

BMJ Open 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. 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 study 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, is multilevel in nature and has been codesigned 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 will focus on the implementation of the sector-wide approach in one healthcare service in the jurisdiction. This research 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 managers 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 workshops and dissemination events as part of the broader project.

INTRODUCTION

As with other Organisation for Economic Co-operation and Development (OECD) health systems, Australia's demand for

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.

healthcare services is escalating, driven by an ageing population with complex needs, rising rates of chronic illness, increasing healthcare 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. While frequently effective at the local level in the short term, improvements are often confined to discrete areas within the healthcare 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 programme to build capacity through a redesigning hospital care programme. To date, the programme 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 programme 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 programme has been questioned, generally failing to mobilise 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, multilevel 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.^{3,6,7}

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' (ie. break existing institutional templates such as the current 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 multilevel analysis, from the microlevel 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 study¹⁰ 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 3 and 4 of the parent study. However, since the doctoral project is informed by phases 1 and 2 of the

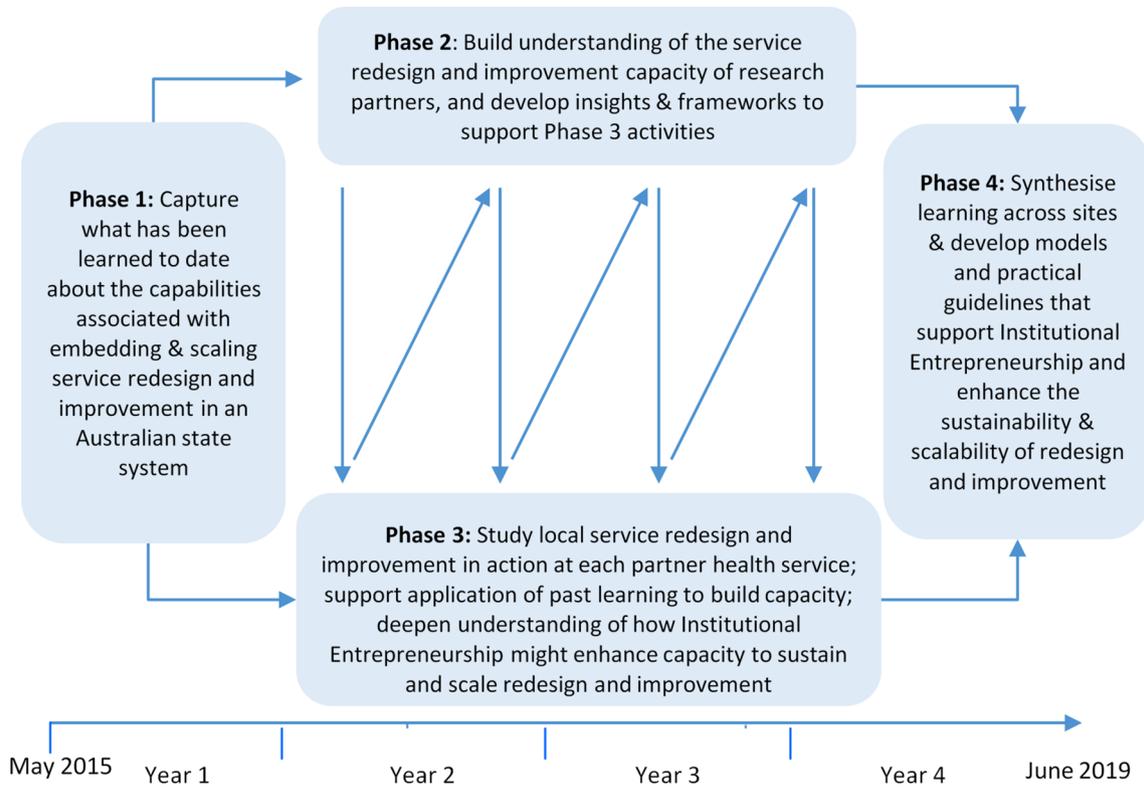


Figure 1 The four phases of the broader parent study.

broader parent research study, and draws for comparative and benchmarking purposes on the findings from phases 3 and 4 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, but is inbuilt into the case studies.

