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Conceptualising contexts, mechanisms and outcomes for implementing large-scale hospital improvement initiatives: a realist synthesis

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Abstract

Objectives:

To examine the implementation strategies used in large-scale hospital initiatives reported in the literature and hypothesise initial program theories for how implementation produces intended or unintended outcomes across various circumstances. We focus particularly on Organisational Readiness Theory.

Design:

Realist synthesis.

Setting

Large-scale hospital improvement initiatives can standardise evidence-based healthcare across multiple sites but results are contingent on the implementation strategies that complement them. There is evidence the benefits of these implemented interventions are rarely able to be replicated in different contexts. Realist studies explore this phenomenon in depth by identifying underlying context-mechanism–outcome interactions.

Methods

An iterative, four-step process was applied, employing literature searching, research team workshops, sense-checking with experts, and staged data extraction. The objectives of each step were: (1) explore the concepts and features inherent in large-scale interventions, (2) identify suites of strategies used in their implementation, (3) workshop potential initial program theories that may explain strategies' mechanisms, (4) focus on one strategy-theory pairing to develop and test context-mechanism-outcome hypotheses.

Results

We found 51 relevant articles (from a total of 381) from which concepts were identified. Large-scale hospital interventions are characterised by a top-down approach, support from both outside agencies and internal management, and use of high-quality evidence-based interventions. We found 302 reports of 28 different implementation strategies. Formal theories proposed for the implementation strategies included Diffusion of Innovation, Theory of Planned Behaviour, and Organisational Readiness Theory. Initial program theories were then hypothesised, based on configurations of context-mechanism-outcomes for implementation strategies associated with planning and assessment activities. Evidence from the published literature supported the hypothesised program theories and were consistent with the tenets of Organisational Readiness Theory.

Conclusion

This paper adds to the literature exploring why large-scale hospital interventions are not always successfully implemented and suggests causative mechanisms and contextual factors that may be driving this.

Key words

Realist synthesis, implementation science, change management, program theory, health services

Article Summary

Strengths and limitations of this study

- This realist synthesis examines the literature to define contextual features and concepts pertinent to large-scale improvement initiatives affecting how implementation strategies work
- It then identifies 28 different implementation strategies that have been deployed for such programs and unpicks how these work in nuanced site contexts to produce intended or unintended outcomes.
- An iterative process was used to search, extract data, validate and analyse results using evidence and expertise from researchers and partners.
- RAMESES Reporting Standards were used to ensure rigour of each staged step.

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Competing interests statement

The authors declare they have no conflicting or competing interests.

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Introduction

The implementation of large-scale, hospital-based improvement initiatives, developed from high quality evidence have the potential to standardise practice, improve safety, continuity and quality of care for patients, reduce unnecessary, unwarranted treatments and provide better value for money.[1] Large-scale hospital interventions as discussed here, are projects that are typically "top down", initiated by Health Departments, local health networks, or high level clinical agencies in contrast to local, clinician-initiated "grass-roots" projects. Such interventions are typically intended to be implemented across multiple hospitals, may be supported by additional staff and resources, and align with other high-level health priorities. The QUARISMA intervention in Quebec, Canada, for example, was implemented in 32 hospitals.[2] Using best practice guidelines derived from recommendations of the Society of Obstetricians and Gynaecologists, the hospitals successfully and safely reduced the rates of clinically unwarranted caesarean sections in low risk mothers.[2] Another example is the successful adoption of the World Health Organisation's surgical safety check-list[3] in six high performing hospitals in The Netherlands which significantly reduced surgical complications and mortality.[4]

Large-scale interventions are expensive and time consuming to implement.[5] Their success is contingent on the implementation programs that accompany them[6]; that is, the suite of individual implementation strategies designed to prepare the hospitals for change, and equip the focal stakeholders to adopt new practices and adapt or discard old ones. Recent systematic reviews have identified a range of strategies linked to successful implementation programs, such as conducting a needs assessment, recruitment of champions or opinion leaders, use of audit and feedback, engaging organisational leaders, and developing implementation teams.[e.g.,7,8] For large-scale interventions, these implementation programs are often required to fit a range of hospitals of different size, geographic and socio-demographic contexts, and health consumer needs.

In recent years, implementation strategies have been compiled, described and categorised[9] but research has failed to explain why strategies that work as intended in one context,[e.g., 10] may be a failure in another.[e.g., 11] Results suggest that those designing implementation strategies have failed to take into account local contextual features,[12] and the underlying mechanism of action, which implies the way strategies work is poorly understood. A program theory that lies beneath the implementation program and that articulates how the strategies are thought to work is often not explicitly stated. Davies and colleagues showed in their review of 235 guideline dissemination and improvement projects in health care, only 23% used theory of any kind to inform the development of the implementation strategies.[13] This, they argue, can result in a poor choice of implementation strategy for the context (e.g., settling for a "default strategy" such as an education session[14]) and corresponding poor results.

Realist approaches take a deep dive into why programs work as intended some of the time but not all of the time.[15] A realist approach asserts that all programs have an underlying program theory that explains how the strategies bring about intended or unintended results. This holds the promise of unpicking the link between the context and outcomes. A realist synthesis is the ideal approach to understand implementation programs for large-scale hospital interventions, as it explores the links between strategies, mechanisms of action, contexts, the responses of clinicians, and outcomes. Terms used in this synthesis referring to types of theories are defined in Box 1.

Formal theories: here, this refers to general implementation science theories that have been used to explain how implementation strategies work broadly and for which there is some empirical support. Also called mid-range theories[16]

Program theory: a theory that explains how and why particular types of interventions work to generate the outcome/s of interest[16]

Initial program theory: a program theory that is hypothesised, tested and refined as a result of the realist synthesis to explain how the focal type of intervention generates the outcome/s of interest

Potential initial program theories: a suite of program theories being considered as an initial program theory

Box 1: Types of theories referred to in this paper

A realist synthesis is a generative process, first understanding the nature of the implementation program and then proposing potential initial program theories around the way a program works. These initial program theories, configured as *contexts* (circumstances under which the program works), *mechanisms* (generative causes of how programs elicit results), and *outcomes* (the results of the program), are then tested using published literature.[15] The *context-mechanism-outcome* configurations (CMOs) that are found through analysis of the literature can be explored and used to formulate and refine initial program theories which explain how and under what circumstances programs achieve different outcomes. Consequently, realist research does not apply value judgements on program outcomes such as "successful" or "unsuccessful". Instead, it acknowledges that programs produce intended and unintended outcomes.[17]

The aim of this realist synthesis was to synthesise evidence and generate initial program theories that explain how implementation strategies work in large-scale hospital interventions; in other words, to gather evidence on what works as intended for whom, in what circumstances, and why. This realist synthesis is divided into two parts. First, we scope the literature seeking to understand the concepts and features of implementation programs for large-scale hospital interventions to understand the sorts of formal theories that may be relevant here. Second, we focus on a single group of implementation strategies and generate initial program theories [18] and CMO configurations to test against the literature. Both parts of the synthesis are part of a larger project [ref redacted] examining seven *XX* projects implemented in metropolitan, remote and regional-based hospitals across New South Wales (NSW), Australia between 2016 and 2018.[ref redacted] These projects are based on a value-based care paradigm and address unwarranted clinical variation, and preventable hospitalisations across seven high impact conditions.[ref redacted]

Methods

We followed the Reporting Standards for realist syntheses recommended by the RAMESES group.[19] We used a combination of academic database and grey literature searches, data extraction and fortnightly research team discussions to collate evidence for the synthesis. Throughout the work, research team discussions around data extraction and interpretation were informed by ongoing discussions with partners at the NSW Ministry of Health, Agency for Clinical Innovation and Bureau of Health Information who were experienced in design and implementation of large-scale hospital initiatives, and colleagues from XXX University's Centre for the Health Economy. All searches were conducted between March and August 2020. Table 1 shows the four iterative steps of our method.

Step 1: Conceptualising large-scale hospital interventions

The first step towards generating initial program theories in a realist synthesis is to identify the key concepts of the topic of interest. Concepts are tightly linked to program theories as they help to understand where key mechanisms leading to expected outcomes are likely to occur.[18] Here, we identified and defined key concepts associated with the implementation of large-scale hospital initiatives by exploring the focal stakeholder cohort, arena of action, social processes, intended outcomes, and the nature of support for the program.

This step drew data from three sources: the research team's knowledge, expert consultation, and a published literature search across three iterative stages. First we built a list of concepts and associated features characterising implementation programs for large-scale hospital interventions from key articles, [e.g., 1] our own research, and clinical experience (JL, MS, EFA, CP are all health services researchers; JL and MS also have a clinical background). This list was verified and expanded through ongoing discussions with partners at the NSW Ministry of Health and Agency of Clinical Innovation and the Bureau of Health Information. Next we examined the published literature

for evidence to support or refute our list and to look for other concepts and features we had not considered. We searched Medline, PubMed, Embase and CINAHL, using the search string: *health AND ((((implementation OR driver) OR change) AND large-scale) AND ((innovation OR intervention) OR program))*. No date limits were set. We snowballed papers from the reference lists, added known key papers not captured by the search, and included individual studies reported in reviews. We assessed whether each of the concepts and features on our list were supported by the literature, noting each as being reported "always", "nearly always," "often," "sometimes", "rarely" or "not at all".

[**INSERT TABLE 1 HERE]**

Using an iterative approach, we refined our definition of large-scale hospital interventions as we built up the list of associated concepts and features. Finally, antecedents and intended outcomes of the features as a whole and individually were developed and considered to further explore possible mechanisms that may be relevant. Articles that we included involved implementation across multiple hospital sites for interventions aimed at improving patient safety or quality of care. We did not include programs situated outside the hospital setting (e.g., implemented solely in community-based health services), interventions at only one site, locally driven interventions (e.g., internally developed, ward-based improvements) or tightly controlled research trials that were not considered "real world interventions" (e.g., randomised controlled trials). We did consider pragmatic trials if they met other parts of our definition. A data extraction sheet was used to organise concepts described in the papers found. Papers not reporting implementation strategies or activities were not included.

Step 2: Scoping suites of implementation strategies

Our next task was to identify and collate all implementation strategies that were reported as part of these types of large-scale interventions. Together with the concepts and features of the

initiatives found in Step 1, this list of strategies and any information reported on how they were intended to work, were needed to understand possible contexts and mechanisms leading to outcomes.

We started our search for implementation strategies with the papers found in Step 1. Next we scanned papers found in an existing systematic review of implementation strategies used in hospital avoidance interventions for people with chronic conditions, choosing projects that met our large-scale, multi-site criteria.[20] We also searched more broadly for systematic reviews looking at implementation strategies targeting other cohorts of patients (Web of Science: "implementation" AND "systematic review"). We included protocol papers hoping these might provide a fuller rationale for their choice of strategies. We also included selected grey literature from a targeted search of implementation materials from agencies known to actively support large-scale implementation programs: United Kingdom's National Health Service, Canada's Advance Care Planning, NSW Agency for Clinical Innovation, Australian Medical Research Council, Enhanced Recovery After Surgery Society, and World Health Organization. We set up a data extraction matrix, recording reported implementation strategies for each project. We also ran a Google search on 'implementation guide' and 'implementation healthcare guides.' Implementation strategies were collated and reviewed in each source.

Initially, we used our own descriptors for the strategies, but then aggregated similar strategies and mapped them to the Expert Recommendations for Implementing Change (ERIC)[9] taxonomy of 68 implementation strategies. Any strategies that did not map to an ERIC strategy were still included but noted.

Step 3: Identifying potential initial program theories

In this next step, the research team workshopped ideas towards identifying potential initial program theories[18] by considering all the data generated so far in the project as well as searching published literature around known formal theories; in particular, we examined together the

concepts identified in Step 1 and the implementation strategies identified in Step 2. That is, we considered what existing formal theories or types of theories might be relevant to explain particular implementation strategies given the concepts and putative mechanisms we had identified. For example, an implementation strategy of *conducting a local needs assessment*, fitted with the concept of *facilitation through provision of resources* and the feature *ensuring a formal period of planning.* Organisational Readiness Theory was identified as a formal theory that promised to explain how this implementation strategy of *conducting a local needs assessment* would work across different contexts. These formal theories became the basis for our initial program theories and were matched with implementation strategies using this process. The initial program theories were general enough to describe what was happening, how and why across a range of contexts, and a range of levels (micro, meso and macro).

Step 4: Further scoping and focus on a key strategy

As realist syntheses aim to explain how and why a program works and have the potential to generate vast amounts of data to do this well, it was necessary to carefully scope the results generated and narrow our focus. Following the example of other realist syntheses,[18,21-23] we looked for a single set of implementation strategies and their accompanying initial program theory that (a) was deemed highly important in informing our parallel tranche of work - the realist evaluation of the *Leading Better Value Care* projects in NSW, Australia - and (b) had not already been researched using realist methodology.

Results

Results of the activities used to synthesise evidence and generate initial program theories that explain how implementation strategies work in large-scale hospital interventions are outlined below. The process was driven by the fortnightly research team meetings and iterative refinements. Table 2 summarises the results from the four steps.

Concepts associated with large-scale hospital intervention implementation programs (Step 1)

The research team initially listed 5 concepts associated with 12 features of large-scale hospital interventions, which grew to a final set of 16 features after further scoping of the literature. Over 400 titles and abstracts were accessed via database searching and data were extracted from a subset of 51 full text articles that met our definition. Table 2 summarises results of Step 1 and Supplementary File 1 shows the full data extraction sheets.

[**INSERT TABLE 2 HERE]**

The five concepts of large-scale hospital improvement initiatives were: (i) External, top-down source, (ii) Evidence-based interventions, (iii) Safety and quality focus, (iv) Facilitation through provision of resources, and (v) Harnessing of local resources and encouraging adaptation. Between two and four features of each were identified.

External, top-down source: Features found associated with this concept were that the interventions being implemented were externally developed: either by peak agencies or research institutes (e.g., WHO,[24] American College of Surgeons[25]), quality collaboratives (e.g., Michigan Surgical Quality Collaborative,[26] German Quality Network[27]), or in one case, mandated, evidence-informed policy (e.g., US Veterans' Affairs (VA) National Disclosure Policy[28]). Support for implementation for the intervention itself was frequently built into this package by the external source: interventions were often presented as a "bundle" of interventions all aimed at addressing a single issue (e.g., surgical site infections,[29] treatment of blunt chest injury[30]). Checklists and implementation guides may also be provided by the external agency that developed the intervention. Contrary to our expectations, the offer of incentives or disincentives for implementation was rarely reported.

Evidence-based interventions: All interventions were identified by the authors as being evidence-based, although the evidence (e.g., the randomised control trial on which the intervention was built) itself was rarely cited. Contrary to the expectations of our research team, de-implementation of processes and practices that presumably were no longer "best practice" was rarely reported. This applied even to upgraded Information Technology systems where legacy systems were allowed to remain alongside the new programs.[31]

Safety and quality focus: A clear aim of improving patient outcomes was consistently found, often by making a case for change from baseline data. Implicit in most programs was the assumption that a positive safety culture, that saw improvement of patient outcomes as core business was present at the site. Also implicit was that there was consensus at each site that the intervention was needed, and that the implementation support provided would be acceptable.

Facilitation through provision of resources: As well as implementation guides and intervention resources, external support was seen in many projects in the form of new equipment, customised forms for documentation, and care pathways. Project officers skilled in the intervention and tasked with data collection or training were funded in some projects, often budgeted as part of an associated research component (e.g.,[32]). Partnership agreements with external agencies facilitated implementation by providing access to specialist advice. Funding for the projects was often a mix of external (e.g., VA (USA)[28]), internal (e.g., Hornsby Ku-ring-gai District Hospital (Australia)[32]), and research-based (e.g., National Institutes of Health grants (USA)[33]). Facilitation was not always a feature. All studies relied on the goodwill of clinicians, and some did not factor in any quarantined time for implementation activities such as audits. Interventions developed by clinical collaboratives were often framed as partnerships, including access to practical support and expert advice (in-kind) for the implementation and monitoring of outcomes, some allowing dissemination of learnings from other sites, and benchmarking. Data was often provided to make a case for change, and support for ongoing audit and feedback were common features.

