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Examining 'institutional entrepreneurship' in healthcare redesign and improvement through comparative case study research: A study protocol

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Abstract

Introduction

Healthcare service redesign and improvement has become an important activity that health system leaders and clinicians realise must be nurtured and mastered, if the capacity issues that constrain healthcare delivery are to be solved. However, little is known about the critical success factors that are essential for sustaining and scaling up improvement initiatives.[1] This situation limits the impact of these initiatives, and undermines the general standing of redesign and improvement activity within healthcare systems. The conduct of the doctoral research detailed in this study protocol will be nested within a broader parent research project that seeks to address this problem by drawing on the theory of 'institutional entrepreneurship'. The doctoral research will apply this idea to understanding the capacities and capabilities required at the organisation level to bring about transformational change in healthcare services.

Methods and analysis

The parent study is predominantly qualitative, multi-level in nature and has been co-designed with five partner healthcare organisations. The focus is a sector-wide attempt in an Australian state jurisdiction to transfer new redesign and improvement knowledge into the public healthcare system. The doctoral research study will be focused on the implementation of the sector-wide approach in one healthcare service in the jurisdiction. This study involves interviews with project team members and stakeholders involved in two improvement initiatives undertaken by the health service. It will involve interviews with redesign and improvement leaders and senior management responsible for the overall health service improvement approach. The methods will also include immersive fieldwork, interviews, and focus groups. Appropriate methods for coding and thematic extraction will be applied to the qualitative data.

Ethics and dissemination

Ethical approval has been granted by the health service and Monash University Human Research Ethics Committee. Dissemination will be facilitated via academic publication, industry reports and a range of workshops and dissemination events as part of the broader project.

Strengths and limitations of this study

- The doctoral research will take place as part of, but is not directly funded by, an Australian Research Council cross-disciplinary study that draws on and applies capacity-building expertise from the following disciplines: management and organisational science, health services management, implementation science, and knowledge translation.
- The doctoral research is underpinned by the broader study's principles of collaborative research, an approach that enables meaningful, in depth, sustained fieldwork and the creation of practical learning and actionable knowledge.
- The collaborative approach is aided in the case of the doctoral research by the fact that the researcher is an employee of the case study partner health service and is conducting this research as part of the in-kind support offered to the parent project by the health service.
- As with the parent project, the doctoral study's theoretical approach, involves studying in situ and in real time the skills and capabilities of 'institutional entrepreneurs' – leaders who seek to change institutionalised behaviours and practices that get in the way of innovation.

- Institutional theory is being used increasingly by health services management researchers as it enables new insights into the process of embedding and scaling up innovation and transforming institutions.[2]
- Limitations include the single health service focus of the doctoral research, although this is mitigated by the comparable case studies being conducted by the broader research project and possible constraints arising from the researcher's dual role as both doctoral candidate and employee of the subject organisation.

Introduction

As with other OECD health systems, Australia's demand for healthcare services is escalating, driven by an ageing population with complex needs, rising rates of chronic illness, increasing health care costs and rapid information and technology innovation.[3] This demand is unlikely to be adequately met given the current and emerging economic limits and pressures affecting the capacity of the health system. Therefore, healthcare services and systems must engage in extensive and profound service innovation if they are to meet these challenges.[3] To date, however, hospital redesign and improvement initiatives have had limited impacts and outcomes at a system level. Whilst frequently effective in the short-term and at the local level, improvements are often confined to discrete areas within the health care system and are difficult to scale beyond their point of origin and sustain.[1, 2, 4-8]

This doctoral study explores the factors that enable and inhibit the take-up, spread, and sustainability of redesign and improvement initiatives, and identifies implications for capacity building at the individual, organisational, and health system levels. More specifically, it examines how redesign and improvement capability is shaped by both local context and circumstances, and broader contextual factors, and seeks to understand how these contexts can be shaped to be more conducive to redesign and improvement intended to bring about innovation in the way healthcare services are delivered. The study draws on the theory of 'institutional entrepreneurship' to understand how healthcare services, clinicians, and leaders might better understand and overcome the barriers to embedding and scaling up innovation, and how this capability might be fostered.

The doctoral study and the broader parent study within which it is nested is set in an Australian state jurisdiction, and is conducted in partnership with five partner organisations. Four research partners are large public health services of varying size and specialty, one of which provides the focus for the doctoral study.

The fifth research partner is the state government department responsible for a jurisdiction-wide initiative to transfer new redesign and improvement knowledge into the public healthcare system. This initiative has delivered a decade-long program to build capacity through a redesigning hospital care program. To date, the program has focused on building the skills of individual redesign and improvement advisors, and health services' improvement capability at the organisational level. The program has been lauded by independent evaluators for its longevity and comprehensiveness, and for achieving admirable efficiency and service delivery improvements at the local level.[5] However, the sustainability of the improvement projects enabled and supported by the program has been found to be questionable, and they have failed to be mobilised beyond their originating locale.[5, 8]

In this context, the aim of this doctoral research is to understand and inform redesign and improvement capability-building processes at the individual and organisational level within its host health service. The intent is to understand how a distributed, multi-level capacity might be

developed, whereby service improvements can be successfully embedded in local contexts where care is delivered, and also mobilised beyond these local contexts on a service-wide basis, thereby enabling the healthcare organisation to deliver quality healthcare outcomes, at pace and scale.

Methods and analysis

Theoretical approach

The theoretical approach for this research draws on institutional theory which underpins much research in the discipline of management concerned with explaining order and stability in organisations and thereby better understanding how transformational change can occur in situations where the bias is towards the maintenance of the status quo. Healthcare researchers are increasingly drawn to this theory since it seems to have particular application to healthcare systems which, despite increasing external and internal pressures to transform the way they deliver care, appear locked into existing and well established ways of delivering care and doing business.[2, 6, 7]

Related to institutional theory is the concept of 'institutional entrepreneurship' referring to actors (organisations, groups of organisations, individuals, or groups of individuals), 'who leverage resources to create new or transform existing institutions' (p.84).[4] Such actors initiate 'divergent change' (i.e. break existing institutional templates such as the existing business/service models of hospitals) and participate actively in driving change by mobilising required resources, including capabilities and knowledge (ideas and practices). This concept is highly relevant to the central problem of scaling up discrete innovations to a system level, as it provides a framework for multi-level analysis, from the micro-level of individual actions through to the behaviour of individual organisations, through to communities of organisations in a sector or field, at the system level.

Study design

The doctoral study will be predominantly qualitative, because in many respects it is exploratory and requires "open-ended inquiry".[9] Qualitative enquiry is also appropriate because "sensitivity to context" is important for the study[10] and the aim is to generate 'how to' knowledge,[11, 12] which institutional entrepreneurship suggests is affected by multiple, interacting factors and conditions.

The doctoral study constitutes an integral element of two of the four phases (Phases 3 and 4, discussed below) of the parent research project within which it is nested. The broader project is structured into four principal, inter-related phases designed to help understand the evolution of the jurisdiction's redesign and improvement initiative at the sector level, and the extent to and manner in which this has fostered redesign and improvement capacity at the individual and organisational levels within health services. The broader research design is guided by the idea that the relationship between capacity and context is interconnected and mutually influencing. That is, context shapes capacity at the organisational and individual levels, but individual and organisational capacity also shapes context. Each phase is explained below and depicted in Figure 1.