The parent study began in May 2015 with phase 1 completed by the end of year 1, and phase 2 completed midway through year 2. Phase 3 of the parent study is due for completion by the end of 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).

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 built over time. The redesigning hospital care programme 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 programme to date, and to support the application of that learning. Phase 1 drew out lessons learnt by key programme stakeholders for two key purposes: (1) to identify the contextual contingencies at the system level that shaped the evolution of

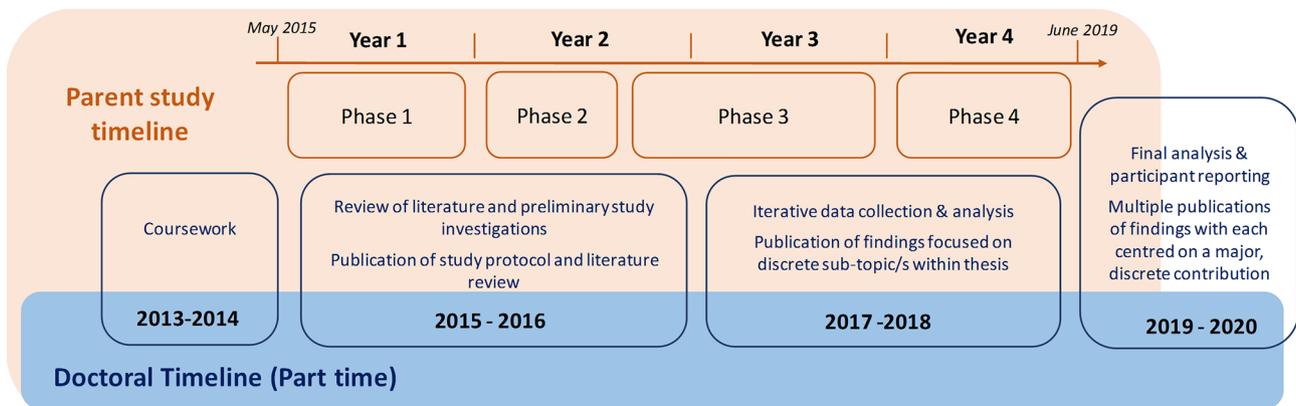


Figure 2 Timelines for the parent study and doctoral project.

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:

(1) 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 programme.

(2) Semistructured, in-depth interviews. A programme of semistructured, face-to-face, in-depth interviews¹³ 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.

(3) 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.

(4) 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 codesign 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 (p. 455) 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 microfoundations of institutional process that affect redesign and improvement work (eg, 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 and 60 min in length), focus groups, documentary analysis and secondary data analysis (eg, 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 of anonymity

and confidentiality.¹⁵ Conversely, it is precisely her internal position and ethnographic approach that stand 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 rigour 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. Supplementary 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 (eg, 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 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 (eg, 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' (Stake, p. 57).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](#)).

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 programme 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 capacity 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 programme, 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 (p. 455) 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

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?

data for the doctoral health service case study will be analysed (see Data Analysis Plan section) 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 (eg, 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' (eg, clinicians) development of 'institutional entrepreneurial' skills and capabilities, and will propose new ways of encouraging the development of these skills (eg, 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 (ie, 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 learnt 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 phases 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 NVivo, along with the field notes taken during observational and shadowing activities, and will be analysed progressively, in order to recognise when saturation is reached. NVivo is a qualitative software analysis programme 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 the second phase of the 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 aims 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-level

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

As the research is codesigned 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 programme, 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 cocreation 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 programme, 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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Contributors AM acted as a principal investigator and contributed to the concept, drafting, design and revision of the protocol. PB contributed to the concept, drafting, design and critical revision of the protocol. HT and IM contributed to the design and critical revision of the protocol. HT and IM conceived the study.

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Competing interests None declared.

Patient consent Not required.

Ethics approval 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 16 390 L, approved on 6 September 2016).

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement When the study has been completed data sharing statement will be completed.

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