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The role of institutional entrepreneurship in building adaptive capacity in community-based health care organisations: Realist review protocol

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Abstract

Introduction: Over the last three decades, there has been a substantial shift to the marketisation of government-funded health services. For organisations traditionally buffered from the competitive pressures of for-profit enterprises, such as community-based organisations, this means developing the capacity to adapt to competitive tendering processes, shifting client expectations, and increasing demands for greater accountability. Drawing on ideas of institutional entrepreneurship, we believe that attempts to build adaptive capacity require the transformation of existing institutional arrangements. Key in this, may be identifying and fostering institutional entrepreneurs- actors who take the lead in being the impetus for, and giving direction to, structural change. This study focuses on the strategies used by institutional entrepreneurs to build adaptive capacity in the community-based health care sector.

Methods and analysis: The research will use an adapted rapid realist review. The review will find underlying theories that explain the circumstances surrounding the implementation of capacity building strategies that shape organisational response and generate outcomes by activating causal mechanisms. An early scoping of the literature and consultations with key stakeholders will be undertaken to identify an initial program theory. We will search for relevant journal articles and grey literature. Data will be extracted based on contextual factors, mechanisms, and outcomes, and their configurations. The analysis will seek patterns and regularities in these configurations and will focus on confirming, refuting, or refining our program theory.

Ethics and dissemination: The study does not involve primary research and therefore does not require formal ethical approval. However, ethical standards of utility, usefulness, feasibility, propriety, accuracy, and accountability will be followed. The results will be written up according to the “Realist and Meta-Review Evidence Synthesis: Evolving Standards” (RAMESES) guidelines. Once completed, findings will be published in a peer-reviewed journal.

Trial registration number: This protocol has been registered with PROSPERO, registration number CRD42015026487.

Strengths and limitations:

- A realist review is rich in explanatory power and builds an understanding of how and why interventions work in complex systems such as health markets.
- The engagement of a reference group, consisting of industry experts and researchers, will ensure complete coverage of the literature, resulting in a powerful program theory.
- Realist reviews are harder to reproduce as relationships are theorised, often based on judgement, intuition, and experience.

For peer review only

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Background

In most developed nations, there has been a substantial shift to the marketisation of government-funded health services [1, 2]. In every part of the health system, whether nominally public or nominally private, healthcare- professional services, social and welfare services, education, training, drugs, case management, and decent, humane treatment-can be bought and sold [3]. Patients are customers, health is a commodity, and the consumption of goods and services takes place through voluntary exchanges in the market [1]. While the broader political agenda oriented towards improving service delivery, maximising consumer choice, and ensuring effective, equitable, responsive, and efficient services, is well understood, the commodification of health is, fundamentally, an issue concerning organisational- rather than simply political- sustainability [2, 4]. The shift to a market approach represents a significant reform process that, ultimately, aims to transform the way in which health services are delivered and consumed [2]. For organisations traditionally buffered from the competitive pressures of for-profit enterprises, such as not-for-profits and community-based organisations (CBOs), the journey into a competitive market is arduous and uncertain. Providers are having to develop the capacity to adapt to competitive tendering processes, shifting client expectations, and increasing demands for greater accountability. The ability of CBOs to adapt and respond in this changing political environment is crucial not only for business continuity, but also for the growth of these organisations. Despite the crucial role that CBOs play in the communities they serve, there is very limited understanding about how and in what circumstances these organisations adapt in anticipation of and in response to exogenous shocks that challenge existing institutional arrangements. Drawing on ideas of institutional entrepreneurship, we believe that attempts to build adaptive capacity require the transformation of existing institutional practices. Key in this may be identifying and fostering institutional entrepreneurs- actors who take the lead in being the impetus for, and giving direction to, structural change. In this research, we draw on ideas from the theory of institutional entrepreneurship to examine how change agents may engage in reshaping existing institutional practices in order to build an organisation's adaptive capacity [5-10].

What is adaptive capacity and why is it important?

Researchers have begun to recognise that the ability to challenge the status quo-that is, established ways of thinking and doing things- and to successfully adopt more effective processes, is a distinct form of organisational capacity: adaptive capacity [11, 12]. In this paper, we define adaptive capacity as the quest for change in pursuit of not only a continuity of

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2 core functions, but also a transformation of these functions in order to capitalise on
3 opportunities for change [11, 13, 14]. It is this notion of adaptive capacity which resonates with
4 Bains and Durham, who suggest that this transformational view of adaptive capacity
5 necessarily includes “concepts of renewal, regeneration and re-organisation”, requiring CBOs
6 to act as learning organisations [13]. Adaptive capacity is therefore a dynamic process,
7 embedded in all aspects of day-to-day activities. An organisation with adaptive capacity will
8 critically reflect on new opportunities and knowledge, and harness this new knowledge to
9 accommodate for growth. For this to happen, however, it requires a mix of key attributes:
10 innovation, flexibility, awareness, change readiness, systems thinking, social capital, strong
11 networks, and leadership [11-13].

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13 Available data suggests that CBOs are finding it increasingly difficult to face changes in the
14 political environment in which they operate [11, 15]. In a sector traditionally buffered from the
15 competitive pressures of for-profit enterprises, CBOs are having to become more adaptive to
16 changes in their operating environments in the form of changing circumstances, service
17 demands, and client expectations. These organisations increasingly face adaptive challenges
18 requiring them to reject the familiar and, instead, develop the capacity to harness creativity and
19 knowledge to fashion innovative responses, integrate lessons learned, and embrace
20 transformational change [11, 14]. The increasing importance of understanding adaptive
21 capacity in CBOs has led to the identification of a key gap in the literature- how and in what
22 circumstances can adaptive capacity be built in CBOs? Key in this may be identifying and
23 fostering institutional entrepreneurs.

24 25 26 27 28 29 30 31 32 33 34 35 36 **Institutional entrepreneurs in building adaptive capacity**

37 Building adaptive capacity in CBOs can be difficult. Institutional theory suggests that
38 institutions are resilient social structures, in which deeply embedded beliefs and patterns of
39 behaviour govern the appropriate conventions of its constituents [5, 6, 9]. Deeply rooted
40 sources of resistance to change in healthcare, for example, are well documented, in that
41 practitioners and managers who are directly affected will resist change [6, 14]. Similarly, non-
42 profits and CBOs are often resistant to dominant market based approaches that directly
43 challenge their not-for-profit mission. Institutional entrepreneurship focuses on the nature of
44 these exogenous shocks that challenge existing institutional arrangements. It suggests that
45 actors may be better placed than others to shape institutions despite pressures towards stasis
46 [10]. Institutional entrepreneurs are defined as “actors who serve as catalysts for structural
47 change and take the lead in being the impetus for, and giving direction to, change” [9]. They
48 are actors with sufficient resources to create new institutions that promote their particular
49 interests. Studies suggest that key to the institutional entrepreneur’s scope to enact
50 institutional change is his or her legitimacy in the organisation, social position in the field, social
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capital, and formal authority [7-9, 16, 17]. According to Bains and Durham, “institutional entrepreneurs have strong leadership skills although they may work invisibly: connecting; spanning boundaries; mobilizing resources and keeping alive a strategic focus” [13].