We divide the subsequent sections of the study protocol to reflect the focus of the doctoral study as part of phases three and four of the parent project. However, since the doctoral study is informed by phases one and two of the broader research project, and draws for comparative and benchmarking purposes on the findings from phase three and four of the broader study, relevant aspects of the overall research design are also outlined.

Figure 1: The four phases of the broader parent research

The broader project began in May 2015 with phase 1 (year 1) and phase 2 completed in year 2. Phase three of the broader project is due for completion by the early year 3 with the final phase to be undertaken in 2019 with completion anticipated by mid-year. The doctoral research which is the subject of this protocol is nested within this framework but is being undertaken to a different timetable in accordance with the requirements of registration and progress for a part-time study (See Figure 2).

Figure 2. Timelines for the parent study and doctoral study

As an "in-service researcher", the doctoral student faces the issue that her position may influence and bias the data collection and analysis, or that her position may indeed limit what is discussed because of issues anonymity and confidentiality.[13] Conversely, it is precisely her internal position, and ethnographic approach that stands to yield reflexive, rich and nuanced insights into explicit *and tacit* knowledge about redesign and improvement work in healthcare. The nested nature with the broader parent research offers a mechanism to mitigate possible biases by using the case studies being conducted across other health services as a comparative benchmark.

Broader Project Phases 1 and 2

The focus of **Phase 1** was the exploration of redesign and improvement capacity at the system level, and how this capacity was been built over time. The redesigning hospital care program referred to earlier provides a focal point for this exercise. Phase 1 of the research sought to capture and understand what had been learnt as a result of the program to date, and to support the application of that learning. Phase 1 drew out lessons learned by key program stakeholders for two key purposes: 1) to identify the contextual contingencies at the system-level that shaped the evolution of the jurisdiction's collective redesign and improvement capacity; and 2) to gain insight into the barriers and enablers that constrained and enhanced, respectively, the embedment and scalability of new redesign and improvement knowledge. Phase 1 also aimed to surface key stakeholders' perceptions regarding critical priorities for capacity building for the future, with the goals of sustainability and scalability in mind. During this phase, the broader project established the nature and current state of redesign and improvement capacity at the sector level, which provides important context for subsequent phases, and a benchmark for evaluating subsequent progress made by individual health services.

For the doctoral study, the relevant aspects of the research methods employed during Phase 1 of the parent research project are:

a) Documentary analysis. A desk review of historical and contemporary policy documents, evaluations, redesign and improvement tools, training and other capacity building materials, and outcome data (where available) held by the government and associated with the redesigning hospital care program.

b) Semi-structured, depth interviews. A program of semi-structured, face-to-face, depth-interviews[14] designed to tap institutional memory and allow the historical evolution of redesign and

improvement capacity within the jurisdiction's public healthcare system to be documented and the factors associated with key capability-building moments identified.

c) A modified Delphi survey. A modified Delphi survey designed to establish key stakeholders' perceptions of redesign and improvement capacity building priorities, with respect to enhancing the sustainability and scaling up of service innovation.

d) Familiarisation with the organisational cultures and contexts of each partner health service, including the health service which now provides the focus for the doctoral study.

Phase 2 provided a consolidation point for the parent project allowing the analysis and synthesis of the data collected during Phase 1. This produced an appraisal of the nature and state of redesign and improvement capacity at the sector-level, with reference to the capacity of other jurisdictions within Australia and internationally. It also provided an understanding of how sector-level redesign and improvement capacity building activity had shaped the organisational capability of health services. Phase 2 also enabled the parent research project to identify learning from the evolution of the redesigning hospital care initiative that might aid the future capacity building activities of health services. This learning also informed the co-design of the health service case studies and the immersive field work for Phase 3, including the identification of appropriate case studies within each health service.

Phase 3

Doctoral Research as part of Phases 3 and 4 of the Broader Project

Narrative Review. A narrative overview of evidence about improvement in healthcare will act to inform interview schedules and observations undertaken within the doctoral research. Aspects including frameworks, theories, strategies and factors that drive or impact the change that comes with healthcare improvement and the role of context improvement and the complex processes involved in undertaking and evaluating improvement will be described. This review will describe key factors that act as critical enablers of, and barriers to, successful large-scale, sustained change (review unpublished).

Case Study Research. Phase 3 of the broader study entails a multiple, comparative case study of redesign and improvement activity at the local level within each of the health service partner sites with the primary method anticipated to be longitudinal, immersive field work. The doctoral research, which is the subject of this protocol constitutes one of these case studies.

Specifically, this fieldwork will include observational and shadowing activities, with attendance at regular and pivotal on-site meetings, and observation of everyday activity associated with redesign and improvement work. This approach allows the observation of "[naturally occurring social processes and meanings]"[15] (p455) that are not captured by quantitative methods or purely interview-based approaches to data collection. The field work will be complemented by interviews, focus groups, documentary analysis, and secondary data analysis (e.g. outcome data related to performance targets).

The objective of the fieldwork will be to observe the processual detail of redesign and improvement activity, including the informal, relational dimensions of this activity, which are often not reported in the literature. Insights will be sought into the tacit and explicit knowledge and capabilities employed to do this work, and how organisational conditions affect the prospects of improvement initiatives in terms of their sustainability and scalability. Relevant insight from phases 1 and 2 of the broader

study will be used to sensitise the research to influential factors likely to impact on redesign and improvement activity, and also to inform the health service's ongoing developmental intentions. The research will therefore contain elements of action research and be designed to produce 'practical knowledge'[16] that can be applied throughout the period of the study. In this way, the doctoral study aims to both observe and inform the process of capability building within the host partner health service.

The doctoral project aims will be pursued through detailed study of illustrative redesign and improvement projects being conducted by the host health service. The approach will be an intensive ethnographic study, offering an internal vantage with opportunity to observe, planned and unplanned observations of redesign and improvement activities on a day-to-day basis of the case studies involved in the doctoral research.[17] Cases will be selected with reference to our partners' interests and needs; in accordance with the theoretical approach guiding the research (institutional entrepreneurship), and informed by the requirements of the broader study. Pragmatism will guide case selection to ensure that the case studies selected are likely to have sufficient longevity, that access will be reasonably unproblematic, and that the study can be completed successfully within the timeframes requited for the progress and completion of doctoral research.

Ideally, each illustrative redesign and improvement project will provide an "excellent opportunity to learn" (p57).[18] To encourage this outcome, a number of criteria developed to inform the broader research study will be deployed to ensure that the illustrative projects selected will provide rich learning opportunities that are consistent with the aims of the research and practical to explore (see Table 1).