Harnessing local resources and encouraging adaptation: The provision of a lead-in time for each site to assess for readiness and local needs was sometimes reported, and internal support for implementation from senior management was reported in most papers. Design amenable to adaptation to fit different local practices, patient cohorts or workflows, developed by clinically based implementation teams, was also frequently reported. Clinical leadership, mentoring, supervision and in-house education were also key features.

Following this, features were refined by determining their antecedents and intended outcomes, to help with the next step of defining associated implementation strategies, mechanisms and potential initial program theories. Supplementary File 2 shows the results of this step.

Collated suites of implementation strategies (Step 2)

We found 302 reports of 28 different implementation strategies associated with large-scale hospital interventions from 45 peer-reviewed papers and five sets of grey literature documents (each linked to a single website). All of the strategies except one mapped to one or a combination of strategies in the ERIC taxonomy.[9] The strategy that did not map was *Aligned with organisational/ District and Departmental priorities*. Some strategies that were similar were combined as descriptions in the articles were not sufficient to determine exact details (e.g., *Involve executive boards* was combined with *obtain formal commitments* as it was often the executive group which was negotiating on behalf of the site. The 28 strategies are summarised in Table 3 and shown in full in Supplementary File 3. Most frequently reported or recommended strategies were: *Promote adaptability/purposely re-examine the implementation* (n=34); *Involve executive boards/obtain formal commitments* (n=24); and *Assess for readiness and identify barriers and facilitators* (n=24).

[**INSERT TABLE 3 HERE]**

Identify potential initial program theories (Step 3)

The research team workshop started by considering both the concepts and features from Step 1 and the strategies from Step 2 to identify high level domains in which our potential initial program theories and their underlying mechanisms would be expected to work. Four of these domains were identified: social processes and influences; assessment and planning; accessing resources; and partnering outside the organisation. Domains were not seen as mutually exclusive but connected and interdependent. A list of formal theories that addressed these domains was compiled through researcher knowledge and discussion, searching other published realist studies, literature on program theories, and online searches. Five formal theories that explained in a very broad sense, how various strategies might be expected to work were selected through discussion. The theories that were selected were: Organisational Readiness Theory, Social Cognitive Theory, Partnership Synergy Theory, Diffusion of Innovation, and the Theory of Planned Behaviour. Table 4 summarises the selected formal theories. Table 5 shows the strategies, concepts, domains and their matched theories.

[INSERT TABLE 4 HERE]

CMO statements from the Organisational Readiness Theory (Step 4)

Weiner defines organisational readiness as multi-level and multi-faceted construct referring to an organisational members' shared commitment to change - encompassing both willingness and capacity.[34] This readiness for change is crucial in producing collective engagement; that is achieving buy in and commitment from those at the front lines enacting the change. This engagement results in valuable implementation outcomes: a collective commitment to initiate change, greater effort to make the change successful, greater perseverance when barriers are encountered and an increase in pro-social collaborative behaviours that promote the change.[34] Holt, Amenakis and colleagues,[39] state the most potent mechanisms were shared perceptions and beliefs among stakeholders in the organisation that (a) they are capable of implementing the proposed change (i.e., *change-specific*

efficacy), (b) the proposed change is appropriate for the organisation (i.e., *appropriateness*), (c) leaders are committed to the proposed change (i.e., *management support*), and (d) the proposed change is beneficial to organisational members (i.e., *personal valence*). Perceptions about resources are considered the active means to achieve readiness rather than the resources themselves.[34]

In an iterative process undertaken by the research team, CMOs were configured, to understand what circumstances (context) needed to be present in an implementation strategy to trigger an identified mechanism leading to an outcome. Since many of the strategies overlapped in their mechanisms and outcomes, we considered them both together and separately. We limited our enquiry to how the mechanisms worked on the implementers within an organisation; i.e., the people delivering the intervention directly to patients, rather than the designers or facilitators of the intervention. The outcomes associated with the Theory of Organisational Readiness were all around engagement, buy-in and commitment to the change.

At the same time as the CMO statements were being configured, articles that reported enough detail on these strategies were reviewed for evidence. A further search specifically for implementation projects across multiple sites that reported using organisational readiness theory was also performed, yielding another three papers. The final column of Table 6 indicates the articles that give evidence to support or not support the CMO configurations.

[**INSERT TABLE 5 HERE]**

[INSERT TABLE 6 HERE]

Discussion

In this realist review of implementation strategies for large-scale hospital interventions we have used a four-step process to build a clearer picture of the nature and purpose of implementation and identify likely mechanisms driving intended and unintended outcomes. In the final step we focussed on early implementation strategies around baseline assessment and planning to define and test CMO statements explaining outcomes.

In Step 1, we articulated the key concepts associated with implementation programs of large-scale hospital interventions. Providing practical and social support figured prominently, as did establishing credibility, level of evidence and intended outcomes of the intervention through clear blueprints and collaborative learning and planning activities. While many of the interventions themselves were prescriptive (e.g., surgical checklists[10-12]), the need for implementation to include local needs assessments and tailored activities was also clear. In Step 2, we identified suites of implementation strategies for large-scale hospital interventions and found them to be multifaceted, directed at both individual and organisational levels, and often interdependent. For example, while nearly all the large-scale projects reported education and local leadership, these would only be successful as strategies if they were combined with executive support for the project, and a collective sense of the need for change. It can be argued that the precursor to all implementation strategies is the engagement of the implementers, as without their commitment to change, no substantive change can be achieved. The choice to use Organisational Readiness Theory to further develop the initial program theories was prompted by this observation.

Organisational Readiness Theory postulates that engagement and commitment to any proposed change will be strongly influenced by individual and collective perceptions around the need for the intervention, its quality and effectiveness, the level of support from management and executive that is apparent, and the feasibility of using it. Support for the hypothesised CMOs was

found across multiple projects providing strong evidence of the theory's applicability in large-scale hospital interventions.

Evidence found in our set of literature almost all supported CMOs that led to positive, desirable implementation outcomes of engagement and commitment. There was some refuting evidence that pointed to the interdependence of some factors, and that at times one contextual factor could interact and outweigh another. For example, Wyld and colleagues found that although all stakeholders involved with a new biobank highly valued the initiative, doctors tasked with collecting the samples felt early consultation, management support and consideration of the feasibility for them had been lacking.[49] In spite of this, the implementation of the program had been successful with almost universal adherence to the new processes by the doctors. Possibly, the patients' altruistic enthusiasm for the initiative, that was often voiced to the doctors during the informed consent process may have put greater value on the initiative, outweighing the doctors' difficulty.

Evidence for contextual factors that triggered mechanisms leading to poorer outcomes were also found. Bayley and colleagues note the mismatch in perceptions of feasibility found between managers and implementers, and between different healthcare professionals contributing to the multidisciplinary team effort of implementing stroke rehabilitation guidelines.[45] This same project found that perceptions of feasibility were also negatively affected by overly complicated statements of the intervention and called for a "plain English" version that would be more accessible for busy clinicians. Both contextual factors were considered barriers as this collective perception of lack of support and lack of feasibility triggered disengagement and lack of commitment to the change.

Some authors, lacking high quality evidence, suggested the cause of poor implementation outcomes might be linked to contextual factors. For example, Reames and colleagues suggest that the failure of their large-scale hospital intervention to effect change might be because it required staff to follow processes that were not strongly associated with clear patient improvements.[42] This

perception of lack of effectiveness would not trigger the mechanism of building a tension for change, but complacency leading to poor adoption of the intervention. Wand and colleagues found that disagreement voiced by a senior clinician in the early planning stages of an intervention was likely to adversely affect the project's success unless it could be resolved.[43] Here the perception of implementers would be that the intervention was not feasible or appropriate, and trigger disengagement. While these examples do not claim to be high level evidence, but rather the informed opinion of the authors, they are intuitively correct and consistent with the other evidence found in this study.

Strengths and Limitations

Our search for literature was systematic and thorough yet only resulted in 50 papers. This was because while large-scale hospital interventions abound, implementation activities and outcomes are not commonly reported.[56] This meant many articles reporting interventions were not relevant to the present study. Even for papers reporting implementation, reporting of these strategies and the contexts in which they were used was often not detailed enough to develop theories. Articles that were found were mostly reporting successful implementations and this is an acknowledged bias of published literature. While CMOs are useful in explaining single factors, multiple contextual factors may arise that modify how mechanisms work. Lack of detail in reporting meant the O (outcomes) in our CMO configurations were high level and dichotomous: implementers were engaged or implementers were not engaged. Strengths included the expertise of the research team (including clinical and implementation science expertise) and the systematic four step iterative investigation.

Conclusions

Large-scale hospital interventions hold the promise of standardising high quality, evidence-based care for large numbers of patients but must be supported with appropriate implementation

strategies to support and effect change. The study has used realist methodology to tease out how initial planning activities can drive engagement and commitment and delineate the contextual factors required to trigger mechanisms. These findings, using *Organisational Readiness Theory*, will add to understandings around why large-scale projects work some of the time but not all of the time. Evidence has been presented around a set of CMO hypotheses, showing the importance of implementers' perceptions around feasibility, support, and value in triggering engagement and commitment to the proposed change.

Abbreviations

CMO Context Mechanism Outcome

ERIC Expert Recommendations for Implementing Change

NSW New South Wales

Declarations

Ethics approval

Not applicable – using publicly available data.

Consent to participate

Not applicable as there were no participants.

Patient and public involvement

Not applicable as this was a review of the literature.

Consent for publication

Not applicable.

Availability of data and materials

All data generated or analysed during this study are included in this published article [and its supplementary information files].

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

JCL conceptualised the synthesis, and JCL, CP, HMN, MS, EFA and RH contributed to the overall design. JCL, CP and HMN conducted the database search, article screening and data extraction. JCL conducted the synthesis and drafted the first manuscript. MS, EFA, RH and JB contributed to the final versions of the manuscript. All authors read and approved the manuscript.

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Step	Purpose	Research Questions	Activities
1	To conceptualise implementation of large-scale hospital interventions	What are the key concepts and features of large-scale hospital initiatives and their implementation? What mechanisms might these suggest are key to driving the program?	Build an initial list of concepts and associated features based on research team's research and clinical experience Add to the list through a search of published literature on implementation of large-scale hospital interventions Consider antecedents and outcomes of each feature to identify putative relevant mechanisms
2	To scope suites of implementation strategies used with large-scale hospital interventions	What implementation strategies are used for large-scale hospital initiatives? How do they fit with Step 1? What do they tell us about possible mechanisms, contexts and the underlying program theories?	Collation of implementation strategies extracted from Step 1 literature Search of additional published literature including extracted studies from systematic reviews Grey literature search: targeted websites and search terms Strategies aggregated and sorted then mapped to ERIC implementation strategies
3	Identify potential initial	What formal theories might explain the	Identification of formal theories from the published literature. Consideration of theories in the context of implementation strategies we have listed

	program theories	mechanisms of action for the strategies listed?	Refinement of the initial program theory-implementation strategy pairing through research team workshops using all data generated from the project
4	Focus on a promising implementation strategy-theory pairing and development of CMOs.	What context-mechanism-outcome configurations can we develop and test with the literature around implementation strategies linked to Organisational Readiness Theory?	Research team workshop to develop initial CMO statements Testing and refinement of CMO statements through review of literature from Steps 1-3 Final iterations of CMOs

Table 1: The four iterative steps used to search, find, extract and synthesise evidence to generate initial program theories that explain how implementation strategies work in large-scale hospital interventions. (CMO = context, mechanism, outcome configurations)

Step	Purpose	Activity	Interim results	Final result
1	To conceptualise implementation of large-scale hospital interventions	Build an initial list of concepts and associated features based on research team's research and clinical experience. Search databases for implementation of large-scale hospital interventions, screen title and abstract for relevance, data extraction.	5 concepts and 12 features listed 381 articles found. 51 relevant articles 4 additional features identified from the literature	5 concepts and 16 features identified and described.
2	To scope suites of implementation strategies used with large-scale hospital interventions	Extracted data from Step 1 literature that report implementation strategies Search for published literature on implementation and screen for large-scale hospital criteria. Include known literature. Individual studies extracted from reviews Search of targeted websites and other grey literature	45 articles 585 reviews found: 31 found to include relevant studies some reporting on multiple implementation strategies Data extracted from 5 sets of documents	302 reports of 28 different implementation strategies identified and collated

		Strategies aggregated and sorted then mapped to ERIC implementation strategies		28 implementation strategies mapped to ERIC taxonomy, 1 did not map
3	Identify potential initial program theory areas	Identification of potential initial program theories using all data generated from the project so far plus other realist studies, compilations of program theories and literature describing individual formal theories	3 broad domains of action identified	5 initial program theories mapped to implementation strategies
4	Focus on a promising implementation strategy-theory pairing and development of CMOs	Research team workshop to develop initial CMO statements informed by Organisational Readiness Theory Testing and refinement of CMO statements through review of literature from Steps 1-3 Final iterations of CMOs	All data collected so far 51 articles + 3 articles that focused on organisational readiness assessment	

Table 2: Summary of search strategy, activities and results at each of the four steps. (ERIC = Expert Recommendations for Implementing Change; CMO = context, mechanism, outcome statements).

ERIC taxonomy ERIC, [9]	Implementation strategy	Frequency (n=50 sources)
Access new funding	Extra staffing as needed; salary support	6
Assess for readiness and identify barriers and facilitators	Readiness	24
Audit and provide feedback	Audit and Feedback	11
Build a coalition; create new clinical teams; create a learning collaborative	Multidisciplinary involvement; clinical leadership	16
Capture and share local knowledge	Community of practice / knowledge network of clinicians	11
Change physical structure and equipment (a)	Funding for equipment	6
Change physical structure and equipment (b)	Tools to improve communication	4
Conduct cyclical small tests of change	PDSA Cycles	5
Conduct local consensus discussions; Facilitator	Local facilitator / project officer	10
Conduct local needs assessment	Identify resources required	12
Create a learning collaborative	Engaging stakeholders	7
Develop a formal implementation blueprint (a)	Implementation guides	14
Develop a formal implementation blueprint (b)	Intervention Toolkit	10
Develop academic partnerships; use an implementation advisor; use advisory boards and workgroups	Support from external experts/ external support	14
Develop and implement tools for quality monitoring	Monitoring	6

Develop educational materials; distribute educational materials	Education	18
Develop resource sharing agreements	Resources shared	1
Distribute educational materials	Clinical practice guidelines	8
Facilitation	Problem solving	2
Identify and prepare champions	Champion	4
Inform local opinion leaders	Opinion leaders	7
Involve executive boards; Obtain formal commitments	Executive sponsorship/engagement with the state-wide collective	24
Organise clinician implementation team meetings	Quarantined time for skill acquisition	4
Promote adaptability; purposely re-examine the implementation	Local adaptation	34
Provide clinical supervision	Mentoring/ Supervision/ coaching	16
Recruit, designate, and train for leadership	Clinical leadership	10
Use data experts	IT and communication support for new processes	6
(No ERIC equivalent)	Align with organisational/ District or Departmental priorities	12
Total		302

Table 3: List of implementation strategies and their frequency, found in the set of 50 grey and black literature documents. (ERIC= Expert Recommendations for Implementing Change)

Theory	Overview (sources)
Organisational Readiness Theory	Readiness for change refers to organisational members' shared resolve to implement a change (change commitment) and shared belief in their collective capability to do so (change efficacy).[34]
Social Cognitive Theory	Behaviour is influenced by three mechanisms operating in concert: direct personal agency; proxy agency that relies on others to act on one's behalf to attain the desired goals; and collective agency where the larger group acts.[35]
Partnership Synergy Theory	Partners who effectively collaborate and share knowledge, skills and perspectives are able to achieve more value than the sum of the individual parts contributed.[36]
Diffusion of Innovation	Explains how an innovation, new idea, or product spreads, mediated by social processes within a population over time. A slow start by innovators and early adopters demonstrates the innovation in practice, increasing confidence. A tipping point is reached after a time when the majority take up the new practice. A small group of conservative and risk aversive "laggards" will be the last to adopt.[37]
Theory of Planned Behaviour	Three independent constructs determine a person's intention to perform a specific behaviour: "attitude" refers to how positively or negatively a person perceives the behaviour; "social norm" refers to the perceived pressure from others to perform the behaviour; "perceived behaviour control" relates to how easy or difficult the person thinks it will be to perform the behaviour.[38]

Table 4: Summaries of formal theories selected as potential initial program theories to explain mechanisms across different contexts of the implementation strategies identified.