We propose that the theory of institutional entrepreneurship provides a powerful theoretical lens for understanding the processes of building adaptive capacity. However, there is limited research that explains how and in what circumstances institutional entrepreneurs could enact institutional change in order to build adaptive capacity in CBOs. Furthermore, while there is some research available on the process of institutional entrepreneurship in the health arena, the research that is available provides limited practical guidance for CBOs and institutional entrepreneurs on how to build adaptive capacity. In this review, our objective is to understand the circumstances surrounding the implementation of capacity building strategies that shape organisational response and generate outcomes by activating causal mechanisms. The information gathered can bolster successful CBO adaptation to better serve the communities they support.

Methods

Realist review

The research questions will be addressed using a realist review [18-23]. Realist review is an interpretative, theory-driven approach that uses qualitative, quantitative, and mixed-methods research evidence to understand and explain how and why the ‘same’ program, intervention, or policy generates different outcomes, in different situations [20, 24].

Realism is typically used to understand complex interventions. We classify capacity building strategies as a complex intervention that is context sensitive, in that it relies on the behaviour of a number of human components (institutional entrepreneurs, management, service providers, etc.) who interact in a non-linear way to produce multiple, contested outcomes [22, 25, 26]. For example, there are multiple layers of human behaviour, cognitive reasoning, and resources, and well as interactions between these different components [19, 27]. Furthermore, outcomes of capacity building strategies (e.g. shared understanding and purpose, willingness to question accepted ways of working, and strategic alliances with other organisations) are highly context-dependent- the impact of the ‘same’ strategy will vary “depending on who delivers it, to which learners, in which circumstances and with which tools and techniques” [28].

The realist approach to understanding complex interventions assumes that deterministic theories fail to predict outcomes in every context ([26, 27]. Rather, it is based on the principle that an intervention fires particular mechanisms of change somewhat differently in different contexts [22, 29-31]. From this perspective, an intervention does not trigger change; it is the

mechanisms underlying the intervention that generate outcomes [22, 29-31]. Mechanisms refer to the elements in the decision-making process, such as collective beliefs, norms, preferences, and cognitive processes that influence how actors use the resources available to them [19, 20, 23, 29, 32]. These mechanisms are influenced by the context in which the intervention is implemented. Context generally refers to cultural, social, historical, or institutional factors within the implementation setting, in this case the not-for-profit organisation, that enables or constrains actors [2, 23, 32]. Outcomes are the intended or unintended intermediate and final outcomes [2, 23]. Thus, a realist review seeks to explain how context (C) influences mechanisms (M) to generate outcomes (O), often called C-M-O configurations. The basic realist formula is:

Context (C) + Mechanism (M) = Outcome (O)

While Cochrane-style systematic reviews and meta-analyses can provide causal models to inform 'what works', they fail to recognise the complexities of social context and cannot elucidate the underlying processes that explain 'how', 'why' and 'in what context' [24, 32, 33]. In this review of capacity building strategies, there is a need to go beyond 'what works'. Capacity building strategies are contextual and thus embedded in complex social systems comprising "the interplays of individuals and institution, of agency and structure, and of micro and macro social processes" [30]. Thus, the act of restricting the scope of the review to 'what works', destroys the intricate relationships which we are seeking to understand.

Research aim and objectives

The primary aims of this realist review are (i) to understand how institutional entrepreneurs build adaptive capacity in CBOs and (ii) to find underlying theories that explain 'what works, for whom and in what circumstances'. Drawing on previous work in institutional entrepreneurship and organisational adaptive capacity, the reviewers will focus on synthesising the evidence to identify context-mechanism-outcome (CMO) configurations that explain the contexts in which particular mechanisms generate particular outcomes.

An additional, secondary aim concerns the interface between research, policy, and practice. The results will be useful to policy-makers, CBO institutional entrepreneurs, and academics in understanding how to effectively build CBOs adaptive capacity. The findings will provide policy-makers with explanations that are sensitive to the context (i.e. "in situations like X, use strategy Y and keep an eye out for Z") [24]. Therefore, policy-makers are more likely to be able to interpret an explanation of why a strategy works better in one organisation than another.

Our research questions are as follows:

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1. What strategies do institutional entrepreneurs in CBOs use to enact institutional change in order to build organisational adaptive capacity?
2. What are the outcomes (positive negative, and/or unintended) of the strategies they employ?
3. What are the key mechanisms by which capacity building strategies of institutional entrepreneurs are believed to result in the intended outcomes?
4. What are the important contexts which determine whether these different mechanisms generate the different outcomes (positive, negative, and unintended)?
5. In what circumstances is capacity building likely to be effective and for which organisations?

The review will follow the steps of a rapid realist review (RRR), as proposed by Saul et al [21]. The RRR process streamlines the review process by engaging knowledge users and review stakeholders to rapidly identify relevant documents for review, resulting in a review within three to six months. However, stakeholder involvement does not replace a literature search; rather, it provides a method to quickly identify relevant material for tailoring the search strategy and recommending C-M-O configurations. The RRR process is particularly useful if there is a small evidence base. A limitation of the RRR process is that it bypasses the initial identification of C-M-O configurations, which may limit the generalisability and potency of findings. Therefore, the study will use an adapted RRR process, moving between the following steps: drawing on external stakeholder expertise, describing the initial hypotheses or relevant program theories, undertaking a thorough search of the literature for relevant papers, appraising the evidence, synthesizing the data, and interpreting the evidence to test and refine our theoretical framework.

Study design

Step 1: Identify potential theories

The initial identification of a rough program theory is the first step to developing an overall, more powerful program theory of how institutional entrepreneurs build adaptive capacity [20, 27]. The initial theory is a preliminary sketch of what it is the research question is investigating, whereas the revised program theory describes what a program, or in this case, a strategy, is expected to do and how it is expected to work. We are looking for substantive theories-existing theories within particular disciplines- that explain the process of institutional entrepreneurship, but also how institutional entrepreneurs might work to build adaptive capacity

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2 in CBOs. We will use a variety of methods to derive our list of theories, including brainstorming
3 within the review team, scoping the literature, and consulting individual experts in the field.
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6 An initial scoping review of the literature uncovered a number of strategies through which
7 institutional entrepreneurs may enact institutional change that promotes adaptive capacity. For
8 example, because they can seldom transform institutions alone, institutional entrepreneurs
9 must mobilise key constituents with a diverse range of social skills depending on the kind of
10 change they intend to enact [34]. According to Rao et al. (2000), “institutional entrepreneurs
11 can mobilize legitimacy, finances, and personnel only when they are able to frame the
12 grievances and interests of aggrieved constituencies, diagnose causes, assign blame, provide
13 solutions, and enable collective attribution processes to operate” [35]. These findings will
14 contribute to the formation of our initial program theory. Using the online Delphi technique, we
15 will consult with key stakeholders in an expert reference group, including academics, CBO
16 member representatives, managers, staff, and public servants, to assist us in the identification
17 of relevant articles and documents for inclusion in the review. The Delphi technique is used to
18 prompt reflection and discussion among a group of experts with the aim of reaching consensus
19 about the program theory [36]. The reference group will act as a ‘reality check’ to test our
20 emerging understandings of the program theory [25]. The authors will meet regularly with the
21 stakeholder group and will also communicate via email.
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24 Step 2: Search strategy