Doctoral Study interests and pragmatic concerns	Illustrative project selection criteria
Essential fit	*Does the proposed initiative aim to improve / redesign / transform a model of care/service, or to improve the effectiveness of an existing model of care/service?*
Sustainability	*Is the proposed initiative likely to endure for a period sufficient to derive insights into how the sustainability of redesign and improvement initiatives might be enhanced?*
Scaling	*Does the proposed initiative intend to impact a range of locations / work areas / disciplines within the health service, and/or impact external services?* *AND/OR* *Is the initiative of potential significance to other health services and/or sector policy priorities?*
Capability	*Does the proposed initiative involve mobilising and applying the organisation's redesign and improvement capabilities, knowledge, and/or methodologies?*

Role of evidence	*Has the initiative been justified locally in terms of evidence for change, and has consideration been given to how the effectiveness of the intervention might be judged and its outcomes in terms of effects and impact assessed?*
Resource mobilisation	*Does the proposed initiative involve mobilising, harnessing, or redirecting resources, whether these be material, relational, political, or capability-oriented resources?*
Engagement and buy-in	*Does the initiative have senior management buy-in and support? Have sponsor/s and local leaders involved in the change expressed / displayed a willingness to support it?*
Dissemination	*Are senior executives, project sponsors, and local leaders involved in the initiative likely to see added value in engaging with independent academic researchers to capture learning and share knowledge?*

Context: Health Service Approach to Redesign and Improvement

To provide context to the illustrative redesign projects the doctoral research will explore the health service's overall approach to building individual capacity and organisational capability. This will involve documenting the evolution of the health service's approaches to redesign and improvement as part of the jurisdiction's redesigning hospital care program and the manner in which the organisational context has affected the building of redesign and improvement capacity within the health service. This will involve further depth interviewing with leaders within the organisation who are involved in building redesign and improvement capability at the organisational level, and with those involved in leading or supporting redesign and improvement initiatives within the organisation.

Methods

Semi-structured interviews: the sampling strategy for the semi-structured interviews will target participants who possess historical knowledge of the health service's response to the redesigning hospital care program, and those who are presently involved in the shaping the current approach to redesign and improvement and its future directions. It will also seek participants who are able to provide complementary "experiential knowledge"[19](p455) about redesign initiatives within the health service and also about the challenges of leading, implementing, sustaining, and scaling service innovations, more generally.

Phase 4

As with the broader research project, Phase 4 will provide a consolidation point for the doctoral research. Here, the data for the included health service case study will be analysed and opportunity taken to compare it with the data from the broader study collected at the three other partner sites and the findings from Phases 1 and 2. The analysis will be operationalised by developing models, tools, and practical guidelines that foster institutional entrepreneurship. These outputs will address the issue of capacity building at the individual and organisational levels within a health service and the broader implications at a sector level, and will include consideration of structural barriers that

impede key actors (e.g. clinicians) from engaging in redesign and improvement activity. The outputs of the study will attempt to address conditions that are required to equip clinicians with 'institutional entrepreneurial' skills and capabilities (e.g., new forms of education and training; different kinds of mentoring; hybrid career paths and secondments into environments rich with learning opportunities). Organisational context and culture, which influence how capacities are successfully enhanced and applied, will also be addressed. Bespoke, practical (i.e. non-academic) reports will be produced for the host health service partner during this phase of the research. The results of the doctoral study will be written up in a thesis format, in accordance with the requirements of the host University. Elements of this thesis will inform a companion report for industry prepared as part of the broader project which will detail the lessons learned across the four partner case studies, and will be disseminated through the jurisdiction's public healthcare system and beyond.

Data analysis plan. Data that is collected via interviews and focus groups will be transcribed and returned to participants for their checking and approval for data analysis. Transcriptions will be uploaded onto N-Vivo, along with the field notes taken during observational and shadowing activities. N-Vivo is a qualitative software analysis program that allows complex coding of the data and a fine-grained analysis. Themes will be elicited from the data through an open-coding process[20] allowing first order constructs to be identified in a grounded fashion. Where appropriate, these first order constructs will be progressively collapsed into higher order second- and third-level constructs. Relationships between themes will then be identified, by drawing on the theory of institutional entrepreneurship. These relationships will be modelled diagrammatically to show the inferred relationships between context, capabilities, and redesign and improvement outcomes. These models will serve as a basis for discussions with our health service partners, which form part of the research team's validation and credibility checking processes. Feedback captured through this process will enable the research team to refine the modelling of the data, and incorporate this modelling into the practical frameworks that are to be produced as a key outcome of the research.

Ethics and dissemination

The Monash University Human Research Ethics Committee approved the parent study (Project Number: CF15/1290 – 2015000614) on 27 April, 2015

The health service included in the doctoral research as a case study has provided approval from its governing ethics committee. Reference Number 16390L, approved on 6th September 2016.

As the research is co-designed, all four phases of the research will involve the sharing and discussion of results and the dissemination of findings as they emerge. The principal forum for disseminating the findings of the research will be three participatory workshops, and also reports, and publications. The doctoral research will be included in this process.

Dissemination workshops are central to the research design and funding requirements of the broader project. They, will be structured as follows and the doctoral research will be disseminated where indicated.

Workshop 1 took place during Phase 2 and explored the sustainability and scaling issues revealed through the appraisal of the redesigning hospital care program, and early implications for capacity building at the individual, organisational, and system level. Doctoral researcher in attendance.

Workshop 2 will take place toward the end of phase 3 and will focus on emerging findings from the action research in the case studies. Doctoral researcher will present protocol and any preliminary findings from the field study.

Workshop 3 will focus on the co-creation and refinement of the modelling and frameworks created throughout the life of the study, and will place these outputs in the context of international benchmarking. The progress of the research will also be reported and results will be disseminated to policy-makers and healthcare practitioners through existing state-wide redesign and improvement forums and other events auspiced by the redesigning hospital care program, and by our partner health services. Doctoral researcher to provide presentations and inputs from host partners case study.

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The authors wish to acknowledge the health service partners involved in this research and co-researchers Professor Amrik Sohal and Dr. Evelyn Looi for their contribution to the research described in this publication.

Contributors. AM acted as a principal investigator and contributed to the concept, drafting, design and revising of the protocol. PB contributed to the concept, drafting, design and critical revision of the protocol. HT and IM contributed to the design and critically revising the protocol. HT and IM conceived the study.

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Competing interests statement. None to declare

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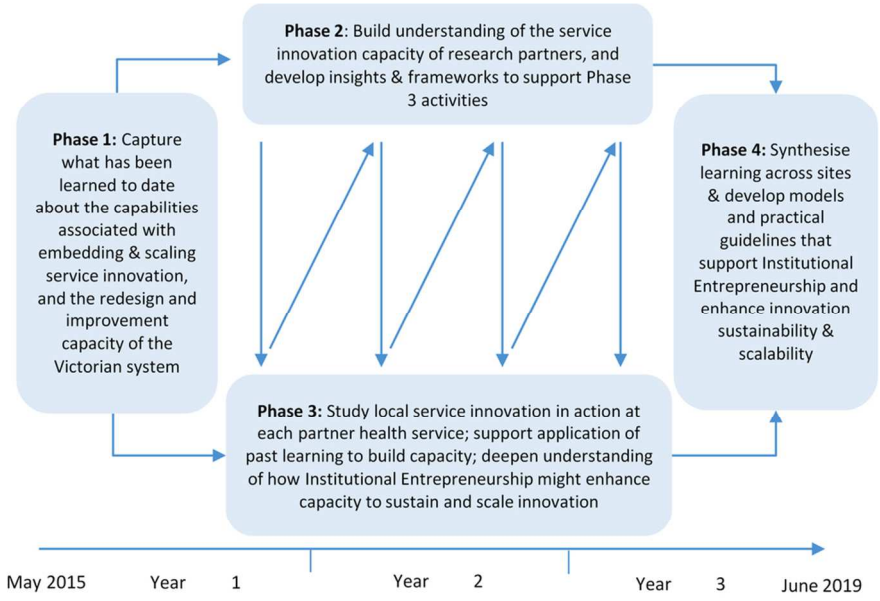
Figure legends