ERIC strategy	Domain	Associated concepts (bold) and intended outcomes	Associated initial program theories
Develop a formal implementation blueprint	Baseline assessment and planning	**Clear implementation plan or blueprint for change** **Clear aim of improving patient outcomes:** Clear communication of expectations across sites; tool for planning changes **Provide support for comparison across sites implementing the intervention**	*Social Cognitive Theory*
Conduct cyclical small tests of change	Ongoing assessment	**Designed with adaptation to local settings in mind:** Incremental changes easier than multifaceted ones	*Social Cognitive Theory*
Promote adaptability; purposely re-examine the implementation	Ongoing assessment	**Designed with adaptation to local settings in mind:** Negotiation, needs assessment, ownership of change	*Social Cognitive Theory*
Build a coalition; create new clinical teams	Partnering	**Facilitate access to reputable advice and problem-solving assistance:** Inclusion, trust, common goal, breadth of expertise	*Partnership Synergy Theory*
Develop academic partnerships; use an implementation advisor; use advisory boards and workgroups	Partnering	**Facilitate access to reputable advice and problem-solving assistance:** Breadth of expertise, social support	*Partnership synergy theory*

Align with other priorities	Social processes	**Formal period of planning and needs assessment**: Assess the fit with current workflow, personal and organisational goals aligned	*Organisational Readiness Theory* *Social Cognitive Theory*
Conduct local needs assessment	Baseline assessment and planning	**Formal period of planning and needs assessment**: Assessing readiness; understanding implications of change on workflow and practice **Designed with adaptation to local settings in mind**	*Organisational Readiness Theory*
Assess for readiness and identify barriers and facilitators	Baseline assessment and planning	**Formal period of planning and needs assessment**: Setting up conditions that support change	*Organisational Readiness Theory*
Change physical structure and equipment	Accessing resources	**Provide or facilitate practical support in the form of resources and equipment**: Aligning structure with process	*Partnership Synergy Theory*
Use data experts	Partnering	**Provide data support for new or changed IT systems, baseline audits and ongoing monitoring:** Partnership with experts to support change	*Partnership Synergy Theory*
Develop resource sharing agreements	Partnering	**Provide or facilitate practical support in the form of resources and equipment**: Working with others to effect change	*Partnership Synergy Theory*
Develop educational materials	Baseline assessment and planning	**Formal period of planning and needs assessment**: Setting up educational support / conditions that support change	*Organisational Readiness Theory*

Distribute educational materials	Accessing resources	**Provide practical support in the form of education and skill acquisition:** Knowledge and skill acquisition, increase in personal and collective competence and confidence	*Social Cognitive Theory*
Provide clinical supervision	Social processes and influences	**Provide practical support in the form of education and skill acquisition:** Social support, role modelling, and practice of new behaviours **Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions**	*Social Cognitive Theory*
Access new funding	Accessing resources	**Provide practical support in the form of resources and equipment**: Setting up conditions that support change	*Partnership Synergy Theory*
Create a learning collaborative	Social processes	**Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:** Social influences supporting change and learning	*Diffusion of innovation* *Organisational Readiness Theory*
Facilitation	Social processes	**Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:** Breadth of expertise, social support	*Diffusion of innovation*

Identify and prepare champions; inform local opinion leaders	Social processes	**Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:** Social influence supporting change	*Diffusion of innovation* *Organisational Readiness Theory*
Involve executive boards; Obtain formal commitments	Social processes	**Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:** Trust, social support, legitimacy, accountability	*Social Cognitive Theory* *Diffusion of Innovation* *Organisational Readiness Theory*
Recruit, designate, and train for leadership	Social processes	**Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:** Social influence supporting change **Provide or facilitate practical support in the form of education and skill acquisition:**	*Social Cognitive Theory* *Diffusion of innovation*
Organize clinician implementation team meetings	Social processes	**Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:** Social influence supporting change, setting common goals and expectations	*Organisational Readiness Theory* *Theory of Planned Behaviour*
Conduct local consensus discussions	Social processes	**Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:** Social	*Organisational Readiness Theory* *Partnership Synergy Theory* *Theory of Planned Behaviour*

		influence supporting the setting of clear objectives, building local trust, planning **Designed with adaptation to local settings in mind**	
Audit and provide feedback	Baseline assessment and planning Ongoing assessment	**Formal period of planning and needs assessment**: Setting up tension for change **Provide support for comparison across sites implementing the intervention:** Standardised collection of data sets up a tension for change, diagnoses areas for individual sites to work on, and tracks progress locally and across sites	*Organisational Readiness Theory*
Capture and share local knowledge	Social processes	**Support for comparison across sites implementing the intervention:** Increase the breadth of expertise, social support	*Social Cognitive Theory*
Develop and implement tools for quality monitoring	Baseline assessment and planning Ongoing assessment	**Support for implementation built into intervention**: Setting up conditions that foster change and decrease participant effort **Provide support for comparison across sites implementing the intervention**	*Organisational Readiness Theory*

Table 5: Theory areas associated with implementation strategies

Implementation strategy (ERIC wording)	**Context**	**Mechanism**	**Outcome**	**Component of Organisational Readiness Theory**	**Evidence from the literature on large-scale hospital projects**
Baseline audit results shared with implementers (Audit and provide feedback)	When implementers see their baseline audit results and perceive that current practice is not optimal	…a tension for change is developed leading to	… members being more likely to engage in the project	Appropriateness Personal valence	Support[10,40]
Clear evidence provided on effectiveness of intervention (Audit and provide feedback)	When implementers see clear evidence that the intervention is effective and will improve patient care When implementers do not see clear evidence of the	… implementers value the change	… members are more likely to engage in the project	Appropriateness Personal valence Appropriateness Personal valence	Support[41]

	effectiveness of the intervention / do not see the link with improved outcomes for patients	… implementers do not value the change	… members are less likely to engage in the project		Limited support[42,43]
Sharing the positive experience of early adopters of the intervention (Create a learning collaborative)	When implementers are told of the success of early adopters at other sites	…a tension for change is developed and perceptions of feasibility at their own site will improve leading to	… members being more likely to engage in the project	Appropriateness Personal valence	Support[44]
A lead-in period is provided when local needs are assessed (Conduct local needs assessment)	When local needs of implementers are assessed before any proposed change	… confidence in capability rises, resulting in greater levels of commitment and collaboration	… resulting in more effective implementation	Appropriateness Change-specific efficacy	Support [10,30,45-48] Not supported[49] Support[45]

	When local needs are not accurately assessed (e.g., time needed for new practice underestimated)	… confidence in capability falls, resulting in poorer levels of commitment and collaboration	… resulting in poor adoption and outcomes		
Executive and management are engaged and support the intervention (Involve executive boards; Obtain formal commitments)	Executive /management support that is visible to the implementers Commitment to support the change from executive level is communicated to implementers Executive /management support is inadequate or not visible to the implementers Executive /management support is inadequate or	… increases perceptions of feasibility and organisational capacity … increases perceptions of feasibility and organisational capacity … decreases perceptions of feasibility and value of the change	… resulting in increased engagement … resulting in increased engagement … resulting in lack of engagement	Management support	Support[10,48,50-52] Support[27,41,46-48] Support[31,45] Supported[53]

	distant, but local or within team leadership is seen as strong and autonomous Executive /management support is inadequate, but local or within team leadership is seen as strong Executive /management support is inadequate, and local or within team leadership is also inadequate/ non participatory	… does not decrease perceptions of feasibility and value of the change … increases perceptions of siloed change, decreasing perceptions of feasibility … decreases perceptions of feasibility and value of the change	... and does not impact intention to commit … resulting in lower staff buy-in and commitment … resulting in lack of engagement		Supported[52] Supported[52]

Support from external agencies / peak bodies for the intervention (Develop academic partnerships; use an implementation advisor; use advisory boards and workgroups)	When external support and/or endorsement of the proposed change is present	implementers may value the change more favourably or feel a greater tension for change	…resulting in increased engagement and commitment	Appropriateness	Support[10,26,41,46,50,54]
Clear and consistent communication with identified /designated leaders of the intervention (Identify and prepare champions; Recruit, designate, and train for leadership)	Consistent messages and actions from leaders, opinion leaders and champions Mixed or missed information from leaders, opinion leaders and champions	… increase perceptions of organisational capacity … decrease perceptions of organisational capacity and disempowerment	… resulting in more effective engagement … resulting in poorer engagement	Management support Appropriateness	Support[46,54] Support[45]

Align intervention with other organisational priorities	When the proposed change aligns with other organisational or national priorities When the proposed change is part of a collaborative effort across multiple sites	… implementers may value the change more favourably and see their efforts as contributing to a larger, more significant program … stakeholders' perceptions of the value of the change may increase	… resulting in more effective engagement … resulting in greater commitment	Personal valence Appropriateness	Support[41,54] Support[26,27,41,55]
Align with known concerns/priorities of implementers	When the proposed change aligns with the personal priorities of implementers	…the change is valued more highly by implementers	… resulting in more effective engagement	Personal valence	Support[31,47]
Provide opportunities for formal and informal planning and knowledge	When there is appropriate and timely information sharing	… may increase collective vision and purpose	… resulting in greater engagement and persistence		Support[10,40,45,47,48,54]

exchange around the intervention (Create a learning collaborative; Capture and share local knowledge)	through social interaction, and shared experience				
Providing appropriate education (Develop educational materials)	Development of educational packages appropriately pitched at key implementers Development of educational packages not tailored to specific group's knowledge base perceived as inappropriate	…… increase perceptions of feasibility and organisational capacity … decreases perceptions of capability	… members are more likely to engage in the project …members are less likely to engage or commit to the project	Change-specific efficacy	Support[30,40,47,54,55] Support[45]
Providing appropriate implementation support	Provision or preparation of implementation blueprints or plans	…… increase perceptions of feasibility and organisational capacity	… members are more likely to engage in the project	Change-specific efficacy	Support[30]

(Facilitation: Develop a formal implementation blueprint)					
Appealing to past successes	In spite of previous successes and capabilities, if local needs and capabilities are not considered adequate by those enacting this specific change proposed ….	… collective capability will be seen as deficient	… levels of commitment will be poor	Change-specific efficacy	No evidence found

Table 6: Context-Mechanism-Outcome configurations for implementation strategies aligning with Organisational Readiness Theory. The broad context is for individual and collective implementers of large-scale hospital interventions.

Reference	Year	Country
Allegranzi B, Aiken AM, Zeyne	2018	Kenya, Uganda, Zimb
Bayley MT, Hurdowar A, Richa	2012	Canada
Borchert M, Goufodji S, Alihor	2012	Benin, W Africa
Brink AJ, Messina AP, Maslo C	2020	South Africa
Cameron M, Jones S, Adedeji (	2015	UK
Cima R, Dankbar E, Lovely J, P	2013	USA
Cresswell K, Morrison Z, Crow	2011	UK
Cuypers M, Al-Itejawi HHM, va	2019	Netherlands
de Groot JJ, Maessen JM, Slan	2015	Netherlands
Dekker-van Doorn C, Wauben	2020	Netherlands
Dumont, A., P. Fournier, M. Ab	2013	Senegal and Mali
Edward, K. L., K. Walker and J.	2017	Australia
Forchuk, C., M. L. Martin, E. Je	2013	Canada
Foy, R., G. C. Penney, J. M. Gri	2004	Scotland
Fuller, C., S. Michie, J. Savage,	2012	England and Wales
Grazioli, V. S., J. C. Moullin, M.	2019	Switzerland
Havers, S. M., P. L. Russo, K. Pa	2019	Australia
Haynes, A. B., L. Edmondson, S	2017	USA

Hendy, J., N. Fulop, B. C. Reev	2007	UK
Keller, H. H., R. Valaitis, C. V. L	2019	Canada
Kotagal, U. R., J. M. Robbins, N	2002	USA
Kourouche, S., T. Buckley, C. V	2019	Australia
Luxton et al 2014, Caring lette	2014	USA
Maguire et al 2016, Evaluating	2016	USA
Makene, et al 2014 Improvem	2014	Africa
Mansoori et al 2012 Picture Ar	2012	USA
Marcus RK, Lillemoe HA, Rice I	2019	USA
McCreight MS, Lambert-Kerzn	2019	USA
McFarland MS, Thomas AM, Y	2020	USA
McNeely J, Troxel AB, Kunins H	2019	USA
Merry AF, Gargiulo DA, Bissett	2019	New Zealamd
Molina G, Jiang W, Edmondso	2016	USA
Monico LB, Oros M, Smith S, M	2020	USA
Moore, J. E., A. Mascarenhas,	2014	Canada
Morrow, E., G. Robert, J. Mabe	2012	UK
Mudge, A. M., M. D. Banks, A.	2017	Australia

Nocera, M., M. Shanahan, R. A	2016	USA
Palomar, M., F. Alvarez-Lerma	2013	Spain
Pronovost, P. (2008). "Interver	2008	USA
Pronovost, P., D. Needham, S.	2006	USA
Pun, B. T., S. M. Gordon, J. F. P	2005	USA
Reames BN, Krell RW, Campbell DA Jr, Dimick JB. A checklist-based intervention to improve surgical outcomes in Michigan: evaluation of the keystone surgery program. JAMA Surg. 2015;150:208–15	2015	USA
Schwarzkopf, D., H. Ruddel, M	2018	Germany
Schweizer, M. L., H. Y. Chiang,	2015	USA
Stolldorf, D. P., J. L. Schnipper,	2019	USA
Terkola R, Czejka M, Berube J.	2017	Europe
Toltzis, P., M. O'Riordan, D. J.	2014	USA
van Harten WH, Goedbloed N,	2018	Netherlands

Vu JV, Collins SD, Seese E, Hendren S, Englesbe MJ, Campbell DA, Krapohl GL. Evidence that a regional surgical collaborative can transform care: surgical site infection prevention practices for colectomy in Michigan. J Am Coll Surg. 2018;226(Epub 2017):91–9.)	2018	USA
Wand, T., C. Crawford, N. Bell,	2019	Australia
Wyld, L., S. Smith, N. J. Hawkir	2014	Australia

Additional papers using Organistional Readiness Theory

Zapka, J., K. Simpson, L. Hiott,	2013	USA
Sharma, N., J. Herrnschmidt, V	2018	Switzerland
Rees, G. H. (2014). "Organisati	2014	New Zealand