25 Following the RAMESES guidelines for a realist review, which recognises the limitations of
26 fixed search protocols, we will undertake an iterative search of the literature with a broad focus
27 that responds flexibly to emerging findings [19, 24].
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29 The initial search strategy will involve two phases: (1) we will search for research evidence
30 that explains how institutional entrepreneurs facilitate institutional change and build adaptive
31 capacity in community-based, non-profit organisations, and (2) we will seek additional data to
32 test and refine our program theory. Table 1 provides preliminary search terms based on key
33 concepts provided by the research team; the search terms will be iteratively narrowed based on
34 the relevance of the retrieved documents, inclusion and exclusion criteria, and the extent to
35 which each study clarifies the C-M-O configurations. The literature will be searched using
36 combinations of these key terms in English and their truncations from 1988, the year
37 institutional entrepreneurship was introduced by DiMaggio, to the present. We anticipate our
38 search strategy to include databases such as PubMed, Web of Science, PsycINFO, Scopus,
39 EMBASE, EconLit, the Cochrane Library, CINAHL, JSTOR, Emerald, Google, and any other
40 relevant databases identified by the team (these databases were selected as they offer
41 extensive indexing of the literature). This search will be supplemented with bibliographic
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searches of reference lists in identified documents using the snowballing technique to identify additional documents. Grey literature, including evaluation reports and policy documents by governments, organisations, and consultancy firms, as well as dissertations and theses, will also be included in the search. Searching for new documents will end at the point of theoretical saturation; that is, when there is sufficient evidence to claim that the revised program theory is plausible. Documents meeting inclusion criteria will be compiled in Endnote.

Table 1- Search strategy	
Search number	Search terms
EMBASE platform	
1.	institutional NEXT/1 entrepreneur*
Scopus platform	
1.	TITLE-ABS-KEY (institutional PRE/1 entrepreneur*)
2.	(TITLE-ABS-KEY (ngos) OR TITLE-ABS-KEY (ngo) OR TITLE-ABS-KEY (engo) OR TITLE-ABS-KEY (engos) OR TITLE-ABS-KEY (" Community Base* ") OR TITLE-ABS-KEY (" Not for profit* ") OR TITLE-ABS-KEY (" Non profit ") OR TITLE-ABS-KEY (" non profit* "))
3.	(TITLE-ABS-KEY (institutional PRE/1 entrepreneur*)) AND ((TITLE-ABS-KEY (ngos) OR TITLE-ABS-KEY (ngo) OR TITLE-ABS-KEY (engo) OR TITLE-ABS-KEY (engos) OR TITLE-ABS-KEY (" Community Base* ") OR TITLE-ABS-KEY (" Not for profit* ") OR TITLE-ABS-KEY (" Non profit ") OR TITLE-ABS-KEY (" non profit* "))))
Web of Science platform	
1.	((" institutional entrepreneur* ") AND (NGO OR NGOs OR ENGOS OR ENGO OR " Community base* " OR " Not for profit* " OR nonprofit*))
*The above searches will be modified for other databases	

Step 3: Study selection criteria and procedures

Documents will be selected for the review based on what new knowledge they bring to our thinking about the program theory and the extent to which they can refine C-M-O configurations. This is likely to include editorials, opinion pieces, evaluations, program manuals, reviews, and commentaries. Focus will be placed on aspects of the document that relate to contexts, mechanisms, and outcomes which contribute to our understanding of how institutional entrepreneurs transform CBOs to build adaptive capacity. Based on discussions between the reviewers (SI, JD and AK), the inclusion criteria will include papers related to the process of institutional entrepreneurship in community-based, non-profit settings, in any

country. The inclusion criteria may extend to papers in CBOs outside of health care if insufficient papers are found that relate specifically to community-based health services.

In the first stage of searching, SI will screen the title, abstract, and keywords against the broad inclusion criteria outlined in Table 2. Articles meeting the inclusion criteria will be obtained for full text screening. A random sample of 10% of documents will be selected, assessed, and discussed by all review authors. It is expected that a number of documents will require discussion between the reviewers to decide whether to integrate the paper into the review. Documents meeting inclusion criteria will proceed to data extraction.

Table 2- Inclusion criteria	
Inclusion criteria	Description
1.	Document discusses the process of institutional entrepreneurship as it relates to transformation and change and is implicitly or explicitly underpinned by institutional theory
2.	Document is about the capacity of an organisation/institution to transform, including the ability to adapt and capitalise on opportunities for change
3.	Document describes a community-based, non-profit organization(s) that provides health care services or public services to individuals
4.	Document discusses at least one of the following factors that will contribute to the synthesis of our emerging program theory: <ul style="list-style-type: none"> -the strategies used by institutional entrepreneurs in transformative efforts to build adaptive capacity -the outcomes of the strategies they employ -the beliefs, norms, values, preferences, and cognitive processes that influence behaviour -the circumstances/conditions in which these different outcomes are generated

Step 4: Data extraction

Realist reviews typically synthesise information by note-taking and annotation rather than using a standardised list of questions as used in a traditional systematic review. The documents included in the review will initially be tabulated in an Excel spreadsheet and will be examined for study characteristics (e.g. sample size, setting, study objectives), as well as theories based on how, why, and in what contexts institutional entrepreneurs impose institutional change in

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order to build capacity in CBOs. During extraction, aspects of each paper will be assessed for relevance based on various factors, including definitions, theoretical frameworks employed, strategies and processes, mechanisms, contexts, and outcomes. In a second phase, the NVivo qualitative software will be used for coding; that is, to index and link relevant sections of included articles in an iterative manner allowing integration of new elements to our emerging theory [37].

Relevance and rigour of papers will be assessed using the Mixed Methods Appraisal Tool which has theoretical and content validity and has been tested for efficiency and reliability [38]. The tool will only be applied to pertinent aspects of the studies that relate to our program theory, rather than the studies as a whole. To ensure transparency in the data extraction process, we will develop a summary table specifying the publication title, authors, year of publication, objectives, type of study, setting, and different methodological aspects.

Step 5: Data synthesis

The initial candidate theories identified in step 1 will be used as a basis to analyse the data. We will synthesise the data using a realist approach to interrogate the final program theory which will be to determine what it is about institutional entrepreneurship that works to build adaptive capacity and for whom, in what circumstances, in what respects and why. Using a mix of inductive and deductive analytical processes, sections of texts, which will be coded within NVivo, will be examined to see if they confirm, refute, or refine our candidate theories. We will seek to determine if the coded extracts infer what the causal mechanisms might be, the contexts in which the mechanisms might be triggered, or the outcomes of these mechanisms. Specifically, we will attempt to identify what the C-M-O configurations might be and how it contributes to refining the initial program theory. Following the RAMESES guidelines, the final program theory will be summarised through a narrative synthesis of the interaction between context, mechanism, and outcome, using a logic model where appropriate.

Validity

A number of criteria will be met in establishing the validity of the review. First, the iterative process of understanding how institutional entrepreneurs build adaptive capacity in CBOs will require the reviewers to move between empirical data and formulating C-M-O configurations, which will enhance internal validity. The deliberate inclusion of context in the analysis will increase the generalisation of our program theory. Further, the use of an expert stakeholder group to provide insight, feedback, and to review the findings will also contribute to validity.