Figure 1: The four phases of the broader parent research

Figure 2. Timelines for the parent study and doctoral study



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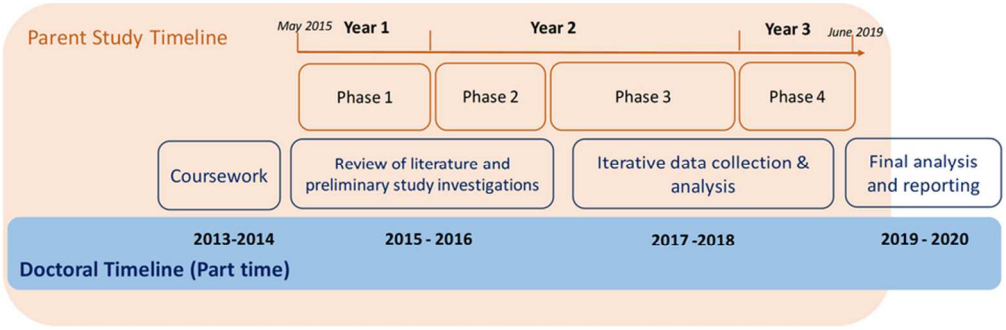

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Abstract

Introduction

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Strengths and limitations of this study

- The doctoral project is underpinned by the broader study's principles of collaborative research, an approach that enables meaningful, in-depth, sustained fieldwork and the creation of practical learning and actionable knowledge drawn from the following disciplines: management and organisational science, health services management, implementation science, and knowledge translation.
- As part of the collaborative approach the student undertaking this project is an employee of the partner health service and is conducting the research as part of the in-kind support offered to the parent study by the health service.
- As with the parent study, the doctoral project's theoretical approach involves studying *in situ* and in real time the skills and capabilities of 'institutional entrepreneurs' – leaders who seek to change institutionalised behaviours and practices that get in the way of innovation.
- Institutional theory is being used increasingly by health services management researchers as it enables new insights into the process of embedding and scaling up innovation and transforming institutions.

- Limitations include the single health service focus of the doctoral research (although this is mitigated by the comparative case studies being conducted by the broader research project) and possible constraints arising from the researcher's dual role as both doctoral candidate and employee of the subject organisation.

Introduction

As with other OECD health systems, Australia's demand for healthcare services is escalating, driven by an ageing population with complex needs, rising rates of chronic illness, increasing health care costs, and rapid information and technology innovation.[1] This demand is unlikely to be adequately met given the current and emerging economic pressures affecting the capacity of the health system. Therefore, healthcare services and systems must engage in extensive and profound service innovation if they are to meet these challenges.[1] To date, however, hospital redesign and improvement initiatives have had limited impacts and outcomes at a system level. Whilst frequently effective at the local level in the short-term, improvements are often confined to discrete areas within the health care system and are difficult to scale and sustain beyond their point of origin.[2-8]

This doctoral project explores the factors that enable and inhibit the take-up, spread, and sustainability of redesign and improvement initiatives, and identifies implications for capacity building at the individual, organisational, and health system levels. More specifically, it examines how redesign and improvement capability is shaped by both local and broader context, and seeks to understand how these contexts can be shaped to be more conducive to the redesign and improvement of healthcare service delivery. The project draws on the theory of 'institutional entrepreneurship' to understand how healthcare services, clinicians, and other leaders might better understand and overcome the barriers to embedding and scaling up innovation, and how this capability might be fostered.

The doctoral project and the broader parent study within which it is nested is set in an Australian state jurisdiction, and is conducted in partnership with five partner organisations. Four research partners are large public health services of varying size and specialty, one of which provides the focus for the doctoral project (the others being the focus of the broader parent study). The fifth research partner is the state government department responsible for a jurisdiction-wide initiative to transfer new redesign and improvement knowledge into the public healthcare system and their role as sponsors and funders of the attempt to transfer improvement knowledge. The department has promoted a decade-long program to build capacity through a redesigning hospital care program. To date, the program has focused on building the skills of individual redesign and improvement advisors, and health services' improvement capability at the organisational level. In its most recent phase it has sought to promote the sharing of knowledge and learning across health services. The program has been lauded by independent evaluators for its longevity and comprehensiveness, and for achieving admirable efficiency and service delivery improvements at the local level.[5] However, the sustainability of the improvement projects enabled and supported by the program has been found to be questionable, and they have failed to be mobilised beyond their originating locale.[5, 8]

In this context, the aim of this doctoral research is to understand and inform redesign and improvement capability-building processes at the individual and organisational level within the health service that is hosting the doctoral project. The intent is to understand how a distributed, multi-level capacity might be developed, whereby service improvements can be successfully embedded in local contexts where care is delivered, and also mobilised beyond these local contexts

on a service-wide basis, thereby enabling the healthcare organisation to deliver quality healthcare outcomes, at pace and scale.

Methods and analysis

Theoretical approach

The theoretical approach for this research draws on institutional theory, which underpins much research in the discipline of management concerned with explaining order and stability in organisations, and thereby better understanding how transformational change can occur in situations where the bias is towards the maintenance of the status quo. Healthcare researchers are increasingly drawn to this theory since it seems to have particular application to healthcare systems, which appear to be locked into existing and well established ways of working, despite increasing external and internal pressures to transform the way they deliver care.[2, 6, 7]

Related to institutional theory is the concept of 'institutional entrepreneurship', referring to actors (organisations, groups of organisations, individuals, or groups of individuals), "who leverage resources to create new or transform existing institutions" (p.84).[4] Such actors initiate 'divergent change' (i.e. break existing institutional templates such as the existing business/service models of hospitals) and participate actively in driving change by mobilising required resources, including capabilities and knowledge (ideas and practices). This concept is highly relevant to the central problem of scaling up discrete innovations to a system level, as it provides a framework for multi-level analysis, from the micro-level of individual actions through to the behaviour of individual organisations, through to communities of organisations in a sector or field, at the system level.

Study design

The doctoral project will be predominantly qualitative, because in many respects it is exploratory and requires 'open-ended inquiry'.[9] Qualitative enquiry is also appropriate because 'sensitivity to context' is important for the study[10] and the aim is to generate 'how to' knowledge,[11, 12] which institutional entrepreneurship suggests is affected by multiple, interacting factors and conditions.

The doctoral project constitutes an integral element of two of the four phases (Phases 3 and 4, discussed below) of the broader parent study within which it is nested. This parent study is structured into four principal, inter-related phases designed to help understand the evolution of the jurisdiction's redesign and improvement initiative at the sector level, and the extent to and manner in which this has fostered redesign and improvement capacity at the individual and organisational levels within health services. The parent study research design is guided by the idea that the relationship between capacity and context is interconnected and mutually influencing. That is, context shapes capacity at the organisational and individual levels, but individual and organisational capacity also shapes context.

Each phase of the parent study design is depicted in Figure 1. The doctoral project takes place predominantly during phases three and four of the parent study. However, since the doctoral project is informed by phases one and two of the broader parent research study, and draws for comparative and benchmarking purposes on the findings from phase three and four of the parent study, relevant aspects of each phase of the overall research design are outlined.

Patient and Public Involvement

Patient and public involvement was not conducted for either the doctoral project or the parent study.

Figure 1: The four phases of the broader parent study

The parent study began in May 2015 with Phase 1 completed by end of year 1, and Phase 2 completed midway through year 2. Phase three of the parent study is due for completion by end year 3, with the final phase to be undertaken during year 4. Completion of the parent study is anticipated by mid-2019. The doctoral project that is the subject of this protocol is nested within this framework but is being undertaken to a different timetable in accordance with the requirements of registration and progress for a part-time study (See Figure 2).