Name of the Intervention (e.g., WHO Surgical Checklist, QARISMA)	No. of hospitals involved (N)
African Surgical Unit-based Safety Programme (based on WHO guidelines)	5
The Stroke Canada Optimization of Rehabilitation by Evidence project (SCORE project)	5 stroke reh
Obstetric near-miss case reviews	5
Hand hygiene informed by Cochrane reviews	50
Traffic light antibiotic prophylaxis poster based on Scottish Intercollegiate Guidelines Network guidelines	3
American College of Surgeons National Surgical Quality Improvement Program: rsulting in multiple interventions around SSI prevention	1 (but part
Lorenzo software	4 'early adc
International Patient Decision Aids Standards (IPDAS)	33
Enhanced Recovery After Surgery but studying implementation strategies: breakthrough versus stepped	Protocol - n
Time out procedure and debriefing in Operating theatres	10
QUARITE (quality of care, risk management, and technology in obstetrics) trial	46
Translating Research into Practice implementation model.	9
The transitional relationship model (TRM)	6
Tailored multi facteted strategy delivered by Scottish Programme for Clinical Effectiveness inReproductive Health	26 (all hosp
The Feedback Intervention Trial (FIT) of a national cleanyourhands campaign	16 trusts (6
Case Management of frequent users of Emergency departments	Not specie
Aseptic technique policy	Not stated
A customized version of the WHO Surgical Safety Checklist - part of the Safe Surgery South Carolina program	14/58

NHS information and technology (IT) programme	4 Trusts /al
More-2-Eat project	5
Bronchiolitis clinical practice guidelines	11
Blunt chest injury care bundle	2
Caring Letters	6 Defence c
National disclosure policy after adverse events developed by Veterans' Affairs	All 150 VA a
Several interventions for newborns and maternal health	251 facilitie
Picture Archiving and Communication System (PACS)	
Enhanced Recovery Protocols	four special One - acros
Anti-platelet therapy adherence	20 VA medi
Pharmacist-to-Pharmacist Transitions of Care Initiative	2 VA medic
Consult for Addiction Treatment and Care in Hospitals (CATCH)	6
Anaesthetists Be Cleaner	
Safe Surgery 2015 initiative to implement SSCs in South Carolina hospitals	5 hospitals 67 (reportir
Screening, Brief Intervention, and Referral to Treatment (SBIRT)	24 EDs
Mobilization of Vulnerable Elders in Ontario (MOVE ON)	26 hospital
The Productive Ward: Releasing Time to Caree programme	
Eat Walk Engage	5 4

Period ofPURPLE Crying: Keeping Babies Safe in North Carolina,	86
The Bacteremia Zero study	192 ICUs
The Keystone Intensive Care Unit Project	108 ICUs
The Keystone Intensive Care Unit Project	109 ICUs
Society of Critical Care Medicine guidelines re sedation and monitoring	2
Keystone Surgery Program	29
German Quality Network Sepsis	75
Study to Optimally Prevent Surgical Site Iinfections in Select Cardiac and Orthopedic Procedures (STOP SSI)	20
Multi-Centre Medication Reconciliation Quality Improvement Study (MARQUIS2).	18
Gravimetric workflow software systems	10 pharma
Pediatric surgical site infection prevention bundle	18
Fast track cancer diagnostics	One large c

Michigan Surgical Quality Collaborative (MSQC) Surgical Site Infection bundle	52
Mental health model of Care for patient in ED	3
Institutional biobanking	2
Telemedicine outreach service for underserved rural hospitals	4
Matching Registered Nurse Services with Changing Care Demands	23
Lean thinking initiative	3

How is it characterised by the authors? (National, multisite, policy /research /trial /package/ directive/ priority	Source of the intervention I=developed in-house by the team	Evidence of local adaptation? Y; N	Initiative funding: E=external funding; I=internal	External Support e.g., researchers from
multimodal infection control intervention / a	E	Y	E	Y
a pilot implementation study across 5 diverse	E	Y	Not stated	Y
a quality assurance intervention suitable for h	E	Y	E	Y
a five-phase multi-faceted HH management s	E	Y	I	Y
Intervention	E	Y	R	Y
nationally validated system that uses clinically	E	Y	Not stated	Y
the implementation of Lorenzo as a complex	E	N	E	N
multi-regional implementation	E	Y	E, R	Y
multi-regional implementation	E	Protocol	I	Y
multi-site study using participatory action res	E	Y	Not stated	Y
multifaceted intervention / a cluster-randomi	E	Y	I/R	Y
Trial of the implementation intervention: add	E	Y	E, R	Y
quasi-experimental testing of implementatior	E	Y	R	Y
a tailored multifaceted strategy implementa=	E	Y	R	Y
Three year stepped wedge cluster RCT of a fe	E	Y	I/R	Y
effectiveness-implementation hybrid trial	E	Protocol	R	Y
the implementation of aseptic technique poli	E	N	I	N
The Safe Surgery 2015 South Carolina prograr	E	Y	E	Y

the largest civilian IT programme in the world	E	N	E	Y
implementation of an evidence-based nutritic	E	Y	E	Y
multisite implementation of an evidence-base	E	Y	Not reporte	Y
implementation of a blunt chest injury care b	E	Y	R	Y
National trial/ research	E	N	R	Y
National policy	E	N	I	N
large-scale quality improvement intervention	E	Y	E	Y
Multisite implementation	E	Y	I	Y
multispecialty implementation of ER protocol	E	Not clear	R,I, E	Y
multi-site randomized stepped wedge trial to	E	N	R, I	Y
large-scale pharmacist-to-pharmacist TOC mc	E	N	R, I	Y
pragmatic trial at six hospitals; program	E	N	R, I	Y
an evidence-based bundle, stepped wedge, cl	E	Y	E	Y
state-wide/ large-scale implementation of sur	E	Y	E	Y
a state-wide effort in Maryland to expand SBI	E	N	E	Y
a multi-site implementation intervention in a	E	Y	I, E, R	Y
large-scale quality improvement	E	Y	Mixed	Y
a multi-site improvement program	E	Y	I, E, R	Y

statewide nurse training program	E	N	Mixed	Y
national mulitmodal intervention	E	Y	Mixed	Y
statewide quality improvement initiative	E	Y	Not clear	Y
statewide quality improvement initiative	E	Y	Not clear	Y
a process-improvement project	E	N	R, I	Y
Statewide, checklist-based quality improveme	E	Y	I	Y
a quality collaborative	E	Y	I/E	Y
the multisite pragmatic trial	E	Y	I	Y
patient safety strategy that is widespread in U	E	y	I/E	Y
a large-scale, multicentre, multinational	E	N	Not clear	Not repor
A quality improvement collaboration in Ohio (	E	Y	I/E	Y
Large scale implementation	E	Y	I	Y

a “bundle” of care processes	E	Y	I	Y
multi-site translation research project to impl	E	Y	I/R	Y
modern, large-scale research initiative	E	Y	I/R	Y
academic-clinician partnership	E	Y	E	Y
a cross-sectional multicentre study	E	N	E	Y
Lean management philosophy and activities	E	Y	E	Y

Formal Internal Support for the project	Formal outcome measures collected. Y;N	Evidence of System Change (e.g., new forms,	Any mention of active de-implemen	Any mention of adaptabili ty? Or
Y	Y		N	Y
Y	Y	Not really	N	Y
Y	Y	Y	N	Y
Y	Y	Y	N	Some
Y - implied	Y	Y poster	N	N
Y	Y	Y - resource	Y new proc	Y - more QI
Y	Y	Y	Not reporte	All tight
Not reporte	Y	Y	N	Y - some ne
Y	Y	protocol	protocol	Y
Y	Y	Yes	Yes some	Y
Y	Y	Y	N	N
Y	Y	Y	Not reporte	Y
Y	Y	Y	Not reporte	Y
Y	Y	N	N	Y
Y	Y	Y	N	N
Y	Y	Protocol	Protocol	Protocol
Y- implied i	Y	Y	N	N
Y	Y	Y	Not reporte	Y

Y	Y	Y	Surprisingly	N
Y	Y	Y	No	Y
Y	Y	Y	N	Y
Y - implied	Not reporte	Y	N	Y
Y	Y	Y, new ema	N	N
Y	Y	Y new proc	N	Learning hc
Y	Y	Y, new equ	Y	Y - each fac
Y	Y	Y; IT, proce	Y	N
Y	Y	Y , processe	N	N
Y	Y	Y, processe	N	N (CT)
Y	Y	Y, processe	N	N
Y	Y	Y - extensiv	N	N
Y	Y	Y, processe	N	Y
Y	not reporte	Y checklist	N	Not reporte
Y	Y	Y screening	N	N
Y	Not reporte	Y	N	Y
Y	Y	Y	Y	Y
Y	Y	Y	Protocol	Y

Y	Y	Y	N	N
Y	Y	Y	N	Y
Y	Y	Y	N	Y
Y	Y	Y	N	Y
Y	Y	Y	N	N
Y	Y	Y	Y - checklist	Yes - local a
Y	Y	Y	N	N
Y	Y	Y	N	Y
Y	Y	Y	N	N
Y	Y	Y new softv	Y	Not reporte
Y	Y	Y	N	N
Y	Y	Y: new processes, new equipment		

Y	Y	Y	Not reporte	N
Y	Y	NA pre-imp	N	Y
Y	Y	Y	N	Y
Y, N	Y	NA pre-imp	N	Y
Y	Y	Y	N	N
Y	Y	Y	N	N

Implementation strategies, frameworks named / discussed?

Comprehensive Unit-based Safety Programme developed in the USA, is a five-step iterative process

No

Some

Yes - Ubuntu pholisphy 'I am what I am because of who we all are' to promote ownership

Yes - based on poor knowledge of extent of SSI - not well reported across UK.

Lean Six Sigma

Yes - developing a framework for how to engage clinical staff Barriers

The Model for Planning Change .

Adaptive Design

Yes

Healthcare Improvement Collaborative Model (HICM) based on Provonost and Johns Hosplins Implementation models. Really a QI process.

Yes at length - make their own Evidence-Based strategy.

Yes theory-based analysis of barriers to implementation of guidelines

Yes

The Generic Implementation Framework and RE-AIM to evaluate

Lack of strategies discussed at length. Assessed using CFIR

Yes

Staged implementation of components, support from Central IT service - focus here is on what didn't happen.

COM-B analysis, PDSA, sudit and feedback, MD imp Teams, clinical leaders/champions; engaing senior management

Yes

Only in terms of barriers / enablers using TDF and COM-B

Mostly based on pilot study

Analysis of barriers using CFIR

No

Yes

No

Yes

No
Not clear

Yes - Table 1 shows their set of IS informed principles.

Yes

No

Yes mapped to context and barriers analysis with TDF

Yes - based on Diffusion of Innovation

integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) framework

Kirkpatrick's typology
Yes "engage, educate, execute and evaluate"
Yes "engage, educate, execute and evaluate"
Yes "engage, educate, execute and evaluate"
A four-phase implementation process incorporated a planning phase, baseline phase, education phase, and maintenance phase
Provonost et al's "translating evidence into practice" model and Comprehensive Unit-based Safety Program (CUSP)
Yes
N
Yes - Framework used to evaluate factors that may have influenced implementation. Not always clear what the implementation at each site was.
No
Yes
Elements from lean management, theory of constraints and mathematical analysis

Promoted by a regional quality improvement collaborative

Realistic evaluation of the pre-implementation

Analysis of barriers

Organisational Readiness Theory
Organisational Readiness Theory
Organisational Readiness Theory

Implementation Strategies

Formation of implementation teams to oversee; senior executive sponsorship; clinical leads; education; audit and feedback; assess safety culture; accountabiity for senior staff and leaders; tools to improve communication; expertise and mentorship from the US experts.

Local facilitator - clinician; salary support for 1 day/week; education and gap analysis;
Audit and case review; paid clinical lead for the audits;
Multidisciplinary Team

Targeted activities for different groups (eg exec vs clinical); audit and feedback; education/retraining; resources such as alcohol rub

Audit and feedback x 2; education as part of M&M meeting; posters

Multidisciplinary Teams, literature review and process mapping; work flow analysis to standardise practice; audit and feedback (using a mulit-institutional data set); new resources; education; Community of Practice

Boundary spanner/ clinical champions; national champions
Discussion of fitting into workflow

Education, PDSA cycles, audits, process audits, cost effectiveness, digital tool; opinion leaders; outreach visit

Education and successive learning cycles; including all professionals, monitoring.

Developing opinion leaders; undertaking educational clinically-oriented, and evidence-based outreach visits focused on emergency obstetric care; clinical audits (maternal death reviews)

PDSA, audit and Feedback, Education, workshops, CoP team support, champions, and expert advisors, map processes, barriers analysis and mitigation strategy, online support and discussion boards, baseline audit.

Education, on-site champions, supportive documentation systems

Audit and feedback, unit educational meetings, dissemination of structured case records and promotion of a patient information booklet.

Observational audit then constructive feedback and planning for improvement; audit and feedback at ward meetings, education for auditers.

Needs and interest assessment, hospital orientation / engagement with research support team, intervention toolkit, imp team, coaching, education

Focus on barriers

Executive sponsorship/engagement with the state-wide collective, coaching, teleconferences, site visits, promotional materials, implementation "leadership" team.

Hospital exec engagement, clinical leadership, support from external experts, harnessing tension for change,

implementation team, audit and feedback, champions, senior management "educated" by champions, education, externalk support

Hosp exec engaged to sponsor project, resources shared, support from TRN collaborative, education, project coordinator, physician champion.

Education, CPGs available,

Clear process to follow, education, coaching, exec sponsorship, clear objectives

Not reported

Observational audits of quality of care, education and skills assessment, coaching, external support, provision/help in sourcing equipment

Consideration of physical infrastructure supporting the IT upgrade (the intervention); training offered at multiple times and through multiple formats -webinar/face to face/written , champions, implementation team with ckear responsibilities and roles; comprehensive communication plan; problem solving by imp team

Not reported

Readiness for change analysis, clinical champions, clear guidelines to follow

Not reported

Not reported

Education: presentations, written material and illustrative videos; co-designed bundle of interventions (so clinicians implementing the bundle have ownership), collection of outcome data; engage senior leadership, clinical champions. building a tension for change, ensuring all interventions"make sense "and are compatible with current workflow, "once intervention has been agreed, compliance should not be negotiable".

Needs analysis/context mapping at start; education; tools to do the intervention; multidisciplinary engagement

Not reported

Education, staff coaching tools, printed education materials, reminders, huddles, posters etc.

Establishing a clear vision, success stories from "early adopters", regional level support for education and planning, alignment of program with organisational targets, dedicated project leadership, senior support, external support, dedicated project time for staff, good communication, and information, establishing a need for change, valuing the initiative, access to modules, voluntary enrolment in the project, sufficient resources, local ownership emphasised.

Facilitator works with MDT to prioritise areas for improvement, PDSA, project officer. Education

offered resources free of charge, diffusion of the course via senior clinicians involved in a regional education network, MOU with exec outlining the program/participation, resources and staff to be freed to do program. Education

Engaged clinicians during meetings etc, audit and feedback via an online tool, other tools, education, problem solving, analsysis of errors

Clinician change agents on each ICU, trained and shown the evidence for the/need for change/

Engage: personally communicate, tell stories and share results from other sites; educate - including skills, Execute: given skills on managing behaviour of others / themselves, streamlining processes, checklists; Evaluate: fidelity checked.

baseline assessment; utilization of existing personnel (e.g., nurse educators, unit managers, charge nurses); education in the form of lectures, posters, and one-on-one reminders; and evaluation of compliance and impact

Education, collaboration, imp teams; interventions aimed at increased safety knowledge and culture

Audit and feedback, collaborative - benchmarking, responding to audits, link between collaborative and local clinical champions, education, engage exec - must pay an annual particpation fee and publication of hospital mortality, expert advice

not reported

MD implementation teams, leadership support,

Not reported

common goal for improvement, engage and educate multidisciplinary teams and senior leaders, simplify and standardize care (bundles, protocols, policies, and briefings), ollect data and offer performance feedback, and to provide opportunities for shared learning

Clinical leadership; executive sponsorship; audit and feedback; process mapping/analysis; predefined plan with project officers; inventory of barriers and facilitators; PDSA cycles to tweak the processes; active involevement of clinicians; external input from consultants to benchmark.

audit-andfeedback system for adherence, face-to-face meetings, and support for quality improvement projects at participating hospitals

Engage with each site, assess willingness for change, identify resources required and flag potential barriers.