Ethics

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2 The study does not involve primary research and therefore does not require formal ethical
3 approval. However, ethical standards of utility, usefulness, feasibility, propriety, accuracy, and
4 accountability will be followed [39].
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7 8 **Dissemination**

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10 The results of the review will be written up according to the “Realist and Meta-Review Evidence
11 Synthesis: Evolving Standards” (RAMESES) guidelines. An international collaborative study
12 providing methodological guidance and reporting standards for a realist review is available
13 online [22, 23]. Findings will be published in a peer-reviewed journal.
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17 18 **Discussion**

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20 Increasingly, government-funded health services are shifting to market-driven approaches. The
21 need to examine the influence of policy forces that are changing existing institutional
22 arrangements is becoming even more urgent. Rigorous research is needed to identify how and
23 in what circumstances adaptive capacity can be built in CBOs so that they have a better
24 chance of surviving and thriving in changing environments. Key to this, is identifying the role of
25 institutional entrepreneurs in helping CBOs to reshape existing institutional practices in order to
26 capitalise on opportunities for change. While there is some research on the process of
27 institutional entrepreneurship, there is limited understanding of how institutional entrepreneurs
28 enact institutional change in order to build adaptive capacity. By capturing the relationship
29 between context, mechanism, and outcome, the findings of this review will provide valuable
30 transferrable lessons in ‘what strategies work, for whom, in what circumstances, to what
31 extent’, and most importantly ‘how and why?’. For CBOs wishing to position themselves for
32 adaptability in light of recent policy changes, the findings of this research may help in
33 identifying capacity building strategies and possible focal points for both decision-makers and
34 institutional entrepreneurs. A better understanding of how CBOs adapt and respond to market
35 driven policy forces is critical to meeting Government’s objectives of using CBOs in the health
36 sector to deliver public, demand-driven services to their communities.
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46 There are strengths and limitations to using a realist review. Unlike a systematic review that
47 explicitly attempts to control context, a realist review is rich in explanatory power and builds an
48 understanding of how and why interventions work. Instead of providing a judgement on whether
49 certain capacity building strategies used by institutional entrepreneurs are ‘good’ or ‘bad’, the
50 realist review will explain ‘what strategies work, for whom, in what circumstances, to what
51 extent’, and ‘how and why?’. However, compared to systematic reviews, realist reviews are
52 harder to reproduce as relationships are theorised, often based on judgement, intuition, and
53 experience. To minimise this limitation, we will include a summary table and methodological
54 details of papers included in this review. Furthermore, often context and mechanism details
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are lacking, limiting the information that can be extracted from documents. In these instances, the engagement of the expert reference group serves to explore possible C-M-O configurations in relation to current experiences and other relevant literature.

Contributors

SI and JD conceived and designed the study. SI drafted the first manuscript with AK and JD revising for important intellectual content. All authors have given final approval of the version to be published.

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Competing interests. None.

Abbreviations

CBOs- Community-based organisations

C-M-O- Context-mechanism-outcome configuration

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Table 3 Glossary of terms

Term	Description
Institutional entrepreneur	Change agent with strong leadership skills and sufficient resources, who takes the lead in creating a strategic focus and giving direction to structural change.
Capacity building	The act of developing the processes, skills, activities, and resources needed for organisations to survive, adapt, and thrive in a fast-paced changing environment.
Adaptive capacity	The ability of a system to modify or transform its behaviour, in anticipation of and in response to change, in an adaptive way in order to capitalise on opportunities for improvement.
Community-based organisation	Typically comprises non-government, not-for-profit organisations, representative of a community, that provide social, health, and welfare services to meet community needs.
Mechanism	Agents of change in the decision-making process, such as collective beliefs, norms, preferences, and cognitive processes that influence how actors use the resources available to them.
Context	Conditions, including cultural, social, historical, or institutional factors, within the implementation setting that modify the behaviour of mechanisms.
Context-Mechanism-Outcome configuration (CMO)	The relationship between particular contextual features, particular causal mechanisms, and particular intended and unintended outcomes.
Program theory	A program theory describes what a program is expected to do and how it is expected to work, and includes explanations of contexts, mechanisms, outcomes, and their configurations.

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PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review ✓ (identified as a realist review)
Update	1b	If the protocol is for an update of a previous systematic review, identify as such
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number ✓
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author ✓
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review ✓
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments (not applicable)
Support:		
Sources	5a	Indicate sources of financial or other support for the review ✓
Sponsor	5b	Provide name for the review funder and/or sponsor (not applicable)
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol (not applicable)
INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known ✓
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) ✓ (did not use PICO as using a realist review)
METHODS		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review ✓
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage ✓
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated ✓
Study records:		

Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review ✓
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis) ✓
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators ✓
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications ✓
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale ✓
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis ✓
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised ✓
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ) (not applicable)
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression) (not applicable)
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned ✓
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies) ✓
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE) (not applicable)

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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The role of institutional entrepreneurship in building adaptive capacity in community-based health care organisations: Realist review protocol

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The role of institutional entrepreneurship in building adaptive capacity in community-based health care organisations: Realist review protocol

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Keywords: realist review, adaptive capacity, institutional entrepreneur, non-profit, community-based organisation

Word count: 4,689

The role of institutional entrepreneurship in building adaptive capacity in community-based health care organisations: Realist review protocol

ABSTRACT

Introduction: Over the last three decades, there has been a substantial shift to the marketisation of government-funded health services. For organisations traditionally buffered from the competitive pressures of for-profit enterprises, such as community-based organisations, this means developing the capacity to adapt to competitive tendering processes, shifting client expectations, and increasing demands for greater accountability. Drawing on ideas of institutional entrepreneurship, we believe that attempts to build adaptive capacity require the transformation of existing institutional arrangements. Key in this, may be identifying and fostering institutional entrepreneurs- actors who take the lead in being the impetus for, and giving direction to, structural change. This study focuses on the strategies used by institutional entrepreneurs to build adaptive capacity in the community-based health care sector.

Methods and analysis: The research will use an adapted rapid realist review. The review will find underlying theories that explain the circumstances surrounding the implementation of capacity building strategies that shape organisational response and generate outcomes by activating causal mechanisms. An early scoping of the literature and consultations with key stakeholders will be undertaken to identify an initial program theory. We will search for relevant journal articles and grey literature. Data will be extracted based on contextual factors, mechanisms, and outcomes, and their configurations. The analysis will seek patterns and regularities in these configurations and will focus on confirming, refuting, or refining our program theory.

Ethics and dissemination: The study does not involve primary research and therefore does not require formal ethical approval. However, ethical standards of utility, usefulness, feasibility, propriety, accuracy, and accountability will be followed. The results will be written up according to the “Realist and Meta-Review Evidence Synthesis: Evolving Standards” (RAMESES) guidelines. Once completed, findings will be published in a peer-reviewed journal.

Trial registration number: This protocol has been registered with PROSPERO, registration number CRD42015026487.

Strengths and limitations:

- A realist review is rich in explanatory power and builds an understanding of how and why interventions work in complex systems such as health markets.
- The engagement of a reference group, consisting of industry experts and researchers, will ensure complete coverage of the literature, resulting in a powerful program theory.
- Realist reviews are harder to reproduce as relationships are theorised, often based on judgement, intuition, and experience.