Figure 2. Timelines for the parent study and doctoral project

Parent Study Phases 1 and 2

The focus of Phase 1 of the parent study was the exploration of redesign and improvement capacity at the system level, and how this capacity was been built over time. The redesigning hospital care program referred to earlier provides a focal point for this exercise. Phase 1 of the research sought to capture and understand what had been learnt as a result of the program to date, and to support the application of that learning. Phase 1 drew out lessons learned by key program stakeholders for two key purposes: 1) to identify the contextual contingencies at the system-level that shaped the evolution of the jurisdiction's collective redesign and improvement capacity; and 2) to gain insight into the barriers and enablers that constrained and enhanced the embedment and scalability of new redesign and improvement knowledge. Phase 1 also aimed to surface key stakeholders' perceptions regarding critical priorities for capacity building for the future, with the goals of sustainability and scalability in mind. During this phase, the parent study established the nature and current state of redesign and improvement capacity at the sector level, which provides important context for subsequent phases, and a benchmark for evaluating subsequent progress made by individual health services.

For the doctoral project, the relevant aspects of the research methods employed during Phase 1 of the parent study are:

a) Documentary analysis. A desk review of historical and contemporary policy documents, evaluations, redesign and improvement tools, training and other capacity building materials, and outcome data (where available) held by the government and associated with the redesigning hospital care program.

b) Semi-structured, in-depth interviews. A program of semi-structured, face-to-face, in-depth-interviews[13] designed to tap institutional memory and allow the historical evolution of redesign and improvement capacity within the jurisdiction's public healthcare system to be documented, and the factors associated with key capability-building moments identified. All authors of this protocol informed the design of the interview schedule. The authors, PB (BA, MMgt, PhD) and IM (BA (Hons.) PhD), will conduct the interviews, along with other members of the broader research team; this includes early-career and senior academics.

c) A modified Delphi survey. A modified Delphi survey designed to establish key stakeholders' perceptions of redesign and improvement capacity building priorities, with respect to enhancing the sustainability and scaling up of service innovation.

d) Familiarisation with the organisational cultures and contexts of each partner health service, including the health service which now provides the focus for the doctoral study. All authors participated in site visits, induction days, and meetings with partners as part of this familiarisation process.

Phase 2 provided a consolidation point for the parent study, during which the data collected during Phase 1 were analysed and synthesised. This produced an appraisal of the nature and state of redesign and improvement capacity at the sector-level, with reference to the capacity of other jurisdictions within Australia and internationally. It also provided an understanding of how sector-level redesign and improvement capacity-building activity had shaped the organisational capability of health services within the jurisdiction. Phase 2 also enabled the parent study to identify learning from the evolution of the redesigning hospital care initiative that might aid the future capacity-building activities of health services. This learning also informed the co-design of the health service case studies and the immersive field work for Phase 3, including the identification of appropriate redesign and improvement initiatives to provide focal points for the research team within each health service.

Doctoral Research Project as part of Phases 3 and 4 of the Parent Study

Phase 3

Narrative Review. A narrative overview of evidence about improvement in healthcare will act to inform interview schedules and observations undertaken within the doctoral research. Aspects including frameworks, theories, strategies, factors that drive or impact healthcare improvement, and the complex processes involved in undertaking and evaluating improvement, will be described. This review will describe key factors that act as critical enablers of, and barriers to, successful large-scale, sustained change (Manuscript under review).

Case Study Research. Phase 3 of the broader study entails a multiple, comparative case study of redesign and improvement activity at the local level within each of the health service partner sites. The doctoral project, will constitute one of these case studies.

The primary method of data collection for the project will be longitudinal, immersive field work. Specifically, this fieldwork will include observational and shadowing activities within the health service that is hosting the doctoral researcher, with attendance at regular and pivotal on-site meetings, and observation of everyday activity associated with redesign and improvement work. This approach allows the observation of "naturally occurring social processes and meanings"[14] (p455) that are not captured by quantitative methods or purely interview-based approaches to data collection. Importantly, it will also allow the doctoral researcher (AM, BAppSc, MPH) to identify and explore some of the micro-foundations of institutional process that affect redesign and improvement work (e.g. the beliefs, logics, and taken-for-granted habitual practices of clinicians and other health service workers). Field notes will be taken (see also, 'Data Analysis Plan'). The field work will be complemented by interviews (approximately 40 interviews, between 30 to 60 minutes in length), focus groups, documentary analysis, and secondary data analysis (e.g. outcome data related to performance targets), all of which will be conducted by the first-named author (the doctoral researcher).

As an 'in-service researcher', the doctoral student faces the issue that some participants will be known to the student, and vice versa, and that her formal position within the organisation as the manager of an evidence support service may influence and bias the data collection and analysis for her doctoral research. Indeed, her position may limit what is discussed because of issues anonymity and confidentiality.[15] Conversely, it is precisely her internal position and ethnographic approach that stands to yield reflexive, rich, and nuanced insights into both explicit and tacit knowledge about redesign and improvement work in healthcare. In recognition of these tensions, and to strengthen the rigor and quality of the research, the design of the doctoral research has been guided by the Consolidated Criteria for Reporting Qualitative Research (COREQ).[16] Similarly, these criteria will also guide the conduct and reporting of the parent study research. Appendix 1 includes the appropriately completed COREQ checklist for the research described here. The objective of the fieldwork will be to observe the processual detail of redesign and improvement activity, including the informal, relational, and normative dimensions of this activity, which are often not reported in the literature and are key to understanding how institutions are enacted in practice, and the leverage points via which they may be changed. Insights will be sought into the tacit and explicit knowledge and capabilities drawn on to undertake redesign and improvement, and how organisational conditions affect the prospects of improvement initiatives in terms of their sustainability and scalability. Relevant insights from Phases 1 and 2 of the broader study will be used to sensitise the doctoral researcher to influential factors likely to impact on redesign and improvement activity (e.g. perceptions of key stakeholders regarding the legitimacy of redesign and improvement as a core organisational activity), and also to inform the case study health service's ongoing developmental intentions. The research will therefore contain elements of action research and will be designed to produce 'practical knowledge'[17] that can be applied throughout the period of the study, with the view to challenging institutionalised beliefs and practices. In this way, the doctoral study aims to both observe and inform the process of capability building within the host partner health service.

The doctoral project aims will be pursued and given focus through the detailed study of redesign and improvement initiatives being conducted by the health service where the doctoral researcher is employed. The approach will be an intensive ethnographic study, offering an internal vantage point with opportunities to observe on a day-to-day basis both planned and unplanned redesign and improvement activities associated with the initiatives that are the focus of the doctoral research.[18] As with the focal redesign and improvement initiatives selected at all health service partner sites, initiatives within the health service auspicing the research will be selected with reference to the health service's interests and needs, and in accordance with the theoretical approach (institutional entrepreneurship) guiding the broader study.

