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

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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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Scientific summary

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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.

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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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