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The role of institutional entrepreneurship in building adaptive capacity in community-based health care: Realist review protocol

BACKGROUND

In most developed nations, there has been a substantial shift to the marketisation of government-funded health services [1, 2]. In every part of the health system, whether nominally public or nominally private, healthcare- professional services, social and welfare services, education, training, drugs, case management, and decent, humane treatment-can be bought and sold [3]. Patients are customers, health is a commodity, and the consumption of goods and services takes place through voluntary exchanges in the market [1]. While the broader political agenda oriented towards improving service delivery, maximising consumer choice, and ensuring effective, equitable, responsive, and efficient services, is well understood, the commodification of health is, fundamentally, an issue concerning organisational- rather than simply political- sustainability [2, 4]. The shift to a market approach represents a significant reform process that, ultimately, aims to transform the way in which health services are delivered and consumed [2]. For organisations traditionally buffered from the competitive pressures of for-profit enterprises, such as not-for-profits and community-based organisations (CBOs), the journey into a competitive market is arduous and uncertain. Providers are having to develop the capacity to adapt to competitive tendering processes, shifting client expectations, and increasing demands for greater accountability. The ability of CBOs to adapt and respond in this changing political environment is crucial not only for business continuity, but also for the growth of these organisations. Despite the crucial role that CBOs play in the communities they serve, there is very limited understanding about how and in what circumstances these organisations adapt in anticipation of and in response to exogenous shocks that challenge existing institutional arrangements. Drawing on ideas of institutional entrepreneurship, we believe that attempts to build adaptive capacity require the transformation of existing institutional practices. Key in this may be identifying and fostering institutional entrepreneurs- actors who take the lead in being the impetus for, and giving direction to, structural change. In this research, we draw on ideas from the theory of institutional entrepreneurship to examine how change agents may engage in reshaping existing institutional practices in order to build an organisation's adaptive capacity [5-10]. A full glossary of terms is provided in Supplementary file 1.

What is adaptive capacity and why is it important?

Researchers have begun to recognise that the ability to challenge the status quo-that is, established ways of thinking and doing things- and to successfully adopt more effective processes, is a distinct form of organisational capacity: adaptive capacity [11, 12]. In this

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paper, we define adaptive capacity as the quest for change in pursuit of not only a continuity of core functions, but also a transformation of these functions in order to capitalise on opportunities for change [11, 13, 14]. It is this notion of adaptive capacity which resonates with Bains and Durham, who suggest that this transformational view of adaptive capacity necessarily includes “concepts of renewal, regeneration and re-organisation”, requiring CBOs to act as learning organisations [13]. Adaptive capacity is therefore a dynamic process, embedded in all aspects of day-to-day activities. An organisation with adaptive capacity will critically reflect on new opportunities and knowledge, and harness this new knowledge to accommodate for growth. For this to happen, however, it requires a mix of key attributes: innovation, flexibility, awareness, change readiness, systems thinking, social capital, strong networks, and leadership [11-13].

Available data suggests that CBOs are finding it increasingly difficult to face changes in the political environment in which they operate [11, 15]. In a sector traditionally buffered from the competitive pressures of for-profit enterprises, CBOs are having to become more adaptive to changes in their operating environments in the form of changing circumstances, service demands, and client expectations. These organisations increasingly face adaptive challenges requiring them to reject the familiar and, instead, develop the capacity to harness creativity and knowledge to fashion innovative responses, integrate lessons learned, and embrace transformational change [11, 14]. The increasing importance of understanding adaptive capacity in CBOs has led to the identification of a key gap in the literature- how and in what circumstances can adaptive capacity be built in CBOs? Key in this may be identifying and fostering institutional entrepreneurs.

Institutional entrepreneurs in building adaptive capacity

Building adaptive capacity in CBOs can be difficult. Institutional theory suggests that institutions are resilient social structures, in which deeply embedded beliefs and patterns of behaviour govern the appropriate conventions of its constituents [5, 6, 9]. Deeply rooted sources of resistance to change in healthcare, for example, are well documented, in that practitioners and managers who are directly affected will resist change [6, 14]. Similarly, non-profits and CBOs are often resistant to dominant market based approaches that directly challenge their not-for-profit mission. Institutional entrepreneurship focuses on the nature of these exogenous shocks that challenge existing institutional arrangements. It suggests that some actors may be better placed than others to shape institutions despite pressures towards stasis [10]. Institutional entrepreneurs are defined as “actors who serve as catalysts for structural change and take the lead in being the impetus for, and giving direction to, change” [9]. They are actors with sufficient resources to create new institutions that promote their particular interests. Studies suggest that key to the institutional entrepreneur’s scope to enact

1
2 institutional change is his or her legitimacy in the organisation, social position in the field, social
3 capital, and formal authority [7-9, 16, 17]. According to Bains and Durham, “institutional
4 entrepreneurs have strong leadership skills although they may work invisibly: connecting;
5 spanning boundaries; mobilizing resources and keeping alive a strategic focus” [13].
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10 We propose that the theory of institutional entrepreneurship provides a powerful theoretical
11 lens for understanding the processes of building adaptive capacity. However, there is limited
12 research that explains how and in what circumstances institutional entrepreneurs could enact
13 institutional change in order to build adaptive capacity in CBOs. Furthermore, while there is
14 some research available on the process of institutional entrepreneurship in the health arena,
15 the research that is available provides limited practical guidance for CBOs and institutional
16 entrepreneurs on how to build adaptive capacity. In this review, our objective is to understand
17 the circumstances surrounding the implementation of capacity building strategies that shape
18 organisational response and generate outcomes by activating causal mechanisms. The
19 information gathered can bolster successful CBO adaptation to better serve the communities
20 they support.
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26 27 **METHODS**

28 29 **Realist review**

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31 The research questions will be addressed using a realist review [18-23]. While positivist
32 approaches to understanding interventions, such as Cochrane-style systematic reviews and
33 meta-analyses, can provide causal models to inform ‘what works’ by focusing on differences in
34 outcomes between groups, they fail to recognise the complexities of social context and cannot
35 elucidate the underlying processes that explain ‘how it works’, ‘why it works’ and ‘in what
36 context it works’ [24-26]. Against this logic, realism is typically used to understand complex
37 interventions, such as capacity building, in complex, interactive health systems with substantial
38 heterogeneity. Capacity building strategies are highly contextual (the outcome of the ‘same’
39 strategy will vary “depending on who delivers it, to which learners, in which circumstances and
40 with which tools and techniques” [27]- hence a strategy that is successful in one setting, may
41 be unsuccessful in another setting). In such complex systems, the outcomes depend on
42 individuals making decisions in a semi-predictable (demi-regular) manner about how to use the
43 resources available to them in particular contexts. Thus, the act of restricting the scope of the
44 review to ‘what works’ by only focusing on the outcomes, destroys the intricate relationships
45 and underlying processes which we are seeking to understand [20].
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56 Realist review is an interpretative, theory-driven approach that uses qualitative, quantitative,
57 and mixed-methods research evidence to understand and explain how mechanisms (M)
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produce different outcomes (O) in different contexts (C) [20, 25, 28]. At the heart of realist review lies the concept of generative causation, represented below in the basic realist formula:

Context (C) + Mechanism (M) = Outcome (O)

Realist review is based on the principle that a capacity building strategy does not trigger change; it is the mechanisms underlying the strategy that generate outcomes [22, 28-30]. It is this notion of program “mechanisms” that takes a step away from asking whether a strategy ‘works’ to understanding what it is about a strategy which makes it ‘work’. Mechanisms refer to the elements in the cognitive decision-making process, such as collective beliefs, norms, preferences, which interact with resources, opportunities, and constraints to influence changes in behaviour [19, 20, 23, 24, 28]. Taking capacity building strategies used by institutional entrepreneurs as an example, such strategies, such as providing information to senior management about imminent policy threats may motivate senior management staff to make an internal change in service provision; whereby the mechanism is the decision or reasoning to make an internal change in service provision (*forward planning*), rather than the strategy itself (providing information to senior management).