Implementation team, clinical leadership, no extra resources/time given, case for change clear especially to patients

Organisational Readiness assessment

Organisational Readiness assessment

Organisational Readiness exploration

Supplementary File

Concepts and features associated with implementation of large-scale hospital interventions. (denotes concepts added after literature review)*

Concept	Associated Features	Antecedents	Intended Outcome	Supported by the literature?	Comments and examples
External, top-down source	Implementing externally developed interventions	Basic and applied research undertaken	Standardised, evidence-based practice used across sites	Always	Developed by quality or safety agencies,[34] research institutes / groups,[24] professional colleges
	Support for implementation built into intervention	Current locally held resources may be inadequate for effective implementation; knowledge and skills deficits	Social and practical support and relevant knowledge and skills acquisition assist implementation of intervention with high fidelity	Often	Intervention designed to provide implementation support through tools (e.g.,[35]), checklists (e.g.,[10]), or guidelines (e.g.,[36]). Education and skills building key elements
	Aligns with organisational or state/nation-wide priorities	Clear, coherent intentions developed and presented	Adoption of intervention through collective understanding of a clear intention	Often	Often synonymous with the large-scale intervention model[12]
	Incentives and disincentives for implementation are offered			Rarely	For one project a participation fee was charged for organisations,[35] for another, selected participants were paid[37]
Evidence-based interventions	Implementing evidence-based interventions	Basic and applied research undertaken	Standardised, evidence-based practice used across sites	Always	Usually based on Level 1 evidence; sometimes informed by a pilot at a subset of sites[38,39]

	De-implementation of previous practices	Current practices have been updated/outmoded	New interventions	Rarely	Rarely reported explicitly. Even for implementation of new IT systems, legacy software may be kept alongside the new [31]
Safety and quality focus	Clear aim of improving patient outcomes*	Clear, coherent intentions developed and presented	Adoption of intervention through collective understanding of a clear intention	Always	With or without baseline data setting up a case for change, consistent understanding that intervention is needed to improve patient outcomes
	Sites harness their positive safety culture	Work of improving patient outcomes seen as core business	Higher adoption and engagement through collective competencies and intentions	Rarely	Rarely reported explicitly. Assumption made in most that positive safety culture exists.
Facilitation through assessment and provision of resources	External funding	Current locally held resources may be inadequate for effective implementation; knowledge and skills deficits	Social and practical support and relevant knowledge and skills acquisition assist implementation of intervention with high fidelity	Sometimes	Mix of external, internal or research funding
	Support for comparison across sites implementing the intervention*	Siloed working may hide need for change	Benchmarking and social support allow implementation of intervention with high fidelity	Sometimes	Often included in research-based design or collaborative groups
	Support for planning and implementation activities from	Current locally held resources may be inadequate for effective implementation;	Social and practical support and relevant knowledge and skills	Sometimes	Research-based projects and those involving a collaborative group

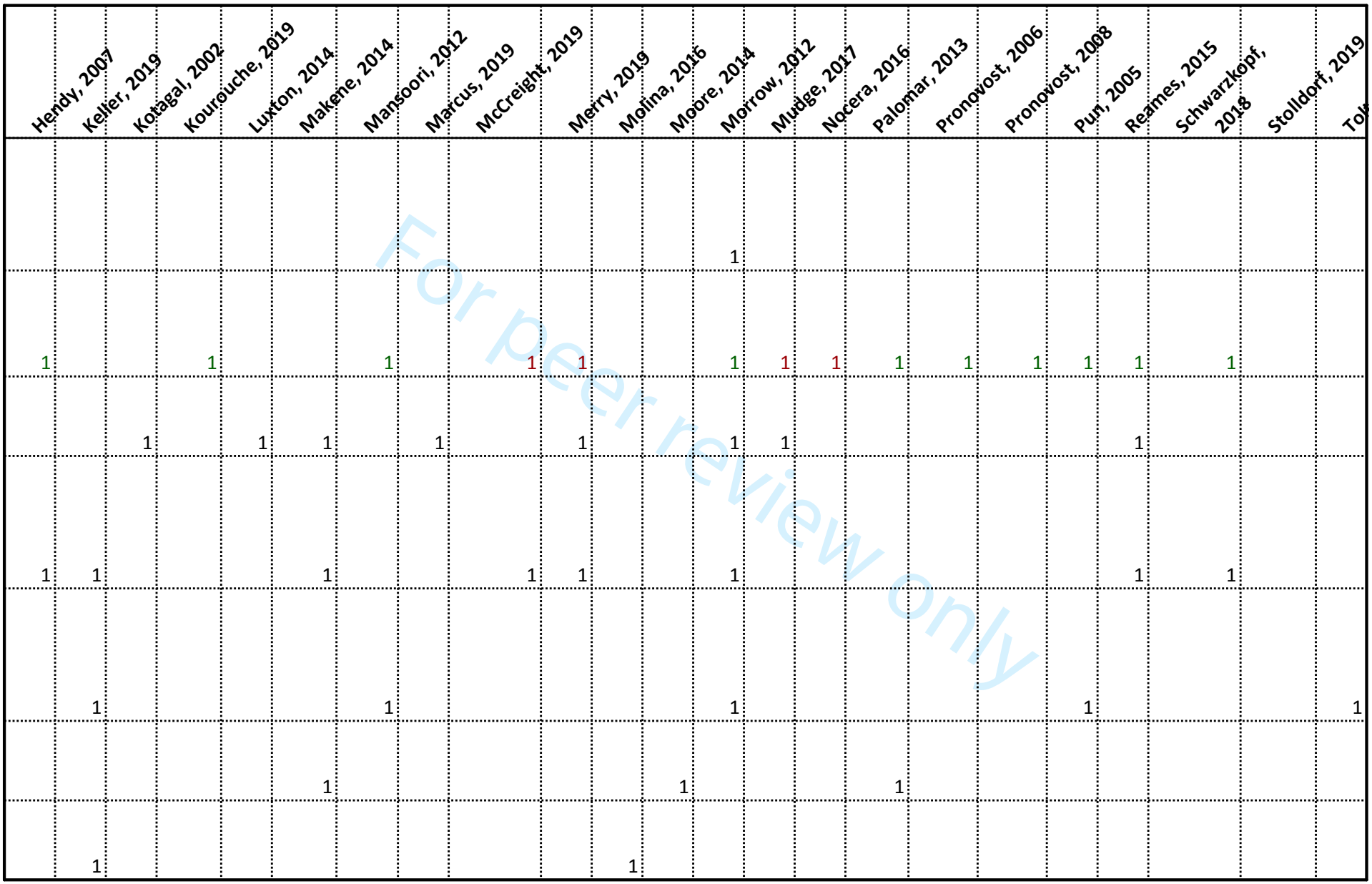
	external agencies*	knowledge and skills deficits	acquisition assist implementation of intervention with high fidelity		were most likely to give support; (e.g.,[26,40]) often given in-kind
	Case for change made through data	Limited or no understanding of the need for change; complacency	Tension for change fosters adoption of the intervention	Always	Baseline data and local audit and feedback were common implementation strategies
	Sites given a lead-in time to assess for readiness and local needs*	Naïve site, unprepared (even if willing) for change	Participants more likely to adopt change, exert greater effort, exhibit greater persistence, and display more cooperative behaviour	Sometimes	Formal needs/readiness assessments were sometimes reported[39]
Harnessing local resources and encouraging adaptation	Executive support/ sponsorship	Social and practical support for work of implementation not initially explicit	Intervention driven by local organisational ownership, active support, accountability and responsibility	Always	While commonly reported, it was only implied in some papers Variable use of the terms “support” and “sponsorship”
	Local adaptation encouraged / expected	Diversity of sites and contextual factors	Both implementation and intervention can be tailored to suit local context without loss of fidelity	Often	Assumed step, often based on a quality assurance / improvement model
	Clinical leadership	Social and practical support for work of implementation not initially explicit	Intervention driven by local organisational ownership, active support, accountability and responsibility	Often	Involvement of clinical leads gave credibility, accountability to implementation efforts. Social influence through mentorship, leading by example.

ERIC implementation strategy	Our listed strategies	Allegranzi, 2018	Bayley, 2012	Borchert, 2012	Brink, 2020	Cameron, 2015	Cima, 2013	Cresswell, 2011	Cuypers, 2019	de Groot, 2015	Dekker-van Doorn, 2020	Dumont, 2013	Edward, 2017	Forchuk, 2013	Foy, 2004	Fuller, 2012	Grazioli, 2019)	Havers, 201	Ha
Access new funding	Extra staffing as needed; salary support; monetary incentives		1						1								1		
Assess for readiness and identify barriers and facilitators	Readiness / give sites planning or lead-in time		1						1	1						1		1	
Audit and provide feedback	Audit and Feedback											1							
Build a coalition; create new clinical teams; create a learning collaborative	Multidisciplinary involvement	1					1					1	1			1			
Capture and share local knowledge	Community of practice / knowledge network of clinicians	1												1	1	1		1	
Change physical structure and equipment	Funding for equipment									1		1							
Change physical structure and equipment	Tools to improve communication						1					1							

Conduct cyclical small tests of change	**PDSA Cycle**										1			1						
Conduct local consensus discussions; Facilitator	**Local facilitator / project officer**	1	1								1		1							
Conduct local needs assessment	**Identify resources required**	1	1										1							
Create a learning collaborative	**Engaging stakeholders**																			1
Develop a formal implementation blueprint	**Implementation guides**	1			1												1			
Develop a formal implementation blueprint	**Intervention Toolkit**				1							1					1			
Develop academic partnerships; use implementation advisor; use advisory boards and workgroups	**Support from external experts/ external support**											1			1	1		1	1	1
Develop and implement tools for quality monitoring	**Monitoring**											1					1			
Develop educational materials; distribute educational materials	**Education**	1	1			1	1						1	1		1	1			

Develop resource sharing agreements	**Resources shared**																		
Distribute educational materials	**Clinical practice guidelines**				1	1													
Facilitation	**Problem solving**																		
Identify and prepare champions	**Champions**									1									
Inform local opinion leaders	**Opinion leaders; fostering positive safety culture**	1		1	1														1
Involve executive boards; Obtain formal commitments	**Executive sponsorship/engagement with the state-wide collective**	1			1		1	1	1	1			1						
Organize clinician implementation team meetings	**Quarantined time for skill acquisition**																		1
Promote adaptability; purposely re-examine the implementation	**Evidence of local adaptation**	1	1	1	1	1	1		1		1	1	1		1	1			
Provide clinical supervision	**Mentoring/ Supervision/ coaching**	1		1	1		1		1	1				1					
Recruit, designate, and train for leadership	**Clinical leadership**		1	1									1						

Use data experts	**IT and communication support for new processes**						1				1					1			
(No ERIC strategy)	**Align with organisational/ District and Departmental priorities**	1																	
Footnotes																			
[1] https://aci.health.nsw.gov.au/__data/assets/pdf_file/0007/291742/Clinical_Innovation_Program_Implementation_Guide.pdf																			
[2] https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/hcs-sss/alt_formats/pdf/pubs/palliat/2008-acp-guide-pps/acp-guide-pps-eng.pdf																			
[3] https://www.nhmrc.gov.au/sites/default/files/images/a-guide-to-the-development-and-evaluation-of-clinical-practice-guidelines.pdf																			
[4] https://www.nice.org.uk/guidance/ng106/resources/chronic-heart-failure-in-adults-diagnosis-and-management-pdf-66141541311685																			
[5] https://www.who.int/patientsafety/safesurgery/checklist_implementation/en/																			