Pragmatism will play a role in the selection of focal initiatives, to ensure that the these initiatives are likely to have sufficient longevity, that access will be reasonably unproblematic, and that the study can be completed successfully within the timeframes required for the progress and completion of doctoral research. Face to face meetings with those involved in the initiatives will be held to gain informed consent. During this process, participants will be provided with a written explanatory statement outlining the aims and intent of the research, and participants will have the opportunity to ask the researcher further questions about the purpose and conduct of the research. Purposive sampling will be used to identify stakeholders to invite to participate in the research. It is anticipated that these stakeholders will be key decision-makers and implementers involved in the initiative (e.g. a range of clinicians, in both senior and junior positions, heads of units, and other managers), and others who are influential in the implementation of the initiative, for example health service workers who are touched by the initiative and required to take it on board as part of their role. Broadly

speaking, sampling decisions will be informed by the role and level of involvement of employees in the implementation of the initiatives.

Ideally, each redesign and improvement initiative will provide an "excellent opportunity to learn" (p57).[19] To encourage this outcome, a number of criteria developed to inform the parent study will be deployed to ensure that the initiatives selected will provide rich learning opportunities that are consistent with the aims of the research and practical to explore (see Table 1).

Table 1. Selection criteria for focal redesign and improvement initiatives

Doctoral Project interests and pragmatic concerns	Selection criteria for focal redesign and improvement initiatives
Essential fit	*Does the proposed initiative aim to improve / redesign / transform a model of care/service, or to improve the effectiveness of an existing model of care/service?*
Sustainability	*Is the proposed initiative likely to endure for a period sufficient to derive insights into how the sustainability of redesign and improvement initiatives might be enhanced?*
Scaling	*Does the proposed initiative intend to impact a range of locations / work areas / disciplines within the health service, and/or impact external services?* *AND/OR* *Is the initiative of potential significance to other health services and/or sector policy priorities?*
Capability	*Does the proposed initiative involve mobilising and applying the organisation's redesign and improvement capabilities, knowledge, and/or methodologies?*
Role of evidence	*Has the initiative been justified locally in terms of evidence for change, and has consideration been given to how the effectiveness of the intervention might be judged and its outcomes in terms of effects and impact assessed?*
Resource mobilisation	*Does the proposed initiative involve mobilising, harnessing, or redirecting resources, whether these be material, relational, political, or capability-oriented resources?*
Engagement and buy-in	*Does the initiative have senior management buy-in and support? Have sponsor/s and local leaders involved in the change expressed / displayed a willingness to support it?*

Dissemination	*Are senior executives, project sponsors, and local leaders involved in the initiative likely to see added value in engaging with independent academic researchers to capture learning and share knowledge?*

Context: Health Service Approach to Redesign and Improvement

To provide context to the redesign and improvement initiatives, the doctoral research will also explore the health service's overall approach to building individual and organisational redesign and improvement capability and capacity. This will involve documenting the evolution of the health service's approach to redesign and improvement as part of the wider jurisdiction's redesigning hospital care program and the manner in which the organisational context has affected the building of redesign and improvement capacity within the health service. This will involve further in-depth interviewing with leaders within the organisation who are involved in building redesign and improvement capability at the organisational level, and with those involved in leading or supporting redesign and improvement initiatives within the organisation. The sampling strategy for these context-related interviews will target participants who possess historical knowledge of the health service's response to the redesigning hospital care program, and those who are presently involved in shaping the current approach to redesign and improvement and its future directions. Participants who are able to provide complementary "experiential knowledge"[20](p455) about redesign initiatives within the health service and the challenges of leading, implementing, sustaining, and scaling service innovations, more generally, will also be sought.

Phase 4

As with the broader parent study, Phase 4 will provide a consolidation point for the doctoral research. Here, the data for the doctoral health service case study will be analysed (see Data Analysis Plan, below) and the opportunity will be taken to compare these data with the data collected at the three other partner sites for the broader parent study. During Phase 4 of the research the intention is to develop models, tools, and practical guidelines that foster institutional entrepreneurship. These outputs will address the issue of capability and capacity building at the individual and organisational levels within a health service, and broader implications at a sector level. They will therefore include consideration of structural barriers that impede key actors (e.g. clinicians) from engaging in redesign and improvement activity. The outputs of both the broader parent study and the doctoral study will also take into account the local and system-level conditions that affect key stakeholders' (e.g. clinicians) development of 'institutional entrepreneurial' skills and capabilities, and will propose new ways of encouraging the development of these skills (e.g., new forms of education and training that focus on addressing institutional pressures that impede improvement; different kinds of mentoring; hybrid career paths and secondments into environments rich with learning opportunities). A bespoke, practical (i.e. non-academic) report will be produced for the health service partner hosting the doctoral researcher. The results of the doctoral study will also be written up in a thesis format, in accordance with the requirements of the host University. Elements of this thesis will inform a companion report for industry, prepared as part of the parent study, which will detail the lessons learned across the four partner case studies and will be disseminated throughout the jurisdiction's public healthcare system and beyond.

Data analysis plan. Data collected during the Phase 3 and 4 via interviews and focus groups discussions will be audio recorded and transcribed; transcriptions of interviews will be returned to

participants for their checking and approval for inclusion in the data analysis. Transcriptions will be uploaded onto N-Vivo, along with the field notes taken during observational and shadowing activities, and will be analysed progressively, in order to recognise when saturation is reached. N-Vivo is a qualitative software analysis program that allows complex coding of the data and a fine-grained analysis. During the first phase of analysis, the doctoral student will 'bracket' [21] her theoretical knowledge and elicit themes from the data through an open-coding process,[22] allowing first order constructs to be identified in a grounded fashion. During a second phase of analysis, the student will conduct a theoretically-informed 'reading' of the data, by actively drawing on relevant theoretical constructs from the institutional theory literature. The authors PB, IM, and HT (MBBS PhD FRACP FAAHMS), who are involved in the parent study, will support and challenge this coding process as required. The aim of these discussions will be to minimise bias, substantiate constructs, and support the doctoral researcher to home in on the relevant institutional workings that her data suggest are influential. Where appropriate, the doctoral researcher will progressively collapse these first order constructs into higher order second- and third-level constructs. She will also look for the operation of these institutional influences at the meso level, for example in organisational culture, funding and governance arrangements, and national policies. Themes will then be interrogated and relationships between themes identified, again by drawing on institutional theory, and particularly institutional entrepreneurship. These relationships will be modelled diagrammatically to show the inferred relationships between context, capabilities, and redesign and improvement outcomes. The models produced through this process will serve as a basis for discussions between the research team of the parent study and with the full set of health service partners, who are important contributors to the broader research team's validation and credibility checking processes. In general, the nested nature of the doctoral research within the broader parent study, together with the member-checking discussions with the research partners, offers a mechanism to mitigate possible biases. Feedback captured through this process will enable the doctoral researcher to refine the modelling of her data, and incorporate this modelling into the practical frameworks that are to be produced as a key outcome of her doctoral research, and the broader parent study.

Ethics and dissemination

The Monash University Human Research Ethics Committee approved the parent study (Project Number: CF15/1290 – 2015000614) on 27 April, 2015.

The health service that is hosting the project has provided approval from its governing ethics committee for the research conducted on its sites and with its employees. Reference Number 16390L, approved on 6th September 2016.

As the research is co-designed with the partner health services, all four phases of the research will involve the sharing and discussion of results and the dissemination of findings as they emerge. The principal forum for disseminating the findings of the research will be three participatory workshops, and also reports, and publications. The doctoral research will be included in this process.

Dissemination workshops are central to the research design and funding requirements of the broader parent study. They will be structured as follows, and the doctoral research will be disseminated where indicated.