These mechanisms, such as *forward planning*, are enabled or disabled by the context in which the intervention is implemented. This is because similar mechanisms may be triggered in some contexts, producing similar patterns of behaviour, or triggered in other contexts, producing different patterns of behaviour. Context may refer to broad cultural, social, historical, or institutional features (for example, the degree of heterogeneity and institutionalisation within the not-for-profit organisation) to features affecting the implementation of the strategy (for example, whether there is adequate funding within the organisation). It could also relate to the conditions in which individuals seek to enact their choices (for example, senior management will be more likely to enact change in a context in which institutional entrepreneurs are perceived as legitimate) [2, 23, 24]. Drawing once again on examples from the current research, a *resilient culture* within the organisation is a contextual condition which may disable the activation of mechanisms that lead to institutional change.

Outcomes can be intended or unintended, intermediate or final [2, 23]. In the current research, the intended outcome of interest is adaptive capacity (the ability to monitor, assess, respond to, and stimulate change), which necessarily includes concepts of shared understanding and purpose, strategic alliances with other organisations, willingness to question accepted ways of working, and innovative approaches to service provision. While adaptive capacity building strategies are implemented with these desired outcomes in mind, the variations in contexts and mechanisms means that strategies are liable to have mixed outcome patterns [27, 30]. For example, the way in which senior management react to a particular

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2 message may depend on the organisational culture. For example, the institutional entrepreneur
3 may propose a change in service provision. Senior management from a CBO less
4 institutionalised (established norms and patterns of behaviour) may react to this message
5 exactly as institutional entrepreneurs expect and take strategic action. Some senior
6 management, from a more institutionalised organisation, may find the same message
7 threatening to existing institutional arrangements and may dismiss the message altogether. It is
8 also worth noting that an outcome of one strategy can also become a context or mechanism
9 that provides another outcome, creating a 'ripple effect' [31]. For instance, using the example
10 provided previously, the capacity to *forward plan* may become a contextual factor in the next
11 CMO configuration—that is, senior management will be more likely to enact change in a context
12 in which the organisation engages in forward planning.
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20 **Research aim and objectives**

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22 The primary aims of this realist review are (i) to understand how institutional entrepreneurs
23 build adaptive capacity in CBOs and (ii) to test and refine underlying theories that explain 'what
24 works, for whom and in what circumstances'. Drawing on previous work in institutional
25 entrepreneurship and organisational adaptive capacity, the reviewers will focus on synthesising
26 the evidence to identify context-mechanism-outcome (CMO) configurations that explain the
27 contexts in which particular mechanisms generate particular outcomes.
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32 An additional, secondary aim concerns the interface between research, policy, and practice.
33 The results will be useful to policy-makers, CBO institutional entrepreneurs, and academics in
34 understanding how to effectively build CBOs adaptive capacity. The findings will provide policy-
35 makers with explanations that are sensitive to the context (i.e. "in situations like X, use strategy
36 Y and keep an eye out for Z") [25]. Therefore, policy-makers are more likely to be able to
37 interpret an explanation of why a strategy works better in one organisation than another.
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42 Our overarching research question is:

- 43 1. What strategies, contextual factors, and mechanisms are necessary for institutional
44 entrepreneurs in CBOs to build adaptive capacity?
 - 45 a. In what ways do institutional entrepreneurs in CBOs create a vision and mobilise
46 resources to enact change and build adaptive capacity?
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 - 48 b. What is the role of enabling conditions, including field-level determinants and
49 individual-level determinants, in adaptive capacity building efforts?
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 - 51 c. What are the key mechanisms or social processes that influence or drive the
52 successful building of adaptive capacity?
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- d. How do key mechanisms and enabling conditions interact to produce change?

The review will follow the steps of a rapid realist review (RRR), as proposed by Saul, Willis, Bitz, et al [21]. The RRR process streamlines the review process by engaging knowledge users and review stakeholders to rapidly identify relevant documents for review, resulting in a review within three to six months. However, stakeholder involvement does not replace a literature search; rather, it provides a method to quickly identify relevant material for tailoring the search strategy and recommending C-M-O configurations. The RRR process is particularly useful if there is a small evidence base. A limitation of the RRR process is that it bypasses the initial identification of C-M-O configurations, which may limit the generalisability and potency of findings. Therefore, the study will use an adapted RRR process, moving between the following steps: drawing on external stakeholder expertise, describing the initial hypotheses or relevant program theories, undertaking a thorough search of the literature for relevant papers, appraising the evidence, synthesizing the data, and interpreting the evidence to test and refine our theoretical framework.

Study design

Step 1: Identify potential theories

The initial identification of a rough program theory is the first step to developing an overall, more powerful program theory of how institutional entrepreneurs build adaptive capacity [20, 32]. Central to the realist review is developing and refining this candidate theory. The initial theory is a preliminary sketch of what it is the research question is investigating, whereas the revised program theory describes what a program, or in this case, a strategy, is expected to do and how it is expected to work. We are looking for substantiative theories, existing theories within particular disciplines- that explain the process of institutional entrepreneurship, but also how institutional entrepreneurs might work to build adaptive capacity in CBOs. We will use a variety of methods to derive our list of theories, including brainstorming within the review team, scoping the literature, and consulting individual experts in the field.

To date, the concept of institutional entrepreneurship has been commonly applied to institutional change at the organisational level. An initial scoping review of the literature uncovered a range of issues and areas concerning the enabling conditions for, and the process of, institutional entrepreneurship. Research suggests that the work undertaken by institutional entrepreneurs is inevitably contingent on prevailing forms of field-level determinants and individual-level determinants [5, 9]. External pressures and crises, in the form of social upheaval, political pressures, technological disruptions, regulatory changes, and competitive discontinuities, are identified by Child, Yuan, and Tsai (2007) and Greenwood, Suddaby, and Hinings (2002) as field-level enabling conditions for institutional entrepreneurship as they

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disrupt existing institutional arrangements, motivating individuals to reconsider the status quo [33, 34]. Another important field-level determinant is the structure of the organisation, that is, the degree of heterogeneity and institutionalisation. Heterogeneous institutional arrangements (variance in the characteristics of institutional processes) and lower degrees of institutionalisation (established norms and patterns of behaviour) are likely to give rise to institutional incompatibilities, driving individuals to question existing arrangements and take strategic action as institutional entrepreneurs [5, 35].

Although field-level determinants play an important role in enabling institutional entrepreneurship, “only some actors will exploit the opportunity to become institutional entrepreneurs” [5]. Therefore, individual-level determinants, including the social position of an actor, also play an enabling role in institutional entrepreneurship. Social position—the position of an individual in the structure of social networks—might affect both actors’ perception of a field and their access to resources needed to engage in institutional change [36]. Research suggests that actors at the centre of organisations are confined by the institution which prevents them from recognising alternative processes, whereas actors at the margins of organisations are less embedded in organisational practises, thus prompting them to make change [6, 10].