Hendy, 2007	Keller, 2019	Kotagal, 2002	Kourouche, 2019	Luxton, 2014	Makene, 2014	Mansoori, 2012	Marcus, 2019	McCreight, 2019	Merry, 2019	Molina, 2016	Moore, 2014	Morrow, 2012	Mudge, 2017	Nocera, 2016	Palomar, 2013	Pronovost, 2006	Pronovost, 2008	Purı, 2005	Reames, 2015	Schwarzkopf, 2018	Stolldorf, 2019	Tol
											1											
1			1			1		1	1		1	1	1	1	1	1	1	1	1			
		1		1	1		1		1		1	1						1				
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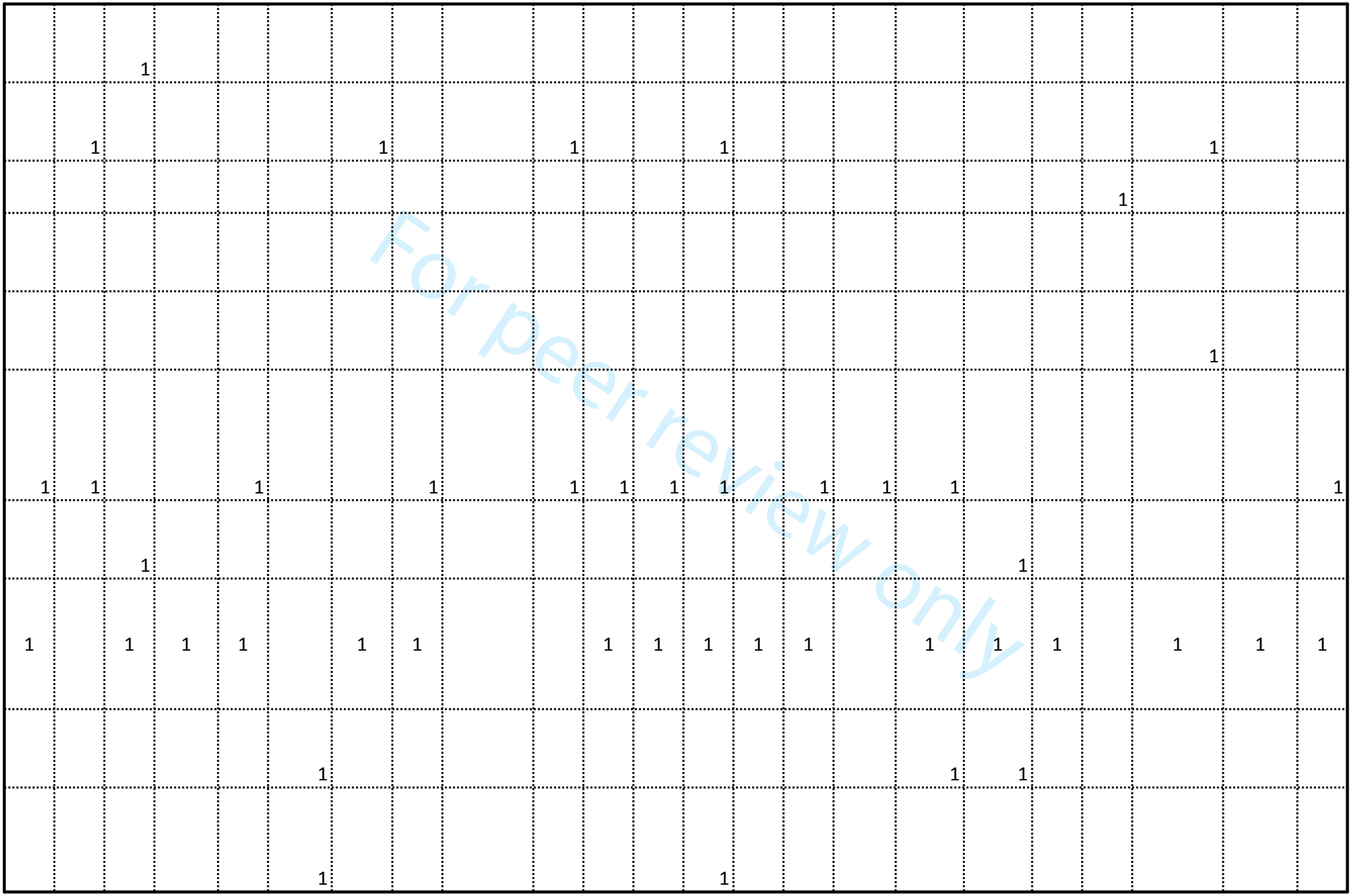
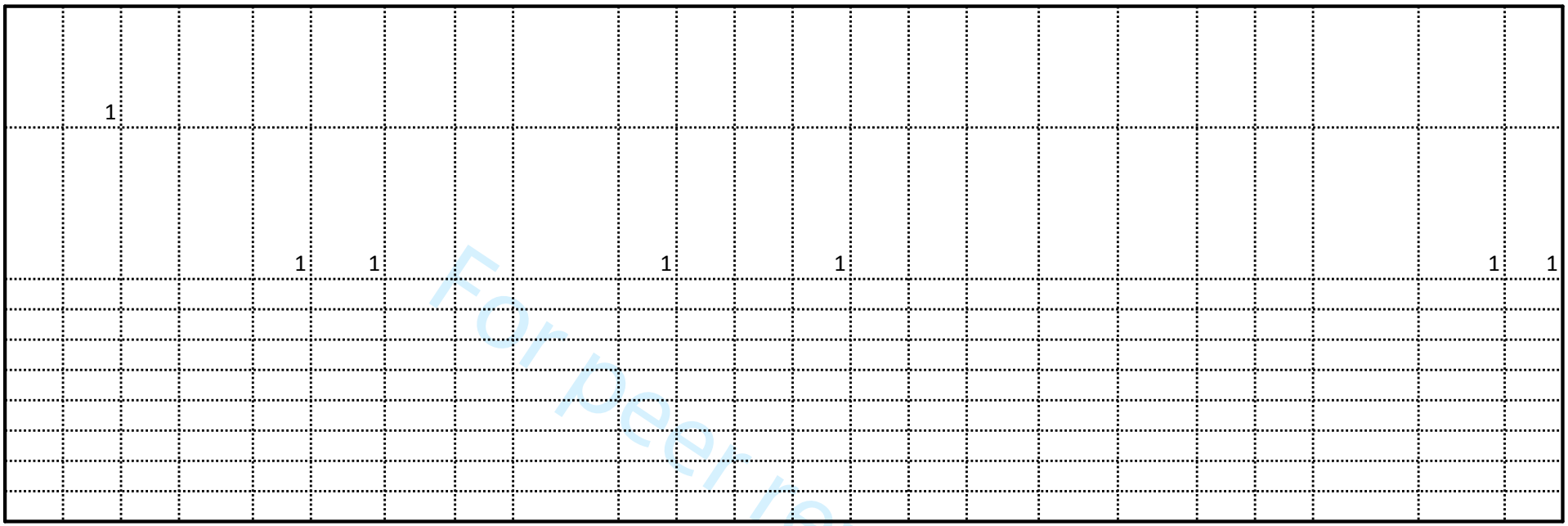
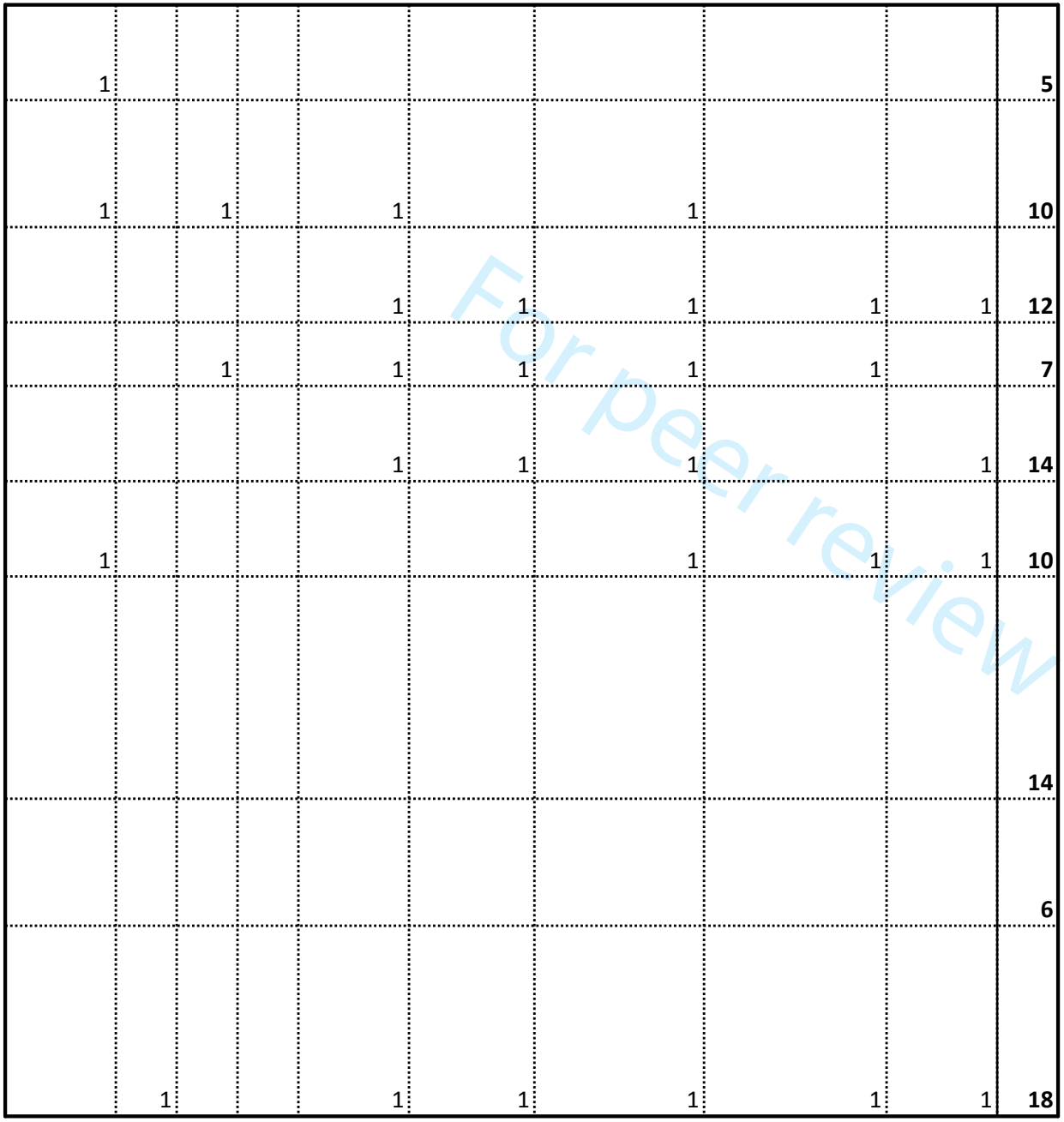
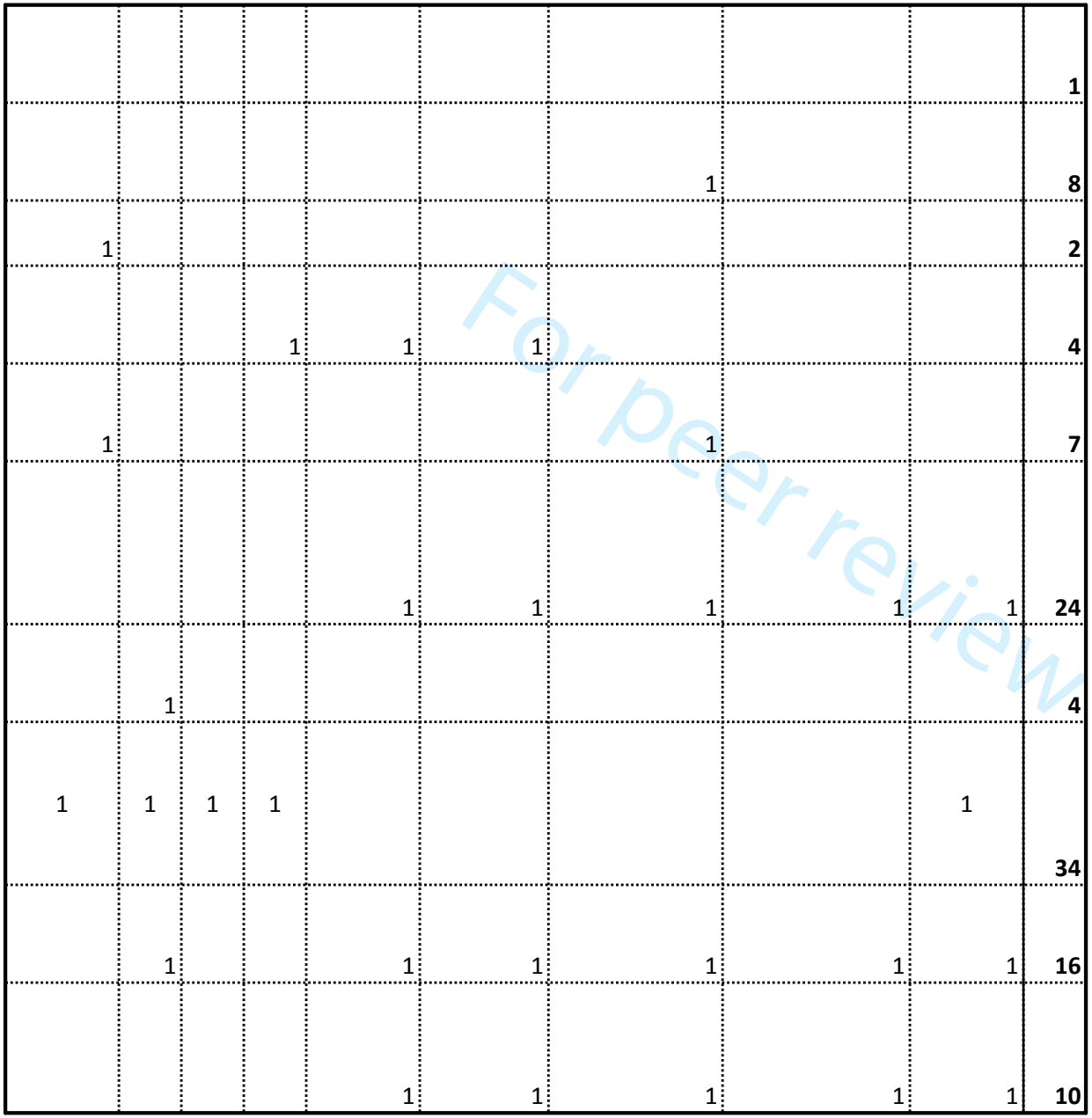
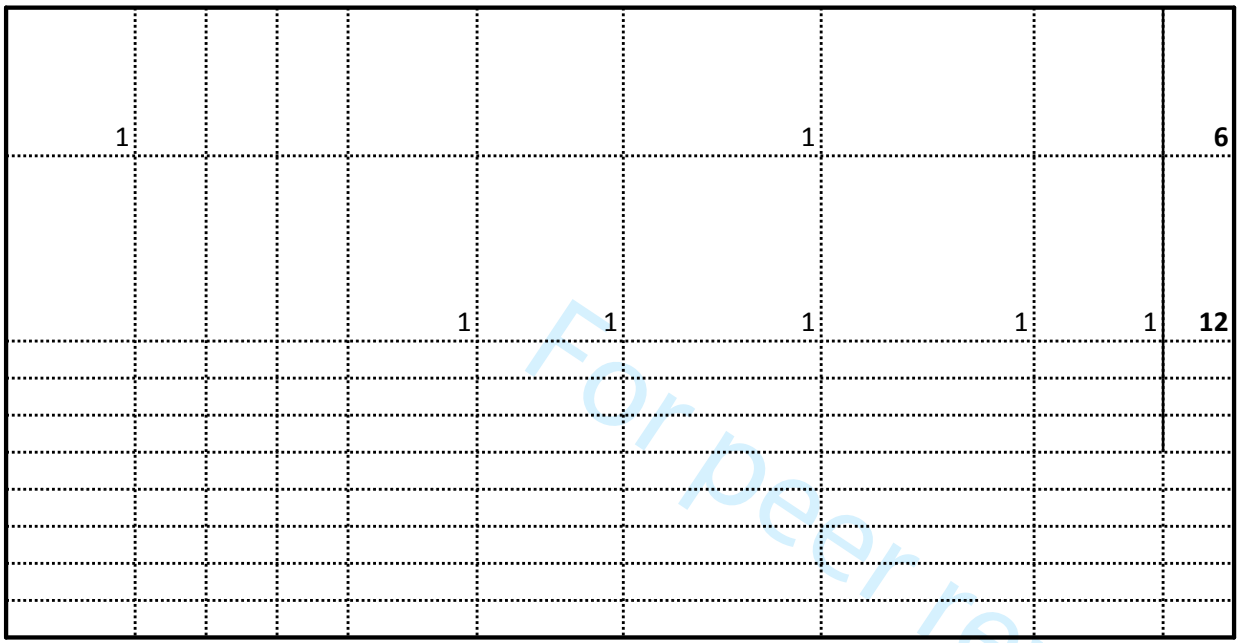




van Harten, 2018	Vu, 2018	Wand, 2019	Wyld, 2014	ACI Redesign [1]	Advance care planning (Canada)[2] NHMRC	Implementation Guideline [3]	NHS NICE Chronic heart failure [4]	WHO Surgical Checklist [5]	Sum
1					1				6
1	1	1	1	1					24
					1		1		11
1		1	1						16
1									11
					1				6
									4







Supplementary file 4: RAMESES publication standards checklist

1	Title, identifies the document as a realist synthesis or review.	Yes
2	Abstracts should ideally contain brief details of the study's background, review question or objectives; search strategy; methods of selection, appraisal, analysis and synthesis of sources; main results; and implications for practice.	Yes
3	Explain why the review is needed and what it is likely to contribute to existing understanding of the topic area.	Yes
4	State the objective(s) of the review and/or the review question(s). Define and provide a rationale for the focus of the review.	Yes
5	Any changes made to the review that was initially planned should be briefly described and justified.	Yes
6	Explain why realist synthesis was considered the most appropriate method to use.	Yes
7	Describe and justify the initial process of exploratory scoping of the literature.	Yes
8	State and provide a rationale for how the iterative searching was done. Provide details on all the sources accessed for information in the synthesis. For example, where electronic databases have been searched, details should include, for example, the name of the database, search terms, dates of coverage and date last searched. If individuals familiar with the relevant literature and/or topic area were contacted, indicate how they were identified and selected.	Yes
9	Explain how judgements were made about including and excluding data from documents, and justify these.	Yes
10	Describe and explain which data or information were extracted from the included documents and justify this selection.	Yes
11	Describe the analysis and synthesis processes in detail. This section should include information on the constructs analyzed and describe the analytic process.	Yes
12	Provide details on the number of documents assessed for eligibility and included in the review with reasons for exclusion at each stage, as well as an indication of their source of origin (for example, from searching databases, reference lists and so on).	Yes
13	Provide information on the characteristics of the documents included in the synthesis.	Yes
14	Present the key findings with a specific focus on theory building and testing.	Yes
15	Summarize the main findings, taking into account the synthesis' objective(s), research question(s), focus and intended audience(s).	Yes
16	Discuss both the strengths of the review and its limitations. These should include (but need not be	Yes

	restricted to) (a) consideration of all the steps in the synthesis process and (b) comment on the overall strength of evidence supporting the explanatory insights that emerged. The limitations identified may point to areas where further work is needed.	
17	Where applicable, compare and contrast the synthesis' findings with the existing literature (for example, other reviews) on the same topic.	Yes
18	List the main implications of the findings and place these in the context of other relevant literature. If appropriate, offer recommendations for policy and practice.	Yes
19	Provide details of funding source (if any) for the synthesis, the role played by the funder (if any) and any conflicts of interests of the reviewers.	Yes

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Conceptualising contexts, mechanisms and outcomes for implementing large-scale, multi-site hospital improvement initiatives: a realist synthesis

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Conceptualising contexts, mechanisms and outcomes for implementing large-scale, multi-site hospital improvement initiatives: a realist synthesis

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Abstract

Design:

Realist synthesis

Study background:

Large-scale hospital improvement initiatives can standardise healthcare across multiple sites but results are contingent on the implementation strategies that complement them. The benefits of these implemented interventions are rarely able to be replicated in different contexts. Realist studies explore this phenomenon in depth by identifying underlying context-mechanism–outcome interactions.