Workshop 1 took place during Phase 2 and explored the sustainability and scaling issues revealed through the appraisal of the redesigning hospital care program, and early implications for capacity building at the individual, organisational, and system level. The doctoral researcher was in attendance.

Workshop 2 will take place toward the end of phase 3 and will focus on emerging findings from the action research in the case studies. The doctoral researcher will present the protocol and any preliminary findings from her study.

Workshop 3 will focus on the co-creation and refinement of the modelling and frameworks created throughout the life of the study, and will place these outputs in the context of international benchmarking. The progress of the research will also be reported and results will be disseminated to policy-makers and healthcare practitioners through existing state-wide redesign and improvement forums and other events auspiced by the redesigning hospital care program, and by our partner health services. The doctoral researcher will provide presentations and input into this process.

The doctoral student will also develop several publications throughout the life of the research to aid the dissemination of her research. Broad plans and timeframes for these publications are provided in Figure 2.

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Competing interests statement. None to declare

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Figure legends

Figure 1: The four phases of the broader parent study

Figure 2. Timelines for the parent study and doctoral study

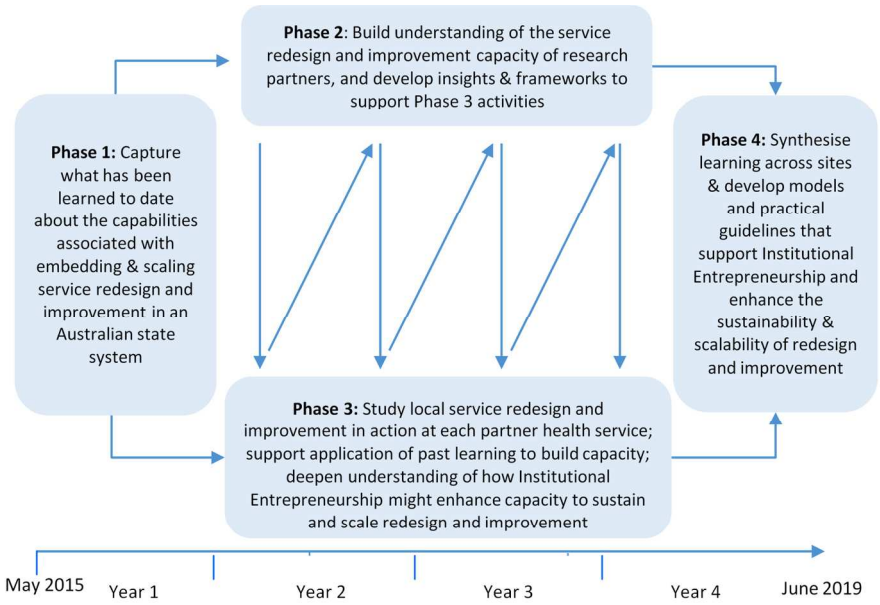

Figure 1: The four phases of the broader parent study

160x99mm (300 x 300 DPI)

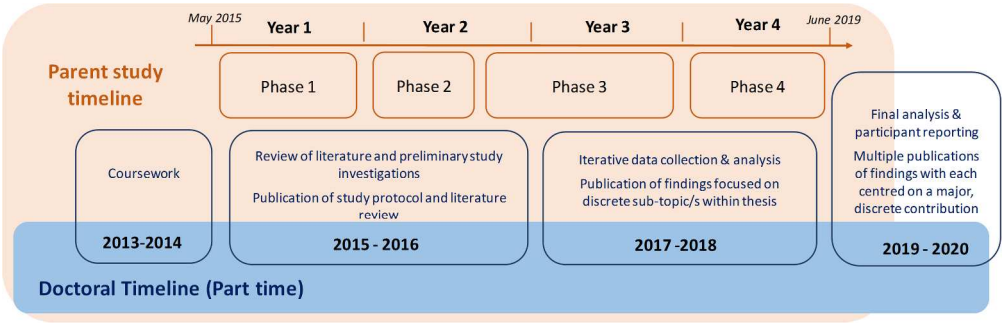

Figure 2. Timelines for the parent study and doctoral study

232x74mm (300 x 300 DPI)

APPENDIX: COREQ (COnsolidated criteria for REporting Qualitative research) Checklist for Manuscript ID bmjopen-2017-020807

Domain and Items	Author Comment (Researcher responsible & location in manuscript)
Domain 1: Research team and reflexivity	
Personal characteristics	
1. Interviewer/facilitator Which author/s conducted the interview or focus group?	Page 5. (pertaining to Phase 1 of the parent study): "All authors informed the design of the interview schedule; the second and third-named authors listed conducted the interviews, along with other members of the broader research team; this includes early-career and senior academics." Page 6. (pertaining to the doctoral research) "The field work will be complemented by interviews (approximately 40 interviews, between 30 to 60 minutes in length), focus groups, documentary analysis, and secondary data analysis (e.g. outcome data related to performance targets), all of which will be conducted by the first-named author, who is the doctoral researcher."
2. Credentials What were the researcher's credentials?	Page 1 (listed after each author).
3. Occupation What was their occupation at the time of the study?	Page 1 (listed after each author).
4. Gender Was the researcher male or female?	Page 6: "As an "in-service researcher", the doctoral student faces the issue that some participants will be known to the student, and vice versa, and that her formal position within the organisation as the manager of an evidence support service may influence and bias the data collection and analysis for her doctoral research. Indeed, her position may limit what is discussed …"
5. Experience and training What experience or training did the researcher have?	Page 1. (Implicit in credentials of authors.) Please also note that the first and second authors have received training and have conducted qualitative studies as part of Masters and doctoral research projects as well using qualitative methods as part of professional roles in healthcare service delivery.
Relationship with participants	
6. Relationship established Was a relationship established prior to study commencement?	For some participants, this will indeed be the case. This is acknowledged on Page 6: "As an "in-service researcher", the doctoral student faces the issue that some participants will be known to the student, and vice versa …"
7. Participant knowledge of the interviewer	Following on from above, the first author (AM) is a manager of an evidence support service and currently undertaking her PhD. Some participants will therefore know the researcher.

What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Participants will receive an explanatory statement about the research (including its aims and rationale) and will have the opportunity to ask the researcher additional questions prior to deciding if they wish to participate. See Page 7: "Face to face meetings with those involved in the initiatives will be held to gain informed consent. During this process, participants will be provided with a written explanatory statement outlining the aims and intent of the research, and participants will have the opportunity to ask the researcher further questions about the purpose and conduct of the research."
8. Interviewer characteristics What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Page 6: "As an "in-service researcher", the doctoral student faces the issue that some participants will be known to the student, and vice versa, and that her formal position within the organisation as the manager of an evidence support service may influence and bias the data collection and analysis for her doctoral research. …"
Domain 2: study design	
Theoretical framework	
9. Methodological orientation and Theory What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Please see pages 4 – 9.
Participant selection	
10. Sampling How were participants selected? e.g. purposive, convenience, consecutive, snowball	There are three levels of sampling that need to be conducted in order to carry out the research. Details of sampling are now included at appropriate locations within the manuscript. Key passages are summarised below: ***Sampling of redesign and improvement initiatives that provide the focus for the doctoral research*** Please see Page 7, beginning with the passage, "The doctoral project aims will be pursued and given focus through the detailed study of redesign and improvement initiatives being conducted by the health service where the doctoral researcher is employed…." Please also see Table 1, which details the sampling criteria. ***Sampling of participants involved in the focal redesign and improvement initiatives.*** Please see Page 7, specifically the following passage: "Face to face meetings with those involved in the initiatives will be held to gain informed consent. During this process, participants will be provided with a written explanatory statement outlining the aims and intent of the research, and participants will have the