In the literature, two main processes of institutional entrepreneurship that have received considerable attention are (1) creating vision and (2) mobilising resources. Institutional entrepreneurs must craft a vision for change in such a way that it appeals to the widest possible audience of potential allies. According to Rao, Morrill, and Zald (2000), “institutional entrepreneurs can mobilize legitimacy, finances, and personnel only when they are able to frame the grievances and interests of aggrieved constituencies, diagnose causes, assign blame, provide solutions, and enable collective attribution processes to operate” [37]. This necessarily includes specification—exposing organisational failings— and justification—proposing solutions as superior to previous arrangements [9]. Because they can seldom transform institutions alone, institutional entrepreneurs must mobilise key constituents with a diverse range of social skills depending on the kind of change they intend to enact [38]. According to Leca, Battilana, and Boxenbaum (2008), “tangible resources such as financial assets can be used during early stages of the process to bypass the sanctions likely to be imposed on the institutional entrepreneur who questions the existing institution by opponents of the proposed change” [9]. Furthermore, intangible resources, such as social capital, legitimacy, and formal authority, can enable institutional entrepreneurs to be taken seriously by allies. These findings from the initial scoping review will contribute to the formation of our initial program theory.

Using the online Delphi technique, we will consult with key stakeholders in an expert reference group, including academics, CBO member representatives, managers, staff, and

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2 public servants, to assist us in the identification of relevant articles and documents for inclusion
3 in the review. The Delphi technique is used to prompt reflection and discussion among a group
4 of experts with the aim of reaching consensus about the program theory [39]. The reference
5 group will act as a 'reality check' to test our emerging understandings of the program theory
6 [40]. The authors will meet regularly with the stakeholder group and will also communicate via
7 email.
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10 Step 2: Search strategy

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12 Following the RAMESES guidelines for a realist review, which recognises the limitations of
13 fixed search protocols, we will undertake an iterative search of the literature with a broad focus
14 that responds flexibly to emerging findings [19, 25].
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20 The initial search strategy will involve two phases: (1) we will search for research evidence
21 that explains how institutional entrepreneurs facilitate institutional change and build adaptive
22 capacity in community-based, non-profit organisations, and (2) we will seek additional data to
23 test and refine our program theory. Table 1 provides preliminary search terms based on key
24 concepts provided by the research team; the search terms will be iteratively narrowed based on
25 the relevance of the retrieved documents, inclusion and exclusion criteria, and the extent to
26 which each study clarifies the C-M-O configurations. The literature will be searched using
27 combinations of these key terms in English and their truncations from 1988, the year
28 institutional entrepreneurship was introduced by DiMaggio, to the present. We anticipate our
29 search strategy to include databases such as PubMed, Web of Science, PsycINFO, Scopus,
30 EMBASE, EconLit, the Cochrane Library, CINAHL, JSTOR, Emerald, Google, and any other
31 relevant databases identified by the team (these databases were selected as they offer
32 extensive indexing of the literature). This search will be supplemented with bibliographic
33 searches of reference lists in identified documents using the snowballing technique to identify
34 additional documents. Grey literature, including evaluation reports and policy documents by
35 governments, organisations, and consultancy firms, as well as dissertations and theses, will
36 also be included in the search. Searching for new documents will end at the point of theoretical
37 saturation; that is, when there is sufficient evidence to claim that the revised program theory is
38 plausible. Documents meeting inclusion criteria will be compiled in Endnote.
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Table 1- Search strategy	
Search number	Search terms
EMBASE platform	
1.	institutional NEXT/1 entrepreneur*
Scopus platform	
1.	TITLE-ABS-KEY (institutional PRE/1 entrepreneur*)
2.	(TITLE-ABS-KEY (ngos) OR TITLE-ABS-KEY (ngo) OR TITLE-ABS-KEY (engo) OR TITLE-ABS-KEY (engos) OR TITLE-ABS-KEY (" Community Base* ") OR TITLE-ABS-KEY (" Not for profit* ") OR TITLE-ABS-KEY (" Non profit ") OR TITLE-ABS-KEY (" non profit* "))
3.	(TITLE-ABS-KEY (institutional PRE/1 entrepreneur*)) AND ((TITLE-ABS-KEY (ngos) OR TITLE-ABS-KEY (ngo) OR TITLE-ABS-KEY (engo) OR TITLE-ABS-KEY (engos) OR TITLE-ABS-KEY (" Community Base* ") OR TITLE-ABS-KEY (" Not for profit* ") OR TITLE-ABS-KEY (" Non profit ") OR TITLE-ABS-KEY (" non profit* ")))
Web of Science platform	
1.	((" institutional entrepreneur* ") AND (NGO OR NGOs OR ENGOS OR ENGO OR " Community base* " OR " Not for profit* " OR nonprofit*))
*The above searches will be modified for other databases	

Step 3: Study selection criteria and procedures

Documents will be selected for the review based on what new knowledge they bring to our thinking about the program theory and the extent to which they can refine C-M-O configurations. This is likely to include editorials, opinion pieces, evaluations, program manuals, reviews, and commentaries. Focus will be placed on aspects of the document that relate to contexts, mechanisms, and outcomes which contribute to our understanding of how institutional entrepreneurs transform CBOs to build adaptive capacity. Based on discussions between the reviewers (SI, JD and AK), the inclusion criteria will include papers related to the process of institutional entrepreneurship in community-based, non-profit settings, in any country. The inclusion criteria may extend to papers in CBOs outside of health care if insufficient papers are found that relate specifically to community-based health services.

In the first stage of searching, SI will screen the title, abstract, and keywords against the broad inclusion criteria outlined in Table 2. Articles meeting the inclusion criteria will be obtained for full text screening. A random sample of 10% of documents will be selected, assessed, and discussed by all review authors. It is expected that a number of documents will require discussion between the reviewers to decide whether to integrate the paper into the review. Documents meeting inclusion criteria will proceed to data extraction.

Inclusion criteria	Description
1.	Document discusses the process of institutional entrepreneurship as it relates to transformation and change and is implicitly or explicitly underpinned by institutional theory
2.	Document is about the capacity of an organisation/institution to transform, including the ability to adapt and capitalise on opportunities for change
3.	Document describes a community-based, non-profit organization(s) that provides health care services or public services to individuals
4.	Document discusses at least one of the following factors that will contribute to the synthesis of our emerging program theory: <ul style="list-style-type: none"> -the strategies used by institutional entrepreneurs in transformative efforts to build adaptive capacity -the outcomes of the strategies they employ -the beliefs, norms, values, preferences, and cognitive processes that influence behaviour -the circumstances/conditions in which these different outcomes are generated

Step 4: Data extraction

Realist reviews typically synthesise information by note-taking and annotation rather than using a standardised list of questions as used in a traditional systematic review. The explanatory accounts will initially be tabulated in an Excel spreadsheet and will be examined for study characteristics (e.g. sample size, setting, study objectives), as well as information on how, why, and in what contexts institutional entrepreneurs impose institutional change in order to build capacity in CBOs. During extraction, aspects of each paper will be assessed for relevance based on various factors, including definitions, theoretical frameworks employed, strategies and processes, mechanisms, contexts, and outcomes. Using a similar approach to Pearson, Brand, Quinn, et al. (2015), we will seek explanatory accounts in the form of “If...then” statements to identify potential contexts and mechanisms [41]. For example, *if* institutional entrepreneurs are perceived as legitimate entities within the institution, *then* intended targets are more likely to believe that the organisation is at risk. However, as explanatory accounts may not always report contexts and mechanisms in a consistent format, we will also seek standalone accounts of each of these elements. In a second phase, the NVivo qualitative software will be used for coding; that is, to index and link relevant explanatory accounts in an iterative manner allowing authors to identify inter-relationships and overlaps before further development [42].