Objectives:

To review implementation strategies used in large-scale hospital initiatives and hypothesise initial program theories for how they worked across different contexts.

Methods

An iterative, four-step process was applied. Step 1 explored the concepts inherent in large-scale interventions using database searches and snowballing. Step 2 identified strategies used in their implementation. Step 3 identified potential initial program theories that may explain strategies' mechanisms. Step 4 focused on one strategy-theory pairing to develop and test context-mechanism-outcome hypotheses. Data was drawn from searches (March-May 2020) of Medline, Embase, PubMed and CINAHL, snowballed from key papers, implementation support websites, and the expertise of the research team and experts. Inclusion criteria: reported implementation of a large-scale, multisite hospital intervention. RAMESES reporting standards were followed.

Results

Concepts were identified from 51 of 381 articles. Large-scale hospital interventions were characterised by a top-down approach, external and internal support, and use of evidence-based interventions. We found 302 reports of 28 different implementation strategies from 31 reviews (from a total of 585). Formal theories proposed for the implementation strategies included Diffusion of Innovation, and Organisational Readiness Theory. Twenty-three context-mechanism-outcome statements for implementation strategies associated with planning and assessment activities were proposed. Evidence from the published literature supported the hypothesised program theories and were consistent with Organisational Readiness Theory's tenets.

Conclusion

This paper adds to the literature exploring why large-scale hospital interventions are not always successfully implemented and suggests 24 causative mechanisms and contextual factors that may drive outcomes in the planning and assessment stage.

Key words

Realist synthesis, implementation science, change management, program theory, health services

Article Summary

Strengths and limitations of this study

- An iterative process was used to search, extract data, validate and analyse results using evidence and expertise from researchers and partners.
- RAMESES Reporting Standards were used to ensure rigour of each staged step.

- In spite of a systematic and thorough search for literature, only 51 papers were found; while large-scale hospital interventions abound, implementation activities and outcomes are not commonly reported.
- The wealth of data constrained our study to consider only a single formal theory, and a subset of implementation strategies.

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Competing interest statement

The authors declare they have no conflicting or competing interests.

Introduction

The implementation of large-scale, multi-site, hospital-based improvement initiatives, developed from high quality evidence have the potential to standardise practice, improve safety, continuity and quality of care for patients, reduce unnecessary, unwarranted treatments and provide better value for money.[1] Large-scale hospital interventions, as discussed here, are projects that are typically intended to be implemented across multiple hospitals (e.g., all public hospitals in a region). They are usually "top down" in nature, in contrast to local, clinician-initiated "grass-roots" projects. The mandate to implement these initiatives is typically from the hospitals' funding or governing bodies (e.g., State Health Departments, or local health networks), or high-level clinical agencies (e.g., a national Quality and Safety Commission). Such interventions may be supported by

additional staff and resources and align with other high-level health system priorities. The focus of these initiatives is improvement of care and did not include mandated, enforceable health orders.

The QUARISMA intervention in Quebec, Canada, for example, was implemented in 32 hospitals.[2] The intervention was based on best practice guidelines derived from recommendations of the Society of Obstetricians and Gynaecologists. The hospitals that implemented it, successfully and safely reduced the rates of clinically unwarranted caesarean sections in low risk mothers.[2] Another example of a large-scale hospital intervention is the World Health Organisation's surgical safety check-list[3] which was successfully adopted in six high performing hospitals in The Netherlands. This significantly reduced surgical complications and mortality.[4]

Large-scale interventions are expensive and time consuming to implement.[5] Their success is contingent on the implementation programs that accompany them[6]; that is, the suite of individual implementation strategies designed to prepare the hospitals for change, and equip the focal stakeholders to adopt new practices and adapt or discard old ones. Recent systematic reviews have identified a range of strategies linked to successful implementation programs, such as conducting a needs assessment, recruitment of champions or opinion leaders, use of audit and feedback, engaging organisational leaders, and developing implementation teams.[e.g.,7,8] For large-scale interventions, these implementation programs are often required to fit a range of hospitals of different size, geographic and socio-demographic contexts, and health consumer needs.

In recent years, implementation strategies have been compiled, described and categorised[9] but research has failed to explain why strategies that work as intended in one context,[e.g., 10] may be a failure in another.[e.g., 11] Results suggest that those designing implementation strategies have failed to take into account local contextual features,[12] and that contextual features are poorly conceptualised and defined in reporting. [13] Moreover, the underlying mechanism of action, working within that context, is only rarely defined, implying that the way strategies work is poorly understood. A program theory that lies beneath the implementation program and that articulates how the

strategies are thought to work is often not explicitly stated. Davies and colleagues showed in their review of 235 guideline dissemination and improvement projects in health care, only 23% used theory of any kind to inform the development of the implementation strategies.[14] This, they argue, can result in a poor choice of implementation strategy for the context (e.g., settling for a "default strategy" such as an education session[15]) and corresponding poor results.

Realist approaches take a deep dive into why programs work as intended some of the time but not all of the time.[16] A realist approach asserts that all programs have an underlying program theory that explains how the strategies bring about intended or unintended results. This holds the promise of unpicking the link between the context and outcomes. A realist synthesis is the ideal approach to understand implementation programs for large-scale hospital interventions, as it explores the links between strategies, mechanisms of action, contexts, the responses of clinicians, and outcomes. Terms used in this synthesis referring to types of theories are defined in Box 1.

Formal theories: here, this refers to general implementation science theories that have been used to explain how implementation strategies work broadly and for which there is some empirical support. Also called mid-range theories[17]
Program theory: a theory that explains how and why particular types of interventions work to generate the outcome/s of interest[16]
Initial program theory: a program theory that is hypothesised, tested and refined as a result of the realist synthesis to explain how the focal type of intervention generates the outcome/s of interest
Potential initial program theories: a suite of program theories being considered as an initial program theory

Box 1: Types of theories referred to in this paper

A realist synthesis is a generative process, first understanding the nature of the implementation program and then proposing potential initial program theories around the way a program works. These initial program theories, configured as *contexts* (circumstances under which

the program works), *mechanisms* (generative causes of how programs elicit results), and *outcomes* (the results of the program), are then tested using published literature.[16] The *context-mechanism-outcome* configurations (CMOs) that are found through analysis of the literature can be explored and used to formulate and refine initial program theories which explain how and under what circumstances programs achieve different outcomes. Consequently, realist research does not apply value judgements on program outcomes such as "successful" or "unsuccessful". Instead, it acknowledges that programs produce intended and unintended outcomes.[18]

The aim of this realist synthesis was to synthesise evidence and generate initial program theories that explain how implementation strategies work in large-scale hospital interventions; in other words, to gather evidence on what works as intended for whom, in what circumstances, and why. This realist synthesis is divided into two parts. First, we scope the literature seeking to understand the concepts and features of implementation programs for large-scale hospital interventions to understand the sorts of formal theories that may be relevant here. Second, we focus on a single group of implementation strategies and generate initial program theories [19] and CMO configurations to test against the literature.

Both parts of the synthesis are part of a larger project [20] examining seven *Leading Better Value Care* projects implemented in metropolitan, remote and regional-based hospitals (n=100) across New South Wales (NSW), Australia between 2016 and 2018.[20] These projects are based on a value-based care paradigm and address unwarranted clinical variation, and preventable hospitalisations across seven high impact conditions.[21] Early results from this project showed that implementation strategies accompanying the projects were variably successful across sites at eliciting buy-in and adoption of the interventions. This current study is informing a realist evaluation of the implementation strategies used to build a nuanced model to support future large-scale hospital implementations; specifically, by defining relevant concepts and proposing initial program theories.

Methods

We followed the Reporting Standards for realist syntheses recommended by the RAMESES group.[22] We used a combination of academic database and grey literature searches, data extraction and fortnightly research team discussions to collate evidence for the synthesis. Throughout the work, research team discussions around data extraction and interpretation were informed by ongoing discussions with partners at the NSW Ministry of Health, Agency for Clinical Innovation and Bureau of Health Information who were experienced in design and implementation of large-scale hospital initiatives, and colleagues from Macquarie University's Centre for the Health Economy. All searches were conducted between March and August 2020. Table 1 shows the four iterative steps of our method.

Step 1: Conceptualising large-scale hospital interventions

The first step towards generating initial program theories in a realist synthesis is to identify the key concepts of the topic of interest. Concepts are tightly linked to program theories as they help to understand where key mechanisms leading to expected outcomes are likely to occur.[19] Here, we identified and defined key concepts associated with the implementation of large-scale hospital initiatives by exploring the focal stakeholder cohort, arena of action, social processes, intended outcomes, and the nature of support for the program.

This step drew data from three sources: the research team's knowledge, expert consultation, and a published literature search across three iterative stages. The research team (JL, MS, EFA, CP, H-MN) was made up of four experienced health services researchers, two with clinical backgrounds, one sociology and the other psychology, and a research assistant (H-MN). The team were actively mentored, and work validated by an experienced realist researcher (RH).

First we built a list of concepts and associated features characterising implementation programs for large-scale hospital interventions from key articles, [e.g., 1] our own research, and clinical

experience. This was done by the research team in two one-hour meetings. This list was verified and expanded through ongoing discussions with partners involved in large-scale, multi-site initiatives at the NSW Ministry of Health (senior policy-makers), Agency for Clinical Innovation (senior implementation support strategists) and the Bureau of Health Information (senior data management and analysis professionals involved in). Discussions occurred as one-on-one interactions (via email) or part of project meetings/updates.

Next, we examined the published literature for evidence to support or refute our list and to look for other concepts and features we had not considered. We searched Medline, PubMed, Embase and CINAHL, using the search string: *health AND ((((implementation OR driver) OR change) AND large-scale) AND ((innovation OR intervention) OR program)) AND hospital.* We set limits on English language but no date limits were set. We snowballed papers from the reference lists and added known key papers not captured by the search, and included individual studies reported in reviews. We assessed whether each of the concepts and features on our list were supported by the literature, noting each as being reported "always", "nearly always," "often," "sometimes", "rarely" or "not at all".

Table 1: The four iterative steps used to search, find, extract and synthesise evidence to generate initial program theories that explain how implementation strategies work in large-scale hospital interventions. (CMO = context, mechanism, outcome configurations)

Step	Purpose	Research Questions	Activities
1	To conceptualise implementation of large-scale hospital interventions	What are the key concepts and features of large-scale hospital initiatives and their implementation?	Build an initial list of concepts and associated features based on research team's research and clinical experience Add to the list through a search of published literature on implementation of large-scale hospital interventions

		What mechanisms might these suggest are key to driving the program?	Consider antecedents and outcomes of each feature to identify putative relevant mechanisms
2	To scope suites of implementation strategies used with large-scale hospital interventions	What implementation strategies are used for large-scale hospital initiatives? How do they fit with Step 1? What do they tell us about possible mechanisms, contexts and the underlying program theories?	Collation of implementation strategies extracted from Step 1 literature Search of additional published literature including extracted studies from systematic reviews Grey literature search: targeted websites and search terms Strategies aggregated and sorted then mapped to ERIC implementation strategies
3	Identify potential initial program theories	What formal theories might explain the mechanisms of action for the strategies listed?	Identification of formal theories from the published literature. Consideration of theories in the context of implementation strategies we have listed Refinement of the initial program theory-implementation strategy pairing through research team workshops using all data generated from the project
4	Focus on a promising implementation	What context-mechanism-outcome configurations can we	Research team workshop to develop initial CMO statements

	strategy-theory pairing and development of CMOs.	develop and test with the literature around implementation strategies linked to Organisational Readiness Theory?	Testing and refinement of CMO statements through review of literature from Steps 1-3 Final iterations of CMOs

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Using an iterative approach, the research team refined our definition of large-scale hospital interventions as we built up the list of associated concepts and features. Finally, antecedents and intended outcomes of the features as a whole and individually were developed and considered to further explore possible mechanisms that may be relevant. Articles that we included involved implementation across multiple hospital sites for interventions aimed at improving patient safety or quality of care. We did not include programs situated outside the hospital setting (e.g., implemented solely in community-based health services), interventions at only one site, locally driven interventions (e.g., internally developed, ward-based improvements) or tightly controlled research trials that were not considered "real world interventions" (e.g., randomised controlled trials). We did consider pragmatic trials if they met other parts of our definition. A data extraction sheet was used to organise concepts described in the papers found. Papers not reporting implementation strategies or activities were not included.

Step 2: Scoping suites of implementation strategies

Our next task was to identify and collate all implementation strategies that were reported as part of these types of large-scale interventions. Together with the concepts and features of the initiatives found in Step 1, this list of strategies and any information reported on how they were intended to work, were needed to understand possible contexts and mechanisms leading to outcomes.

We started our search for implementation strategies with the papers found in Step 1. Next we scanned papers found in an existing systematic review of implementation strategies used in hospital avoidance interventions for people with chronic conditions, choosing projects that met our large-scale, multi-site criteria.[23] We also searched more broadly for systematic reviews looking at implementation strategies targeting other cohorts of patients (Web of Science (all databases selected): "implementation" AND "systematic review"). We included protocol papers hoping these might provide a fuller rationale for their choice of strategies. We also included selected grey

literature from a targeted search of implementation materials from agencies known to actively support large-scale implementation programs: United Kingdom's National Health Service, Canada's Advance Care Planning, NSW Agency for Clinical Innovation, Australian Medical Research Council, Enhanced Recovery After Surgery Society, and World Health Organization. We set up a data extraction matrix, recording reported implementation strategies for each project. We also ran a Google search on 'implementation guide' and 'implementation healthcare guides.' Implementation strategies were collated and reviewed in each source.

Initially, we used our own descriptors for the strategies, but then aggregated similar strategies and mapped them to the Expert Recommendations for Implementing Change (ERIC)[9] taxonomy of 73 implementation strategies. Any strategies that did not map to an ERIC strategy were still included but noted.

Step 3: Identifying potential initial program theories

In this next step, the research team held two, two-hour meetings to workshop ideas towards identifying potential initial program theories.[19] Many theories were proposed in the workshop, mainly from our prior research experience and discussed one by one. We also read up on theories proposed by other realist researchers and added them for consideration. This work was being done in parallel with the realist evaluation of the actual state-wide initiative so this also guided our thinking. This resulted in a short list of promising theories.

The process included consideration of all the data generated so far in the project as well as searching published literature around known formal theories; in particular, we examined together the concepts identified in Step 1 and the implementation strategies identified in Step 2. That is, we considered what existing formal theories or types of theories might be relevant to explain particular implementation strategies given the concepts and putative mechanisms we had identified. For example, an implementation strategy of *conducting a local needs assessment*, fitted with the concept of *facilitation through provision of resources* and the feature *ensuring a formal period of*

planning. Organisational Readiness Theory was identified as a formal theory that promised to explain how this implementation strategy of *conducting a local needs assessment* would work across different contexts. These formal theories became the basis for our initial program theories and were matched with implementation strategies using this process. Theories were retained or excluded on their ability to broadly describe what was happening in one or more implementation strategies, how and why across a range of contexts, and a range of levels (micro, meso and macro).

Step 4: Further scoping and focus on a key strategy

As realist syntheses aim to explain how and why a program works and have the potential to generate vast amounts of data to do this well, it was necessary to carefully scope the results generated and narrow our focus. Following the example of other realist syntheses,[19,24-26] we looked for a single set of implementation strategies and their accompanying initial program theory that (a) was deemed highly important in informing our parallel tranche of work - the realist evaluation of the *Leading Better Value Care* projects in NSW, Australia - and (b) had not already been researched using realist methodology.