	opportunity to ask the researcher further questions about the purpose and conduct of the research. Purposive sampling will be used to identify stakeholders to invite to participate in the research. It is anticipated that these stakeholders will be key decision-makers and implementers involved in the initiative (e.g. a range of clinicians, in both senior and junior positions, heads of units, and other managers), and others who are influential in the implementation of the initiative, for example health service workers who are touched by the initiative and required to take it on board as part of their role. Broadly speaking, sampling decisions will be informed by the role and level of involvement in employees in the implementation of the initiatives." ***Sampling of participants informing the study of organisational context*** Please see page 9, specifically the following passage: "This will involve further depth interviewing with leaders within the organisation who are involved in building redesign and improvement capability at the organisational level, and with those involved in leading or supporting redesign and improvement initiatives within the organisation. The sampling strategy for these context-related interviews will target participants who possess historical knowledge of the health service's response to the redesigning hospital care program, and those who are presently involved in shaping the current approach to redesign and improvement and its future directions. Participants who are able to provide complementary "experiential knowledge"[19](p455) about redesign initiatives within the health service and the challenges of leading, implementing, sustaining, and scaling service innovations, more generally, will also be sought."
11. Method of approach How were participants approached? e.g. face-to-face, telephone, mail, email	Page 7: "Pragmatism will play a role in the selection of focal initiatives, to ensure that the these initiatives are likely to have sufficient longevity, that access will be reasonably unproblematic, and that the study can be completed successfully within the timeframes required for the progress and completion of doctoral research. Face to face meetings with those involved in the initiatives will be held to gain informed consent."
12. Sample size How many participants were in the study?	Page 6: Approximately 40.
13. Non-participation How many people refused to participate or dropped out? Reasons?	Not applicable, as yet.
Setting	
14. Setting of data collection Where was the data collected? e.g. home, clinic, workplace	The research will be conducted within the health service. Reference to the setting of the research is made throughout the

	protocol, particularly in passages that describe the ethnographic approach to the research.
15. Presence of non-participants Was anyone else present besides the participants and researchers?	Not applicable, as yet.
16. Description of sample What are the important characteristics of the sample? e.g. demographic data, date	Please refer to the sampling strategy discussed for Item 10, "Sampling", as this contains the relevant information regarding the characteristics of the samples, and identifies the pages within the manuscript where these details are located. Note that it the roles, responsibilities, and experiential knowledge that participants possess that will drive sampling decisions (rather than demographics etc.).
Data collection	
17. Interview guide Were questions, prompts, guides provided by the authors? Was it pilot tested?	Page 6 provides an outline of the issues to be addressed within the interviews: **"Narrative Review.** A narrative overview of evidence about improvement in healthcare will act to inform interview schedules and observations undertaken within the doctoral research. Aspects including frameworks, theories, strategies and factors that drive or impact the change that comes with healthcare improvement and the role of context improvement and the complex processes involved in undertaking and evaluating improvement will be described. This review will describe key factors that act as critical enablers of, and barriers to, successful large-scale, sustained change" We also note that the theory of institutional entrepreneurship will also inform the questions within the interview guide, and the fieldwork observations.
18. Repeat interviews Were repeat interviews carried out? If yes, how many?	Not applicable, as yet.
19. Audio/visual recording Did the research use audio or visual recording to collect the data?	Page 9: "Data collected during the Phase 3 and 4 via interviews and focus groups discussions will be audio recorded and transcribed; transcriptions of interviews will be returned to participants for their checking and approval for data analysis."
20. Field notes Were field notes made during and/or after the interview or focus group?	Field notes will be taken as part of the ethnographic work, as described within the manuscript. Please see: Page 6: The primary method of data collection for the doctoral research will be longitudinal, immersive field work. Specifically, this fieldwork will include observational and shadowing activities within the health service that is hosting the doctoral researcher, with attendance at regular and pivotal on-site meetings, and observation of everyday activity associated with redesign and improvement work. This approach allows the observation of "naturally occurring social processes and meanings"[15] (p455) that are not captured by quantitative methods or purely interview-

	based approaches to data collection. Importantly, it will also allow the doctoral researcher to identify and explore some of the micro-foundations of institutional process that affect redesign and improvement work (e.g. the beliefs, logics, and taken-for-granted habitual practices of clinicians and other health service workers). Field notes will be taken (see also, "Data Analysis Plan"). Page 9: "Transcriptions will be uploaded onto N-Vivo, along with the field notes taken during observational and shadowing activities, and will be analysed progressively, in order to recognise when saturation is reached."
21. Duration What was the duration of the interviews or focus group?	Page 6: "The field work will be complemented by interviews (approximately 40 interviews, between 30 to 60 minutes in length), focus groups, documentary analysis, and secondary data analysis …"
22. Data saturation Was data saturation discussed?	Page 9: "Transcriptions will be uploaded onto N-Vivo, along with the field notes taken during observational and shadowing activities, and will be analysed progressively, in order to recognise when saturation is reached."
23. Transcripts returned Were transcripts returned to participants for comment and/or correction?	Page 9: "Data collected during the Phase 3 and 4 via interviews and focus groups discussions will be audio recorded and transcribed; transcriptions of interviews will be returned to participants for their checking and approval for data analysis."
Domain 3: analysis and findings	
Data analysis	
24. Number of data coders How many data coders coded the data?	Please see details on Pages 9-10: "During the first phase of analysis, the doctoral student will "bracket" her theoretical knowledge and elicit themes from the data through an open-coding process,[22] allowing first order constructs to be identified in a grounded fashion. During a second phase of analysis, the student will conduct a theoretically-informed "reading" of the data, by actively drawing on relevant theoretical constructs from the institutional theory literature. The second-, third-, and fourth-named authors, who are involved in the parent study, will support and challenge this coding process as required. The aim of these discussions will be to minimise bias, substantiate constructs, and support the doctoral researcher to home in on the relevant institutional workings that her data suggest are influential. Where appropriate, the doctoral researcher will progressively collapse these first order constructs into higher order second- and third-level constructs. She will also look for the operation of these institutional influences at the meso level, for example in organisational culture, funding and governance arrangements, and national policies. Themes will then be interrogated and relationships between themes identified, again by drawing on institutional theory, and particularly institutional entrepreneurship. …"

25. Description of the coding tree Did authors provide a description of the coding tree?	Please see details on Pages 9-10, as provided above.
26. Derivation of themes Were themes identified in advance or derived from the data?	Please see details on Pages 9-10, as provided above.
27. Software What software, if applicable, was used to manage the data?	Please see details on Pages 9-10, as provided above.
28. Participant checking Did participants provide feedback on the findings?	Please see details on Pages 9-10, under the sub-headings “Data Analysis Plan” and “Ethics and Dissemination”.
Reporting	
29. Quotations presented Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number	Not applicable, as yet.
30. Data and findings consistent Was there consistency between the data presented and the findings?	Not applicable, as yet.
31. Clarity of major themes Were major themes clearly presented in the findings?	Not applicable, as yet.
32. Clarity of minor themes Is there a description of diverse cases or discussion of minor themes?	Not applicable, as yet.