking their consent to participate in the study;
- (ii) limited disruption to their routine working day, incurred through the face-to-face or telephone interview process, which will last up to one hour;
- (iii) assured anonymity, and
- (iv) complete confidentiality.

Your inconvenience will be minimised by arranging interviews well in advance.

WHAT IF THERE IS A PROBLEM?

Any complaint about the way you have been dealt with during the study will be addressed. The detailed information on this is given in Part 2.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

The study presents all its research participants with an opportunity to express their beliefs and understanding of hospital patient safety, and specifically the organisational factors which impact upon the local implementation of the three focal patient safety interventions selected from the *1000 Lives*⁺ programme: (i) improving leadership, (ii) reducing hospital acquired infection rates, and (iii) implementing surgical checklists.

Given that the relationships between features of organisational context (e.g., structure, culture, and managerial priorities) and the health outcomes of patient safety programmes are both under-theorized and poorly understood in empirical terms, the information offered by participants is essential to further inform the design of such patient safety initiatives. Therefore, following collation of the study's findings, its research participants—amidst others in the broader healthcare organisational and policy field—will, ultimately, benefit from the roll-out of new patient safety initiatives which are designed to reflect local constraints, challenges, and inherent strengths.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details of this are included in Part 2.

This concludes Part 1.

PART 2

WHAT IF THERE IS A PROBLEM?

If you have a concern about any aspect of this study, you should ask to speak to the researcher team's Chief Investigator, Professor Martin Kitchener, who will do his best to answer your questions.

Professor Kitchener may be contacted by telephone on [REDACTED] or via e-mail ([REDACTED]).

If you remain unhappy and wish to complain formally, contact the [REDACTED]
[REDACTED]
[REDACTED]

CONFIDENTIALITY

Participants' anonymity will be assured throughout this study. Each participant, hospital site, interview transcription, and researcher, will be assigned an identity code. (The study's Senior Research Fellow 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 the research team. 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 study's dedicated shared drive within Cardiff University. Access to this drive will be restricted to the research team. No further person-identifiable information will be stored in the form of an electronic record. All anonymised electronic raw data files—and collated, anonymised, and analysed data—will be password protected, and accessible only by the research team. The electronic transfer of data within the UK (via email or computer networks) between the research team 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.

The publication of direct quotations from the study's participants will be anonymised at the individual, hospital site and organisational level. Hence, no combination of incidental details of the participant's employing organisation, specific role, age or ethnicity will be reported, thereby ensuring individuals remain unidentifiable.

The study's research data will be stored for at least two years post publication of the end stage report, in accordance with Cardiff University's Research Ethics and Governance Guidelines for research records management.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

During the study, half-day interim workshops will be held to check data, feedback initial findings and elicit further comments from invited participants. In addition, our findings will be disseminated to user communities through articles in practitioner journals, and presentations to research forums.

In the final year of the study, knowledge transfer will take place through a half-day final seminar to test the implications of key findings, plus a national, one-day dissemination conference in Cardiff for senior policymakers and practitioners across the UK.

Furthermore, 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 our 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 and participants. In order to maximise use of the site we will publicise it through the workshops, conferences and short reports that we produce and publish.

The academic dissemination of our empirical findings at the main patient safety and health research conferences, and in the highest ranked journals, will ensure impact

among relevant academic communities.

WHO IS ORGANISING THE FUNDING OF THE RESEARCH?

This study is funded by the National Institute for Health Research Service Delivery and Organisation Programme (NIHR SDO), managed by NETSCC, SDO, as part of the NIHR Evaluation, Trials and Studies Coordinating Centre at the University of Southampton.

National Institute for Health Research
Service Delivery and Organisation Programme
Alpha House
University of Southampton Science Park
Southampton
SO16 7NS
sdofund@southampton.ac.uk

WHO HAS REVIEWED THE STUDY?

As the funding organisation, the Commissioning Board of the National Institute for Health Research, Service Delivery and Organisation (NIHR SDO) programme, has undertaken a comprehensive two-stage (outline and full proposal) expert peer review and assessment of the scientific quality of the proposed research.

Furthermore, prior to submission to the NIHR SDO, the research study was subject to internal peer review in Cardiff Business School, and across the wider research team located within the National Institute for Social Care and Health Research (NISCHR), Patient Safety and Healthcare Quality Registered Research Group, at the School of Medicine, Cardiff University, and Nottingham University. The research protocol, provisional questionnaire, and consent form have been approved by the Research Ethics Committee in Cardiff Business School, and by the Main Research Ethics Committee for Wales.

RESEARCH TEAM AND CONTACT DETAILS

For further information about the research, and advice about participation, please contact the Chief Investigator.

CHIEF INVESTIGATOR

Professor Martin Kitchener BSc(Econ) MBA PHD

[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]

Professor Jonathon Gray BSc MBChB PhD MPH

[Redacted]
[Redacted]
[Redacted]
[Redacted]

Dr Justin Waring BA MSc PhD

[Redacted]
[Redacted]
[Redacted]
[Redacted]

Dr Andrea Herepath PhD MBA PhD

[Redacted]
[Redacted]
[Redacted]
[Redacted]

HOSPITAL PATIENT SAFETY: A REALIST ANALYSIS

[NIHR SDO 10-1007-06]

PARTICIPANT DETAILS

Surname:

**First
name(s):**

Organisation:

Job title:

Date:

**FOR STUDY USE
ONLY**

YOUR CONSENT TO PARTICIPATE IN THIS STUDY

Case site code:

Participant code:

1. I confirm that I have read and understand the Participant Information Sheet dated: [_____] [version: _____] for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation in this study is voluntary and that I am free to withdraw at any time without giving any reason.
3. I understand that my participation in this study in this study will involve an interview to discuss the local implementation of the three focal safety interventions selected from the Welsh *1000 Lives Plus* programme, and my opinion of the organisational factors which impact upon hospital patient safety, which will require approximately one hour of my time.
4. I consent to audio-taping, and the possible use of verbatim quotations which will be anonymised.
5. I understand that the information provided by me will be held securely in Cardiff University. I understand that, in accordance with the Data Protection Act (1998), this information may be retained indefinitely.
6. I agree to take part in the above study.

Name of participant:**Date:****Signature:**

Name of person taking consent:**Date:****Signature:**

Name of researcher:

Date:

Signature:

A decorative graphic consisting of numerous thin, parallel green lines that curve from the left side of the page towards the right, creating a sense of movement and depth.

EME
HS&DR
HTA
PGfAR
PHR

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