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Relevance and rigour of papers will be assessed using the Mixed Methods Appraisal Tool which has theoretical and content validity and has been tested for efficiency and reliability [43]. The tool will only be applied to pertinent aspects of the studies that relate to our program theory, rather than the studies as a whole. To ensure transparency in the data extraction process, we will develop a summary table specifying the publication title, authors, year of publication, objectives, type of study, setting, and different methodological aspects.

Step 5: Data synthesis

The initial candidate theory identified in Step 1 will be used as a basis to analyse the data. Using a mix of inductive and deductive analytical processes, explanatory accounts, which will be coded within NVivo during the extraction phase, will be examined to see if they confirm, refute, or refine our candidate theory, that is; Is the account novel and does it add anything to our understanding of the program theory? We will consolidate the explanatory accounts to develop the final program theory which will be to determine what it is about institutional entrepreneurship that works to build adaptive capacity and for whom, in what circumstances, in what respects and why. We will seek to determine if the extracts infer novel accounts of what the causal mechanisms might be, the contexts in which the mechanisms might be triggered, or the outcomes of these mechanisms. While reading the explanatory accounts and in our attempt to synthesise the information alongside existing theory into a consolidated explanatory account (program theory), we will consider: Is this account novel? Does this account add to our understanding of contexts, mechanisms, and outcomes mentioned in related accounts? In terms of expressing C-M-O configurations, we will ask: Does the consolidated explanatory account adequately reflect the contexts, mechanisms, outcomes, and their configurations, proposed in the underlying explanatory accounts? Following the RAMESES guidelines, the final program theory will be summarised through a narrative synthesis of the interaction between context, mechanism, and outcome, using a logic model where appropriate.

Validity

A number of criteria will be met in establishing the validity of the review. First, the iterative process of understanding how institutional entrepreneurs build adaptive capacity in CBOs will require the reviewers to move between empirical data and formulating C-M-O configurations, which will enhance internal validity. The deliberate inclusion of context in the analysis will increase the generalisation of our program theory. Further, the use of an expert stakeholder group to provide insight, feedback, and to review the findings will also contribute to validity.

Ethics

The study does not involve primary research and therefore does not require formal ethical approval. However, ethical standards of utility, usefulness, feasibility, propriety, accuracy, and accountability will be followed [44].

Dissemination

The results of the review will be written up according to the “Realist and Meta-Review Evidence Synthesis: Evolving Standards” (RAMESES) guidelines. An international collaborative study providing methodological guidance and reporting standards for a realist review is available online [22, 23]. Findings will be published in a peer-reviewed journal.

DISCUSSION

Increasingly, government-funded health services are shifting to market-driven approaches. The need to examine the influence of policy forces that are changing existing institutional arrangements is becoming even more urgent. Rigorous research is needed to identify how and in what circumstances adaptive capacity can be built in CBOs so that they have a better chance of surviving and thriving in changing environments. Key to this, is identifying the role of institutional entrepreneurs in helping CBOs to reshape existing institutional practices in order to capitalise on opportunities for change. While there is some research on the process of institutional entrepreneurship, there is limited understanding of how institutional entrepreneurs enact institutional change in order to build adaptive capacity. By capturing the relationship between context, mechanism, and outcome, the findings of this review will provide valuable transferrable lessons in ‘what strategies work, for whom, in what circumstances, to what extent’, and most importantly ‘how and why?’. For CBOs wishing to position themselves for adaptability in light of recent policy changes, the findings of this research may help in identifying capacity building strategies and possible focal points for both decision-makers and institutional entrepreneurs. A better understanding of how CBOs adapt and respond to market driven policy forces is critical to meeting Government’s objectives of using CBOs in the health sector to deliver public, demand-driven services to their communities.

There are strengths and limitations to using a realist review. Unlike a systematic review that explicitly attempts to control context, a realist review is rich in explanatory power and builds an understanding of how and why interventions work. Instead of providing a judgement on whether certain capacity building strategies used by institutional entrepreneurs are ‘good’ or ‘bad’, the realist review will explain ‘what strategies work, for whom, in what circumstances, to what extent’, and ‘how and why?’. However, compared to systematic reviews, realist reviews are harder to reproduce as relationships are theorised, often based on judgement, intuition, and

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experience. To minimise this limitation, we will include a summary table and methodological details of papers included in this review. Furthermore, often context and mechanism details are lacking, limiting the information that can be extracted from documents. In these instances, the engagement of the expert reference group serves to explore possible C-M-O configurations in relation to current experiences and other relevant literature.

Contributors

SI and JD conceived and designed the study. SI drafted the first manuscript with AK and JD revising for important intellectual content. All authors have given final approval of the version to be published.

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Competing interests. None.

Abbreviations

CBOs- Community-based organisations

C-M-O- Context-mechanism-outcome configuration

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Glossary of terms

Term	Description
Institutional entrepreneur	Change agent with strong leadership skills and sufficient resources, who takes the lead in creating a strategic focus and giving direction to structural change.
Capacity building	The act of developing the processes, skills, activities, and resources needed for organisations to survive, adapt, and thrive in a fast-paced changing environment.
Adaptive capacity	The ability of a system to modify or transform its behaviour, in anticipation of and in response to change, to capitalise on opportunities for improvement.
Community-based organisation	Typically comprises non-government, not-for-profit organisations, representative of a community, that provide social, health, and welfare services to meet community needs.
Mechanism	Elements in the cognitive decision-making process, such as collective beliefs, norms, preferences, which interact with resources, opportunities, and constraints to influence changes in behaviour.
Context	Conditions, including cultural, social, historical, or institutional features, within the implementation setting that modify the behaviour of mechanisms.
Context-Mechanism-Outcome configuration (CMO)	The relationship between particular contextual features, particular causal mechanisms, and particular intended and unintended outcomes.
Program theory	A program theory describes what a program is expected to do and how it is expected to work, and includes explanations of contexts, mechanisms, outcomes, and their configurations.

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review ✓ (identified as a realist review)
Update	1b	If the protocol is for an update of a previous systematic review, identify as such
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number ✓
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author ✓
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review ✓
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments (not applicable)
Support:		
Sources	5a	Indicate sources of financial or other support for the review ✓
Sponsor	5b	Provide name for the review funder and/or sponsor (not applicable)
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol (not applicable)
INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known ✓
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) ✓ (did not use PICO as using a realist review)
METHODS		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review ✓
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage ✓
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated ✓
Study records:		

Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review ✓
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis) ✓
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators ✓
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications ✓
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale ✓
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis ✓
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised ✓
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ) (not applicable)
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression) (not applicable)
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned ✓
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies) ✓
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE) (not applicable)

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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