Results

Results of the activities used to synthesise evidence and generate initial program theories that explain how implementation strategies work in large-scale hospital interventions are outlined below. The process was driven by the fortnightly research team meetings, separate two-hour workshops, validation by other authors and stakeholders, and iterative refinements. Table 2 summarises the results from the four steps. Figures 1 and 2 show the PRISMA-style flow diagrams for steps 1 and 2 respectively.

Concepts associated with large-scale hospital intervention implementation programs (Step 1)

The research team initially listed 5 concepts associated with 12 features of large-scale hospital interventions, which grew to a final set of 16 features after further scoping of the literature. Over 400 titles and abstracts were accessed via database searching and data were extracted from a subset of 51 full text articles that met our inclusion criteria. Table 2 summarises results of Step 1 and Supplementary File 1 shows the full data extraction sheets.

Table 2: Summary of search strategy, activities and results at each of the four steps. (ERIC = Expert Recommendations for Implementing Change; CMO = context, mechanism, outcome statements).

Step	Purpose	Activity	Interim results	Final result
1	To conceptualise implementation of large-scale hospital interventions	Build an initial list of concepts and associated features based on research team's research and clinical experience, validated by key informants on the wider project. Search databases for implementation of large-scale hospital interventions, screen title and abstract for relevance, data extraction.	5 concepts and 12 features listed 381 articles found. 51 relevant articles Exclusions: not hospital-based, not large-scale, implementation not described	5 concepts and 16 features identified and described.

			4 additional features identified from the literature	
2	To scope suites of implementation strategies used with large-scale hospital interventions	Extracted data from Step 1 literature that report implementation strategies Search for published literature on implementation and screen for large-scale hospital criteria. Include known literature. Individual studies extracted from reviews Search of targeted websites and other grey literature Strategies aggregated and sorted then mapped to ERIC implementation strategies	45 articles 585 reviews found: 31 found to include relevant studies some reporting on multiple implementation strategies Data extracted from 5 sets of documents	302 reports of 28 different implementation strategies identified and collated 28 implementation strategies mapped to ERIC taxonomy, 1 did not map
3	Identify potential initial program theory areas	Identification of potential initial program theories using all data generated from the project so	3 broad domains of action identified	5 initial program theories mapped

		far plus other realist studies, compilations of program theories and literature describing individual formal theories		to implementation strategies
4	Focus on a promising implementation strategy-theory pairing and development of CMOs	Research team workshop to develop initial CMO statements informed by Organisational Readiness Theory Testing and refinement of CMO statements through review of literature from Steps 1-3 Final iterations of CMOs	All data collected so far 51 articles + 4 articles that focused on organisational readiness assessment	24 CMOs were hypothesised and literature used to support or refute them

The five concepts of large-scale hospital improvement initiatives were: (i) External, top-down source, (ii) Evidence-based interventions, (iii) Safety and quality focus, (iv) Facilitation through provision of resources, and (v) Harnessing of local resources and encouraging adaptation. Between two and four features of each were identified.

External, top-down source: Features found associated with this concept were that the interventions being implemented were externally developed: either by peak agencies or research

institutes (e.g., WHO,[27] American College of Surgeons[28]), quality collaboratives (e.g., Michigan Surgical Quality Collaborative,[29] German Quality Network[30]), or in one case, mandated, evidence-informed policy (e.g., US Veterans' Affairs (VA) National Disclosure Policy[31]). Support for implementation for the intervention itself was frequently built into this package by the external source: interventions were often presented as a "bundle" of interventions all aimed at addressing a single issue (e.g., surgical site infections,[32] treatment of blunt chest injury[33]). Checklists and implementation guides may also be provided by the external agency that developed the intervention. Contrary to our expectations, the offer of incentives or disincentives for implementation was rarely reported.

Evidence-based interventions: All interventions were identified by the authors as being evidence-based, although the evidence (e.g., the randomised control trial on which the intervention was built) itself was rarely cited. Contrary to the expectations of our research team, de-implementation of processes and practices that presumably were no longer "best practice" was rarely reported. This applied even to upgraded Information Technology systems where legacy systems were allowed to remain alongside the new programs.[34]

Safety and quality focus: A clear aim of improving patient outcomes was consistently found, often by making a case for change from baseline data. Implicit in most programs was the assumption that a positive safety culture, that saw improvement of patient outcomes as core business was present at the site. Also implicit was that there was consensus at each site that the intervention was needed, and that the implementation support provided would be acceptable.

Facilitation through provision of resources: As well as implementation guides and intervention resources, external support was seen in many projects in the form of new equipment, customised forms for documentation, and care pathways. Project officers skilled in the intervention and tasked with data collection or training were funded in some projects, often budgeted as part of an associated research component (e.g.,[35]). Partnership agreements with external agencies

facilitated implementation by providing access to specialist advice. Funding for the projects was often a mix of external (e.g., VA (USA)[31]), internal (e.g., Hornsby Ku-ring-gai District Hospital (Australia)[35]), and research-based (e.g., National Institutes of Health grants (USA)[36]). Facilitation was not always a feature. All studies relied on the goodwill of clinicians, and some did not factor in any quarantined time for implementation activities such as audits. Interventions developed by clinical collaboratives were often framed as partnerships, including access to practical support and expert advice (in-kind) for the implementation and monitoring of outcomes, some allowing dissemination of learnings from other sites, and benchmarking. Data was often provided to make a case for change, and support for ongoing audit and feedback were common features.

Harnessing local resources and encouraging adaptation: The provision of a lead-in time for each site to assess for readiness and local needs was sometimes reported, and internal support for implementation from senior management was reported in most papers. Design amenable to adaptation to fit different local practices, patient cohorts or workflows, developed by clinically based implementation teams, was also frequently reported. Clinical leadership, mentoring, supervision and in-house education were also key features.

Following this, features were refined by determining their antecedents and intended outcomes, to help with the next step of defining associated implementation strategies, mechanisms and potential initial program theories. Supplementary File 2 shows the results of this step.

Collated suites of implementation strategies (Step 2)

We found 302 reports of 28 different implementation strategies associated with large-scale hospital interventions from 45 peer-reviewed papers and five sets of grey literature documents (each linked to a single website). Figure 2 shows the PRISMA flow diagram for this step. All of the strategies except one mapped to one or a combination of strategies in the ERIC taxonomy.[9] The strategy that did not map was *Aligned with organisational/ District and Departmental priorities*. Some strategies that were similar were combined as descriptions in the articles were not sufficient

to determine exact details (e.g., *Involve executive boards* was combined with *obtain formal commitments* as it was often the executive group which was negotiating on behalf of the site. The 28 strategies are summarised in Table 3 and shown in full in Supplementary File 3. Most frequently reported or recommended strategies were: *Promote adaptability/purposely re-examine the implementation* (n=34); *Involve executive boards/obtain formal commitments* (n=24); and *Assess for readiness and identify barriers and facilitators* (n=24).

Table 3: List of implementation strategies and their frequency, found in the set of 51 grey and black literature documents. (ERIC= Expert Recommendations for Implementing Change)

ERIC taxonomy ERIC, [9]	**Implementation strategy**	**Frequency (n=51 sources)**
Access new funding	Extra staffing as needed; salary support	6
Assess for readiness and identify barriers and facilitators	Readiness	24
Audit and provide feedback	Audit and Feedback	11
Build a coalition; create new clinical teams; create a learning collaborative	Multidisciplinary involvement; clinical leadership	16
Capture and share local knowledge	Community of practice / knowledge network of clinicians	11
Change physical structure and equipment (a)	Funding for equipment	6
Change physical structure and equipment (b)	Tools to improve communication	4
Conduct cyclical small tests of change	PDSA Cycles	5
Conduct local consensus discussions; Facilitator	Local facilitator / project officer	10
Conduct local needs assessment	Identify resources required	12
Create a learning collaborative	Engaging stakeholders	7

Develop a formal implementation blueprint (a)	Implementation guides	14
Develop a formal implementation blueprint (b)	Intervention Toolkit	10
Develop academic partnerships; use an implementation advisor; use advisory boards and workgroups	Support from external experts/ external support	14
Develop and implement tools for quality monitoring	Monitoring	6
Develop educational materials; distribute educational materials	Education	18
Develop resource sharing agreements	Resources shared	1
Distribute educational materials	Clinical practice guidelines	8
Facilitation	Problem solving	2
Identify and prepare champions	Champion	4
Inform local opinion leaders	Opinion leaders	7
Involve executive boards; Obtain formal commitments	Executive sponsorship/engagement with the state-wide collective	24
Organise clinician implementation team meetings	Quarantined time for skill acquisition	4
Promote adaptability; purposely re-examine the implementation	Local adaptation	34
Provide clinical supervision	Mentoring/ Supervision/ coaching	16
Recruit, designate, and train for leadership	Clinical leadership	10
Use data experts	IT and communication support for new processes	6

(No ERIC equivalent)	Align with organisational/ District or Departmental priorities	12
Total		302

Identify potential initial program theories (Step 3)

The research team workshop started by considering both the concepts and features from Step 1 and the strategies from Step 2 to identify high level domains in which our potential initial program theories and their underlying mechanisms would be expected to work. Four of these domains were identified: social processes and influences; assessment and planning; accessing resources; and partnering outside the organisation. Domains were not seen as mutually exclusive but connected and interdependent. A list of formal theories that addressed these domains was compiled through researcher knowledge and discussion, searching other published realist studies, literature on program theories, and online searches. Five formal theories that explained in a very broad sense, how various strategies might be expected to work were selected through discussion. The theories that were selected were: Organisational Readiness Theory, Social Cognitive Theory, Partnership Synergy Theory, Diffusion of Innovation, and the Theory of Planned Behaviour. Table 4 summarises the selected formal theories. Table 5 shows the strategies, concepts, domains and their matched theories.

Table 4: Summaries of formal theories selected as potential initial program theories to explain mechanisms across different contexts of the implementation strategies identified.

Theory	Overview (sources)
Organisational Readiness Theory	Readiness for change refers to organisational members' shared resolve to implement a change (change commitment) and shared belief in their collective capability to do so (change efficacy).[37]

Social Cognitive Theory	Behaviour is influenced by three mechanisms operating in concert: direct personal agency; proxy agency that relies on others to act on one's behalf to attain the desired goals; and collective agency where the larger group acts.[38]
Partnership Synergy Theory	Partners who effectively collaborate and share knowledge, skills and perspectives are able to achieve more value than the sum of the individual parts contributed.[39]
Diffusion of Innovation	Explains how an innovation, new idea, or product spreads, mediated by social processes within a population over time. A slow start by innovators and early adopters demonstrates the innovation in practice, increasing confidence. A tipping point is reached after a time when the majority take up the new practice. A small group of conservative and risk aversive "laggards" will be the last to adopt.[40]
Theory of Planned Behaviour	Three independent constructs determine a person's intention to perform a specific behaviour: "attitude" refers to how positively or negatively a person perceives the behaviour; "social norm" refers to the perceived pressure from others to perform the behaviour; "perceived behaviour control" relates to how easy or difficult the person thinks it will be to perform the behaviour.[41]

CMO statements from the Organisational Readiness Theory (Step 4)

Weiner defines organisational readiness as multi-level and multi-faceted construct referring to an organisational members' shared commitment to change - encompassing both willingness and capacity.[37] This readiness for change is crucial in producing collective engagement; that is achieving buy in and commitment from those at the front lines enacting the change. This engagement results

in valuable implementation outcomes: a collective commitment to initiate change, greater effort to make the change successful, greater perseverance when barriers are encountered and an increase in pro-social collaborative behaviours that promote the change.[37] Holt, Amenakis and colleagues,[42] state the most potent mechanisms were shared perceptions and beliefs among stakeholders in the organisation that (a) they are capable of implementing the proposed change (i.e., *change-specific efficacy*), (b) the proposed change is appropriate for the organisation (i.e., *appropriateness*), (c) leaders are committed to the proposed change (i.e., *management support*), and (d) the proposed change is beneficial to organisational members (i.e., *personal valence*). Perceptions about resources are considered the active means to achieve readiness rather than the resources themselves.[37]

In an iterative process undertaken by the research team, CMOs were configured, to understand what circumstances (context) needed to be present in an implementation strategy to trigger an identified mechanism leading to an outcome. Since many of the strategies overlapped in their mechanisms and outcomes, we considered them both together and separately. We limited our enquiry to how the mechanisms worked on the implementers within an organisation; i.e., the people delivering the intervention directly to patients, rather than the designers or facilitators of the intervention. The outcomes associated with the Theory of Organisational Readiness were all around engagement, buy-in and commitment to the change.

At the same time as the CMO statements were being configured, articles that reported enough detail on these strategies were reviewed for evidence looking for specific contextual factors (external, organisational or individual [13]) and mechanisms. A further search specifically for implementation projects across multiple sites that reported using organisational readiness theory was also performed, yielding another four papers. The final column of Table 6 indicates the articles that give evidence to support or not support the CMO configurations.

Supplementary file 4 shows the RAMESES checklist for this synthesis. Supplementary file 5 shows the full search string used in the early steps.

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ERIC strategy	Domain	Associated concepts (bold) and intended outcomes	Associated initial program theories
Develop a formal implementation blueprint	Baseline assessment and planning	**Clear implementation plan or blueprint for change** **Clear aim of improving patient outcomes:** Clear communication of expectations across sites; tool for planning changes **Provide support for comparison across sites implementing the intervention**	*Social Cognitive Theory*
Conduct cyclical small tests of change	Ongoing assessment	**Designed with adaptation to local settings in mind:** Incremental changes easier than multifaceted ones	*Social Cognitive Theory*
Promote adaptability; purposely re-examine the implementation	Ongoing assessment	**Designed with adaptation to local settings in mind:** Negotiation, needs assessment, ownership of change	*Social Cognitive Theory*
Build a coalition; create new clinical teams	Partnering	**Facilitate access to reputable advice and problem-solving assistance:** Inclusion, trust, common goal, breadth of expertise	*Partnership Synergy Theory*
Develop academic partnerships; use an implementation advisor;	Partnering	**Facilitate access to reputable advice and problem-solving assistance:** Breadth of expertise, social support	*Partnership synergy theory*

use advisory boards and workgroups			
Align with other priorities	Social processes	**Formal period of planning and needs assessment**: Assess the fit with current workflow, personal and organisational goals aligned	*Organisational Readiness Theory* *Social Cognitive Theory*
Conduct local needs assessment	Baseline assessment and planning	**Formal period of planning and needs assessment**: Assessing readiness; understanding implications of change on workflow and practice **Designed with adaptation to local settings in mind**	*Organisational Readiness Theory*
Assess for readiness and identify barriers and facilitators	Baseline assessment and planning	**Formal period of planning and needs assessment**: Setting up conditions that support change	*Organisational Readiness Theory*
Change physical structure and equipment	Accessing resources	**Provide or facilitate practical support in the form of resources and equipment**: Aligning structure with process	*Partnership Synergy Theory*
Use data experts	Partnering	**Provide data support for new or changed IT systems, baseline audits and ongoing monitoring:** Partnership with experts to support change	*Partnership Synergy Theory*
Develop resource sharing agreements	Partnering	**Provide or facilitate practical support in the form of resources and equipment**: Working with others to effect change	*Partnership Synergy Theory*

Develop educational materials	Baseline assessment and planning	**Formal period of planning and needs assessment**: Setting up educational support / conditions that support change	*Organisational Readiness Theory*
Distribute educational materials	Accessing resources	**Provide practical support in the form of education and skill acquisition:** Knowledge and skill acquisition, increase in personal and collective competence and confidence	*Social Cognitive Theory*
Provide clinical supervision	Social processes and influences	**Provide practical support in the form of education and skill acquisition:** Social support, role modelling, and practice of new behaviours **Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions**	*Social Cognitive Theory*
Access new funding	Accessing resources	**Provide practical support in the form of resources and equipment**: Setting up conditions that support change	*Partnership Synergy Theory*
Create a learning collaborative	Social processes	**Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:** Social influences supporting change and learning	*Diffusion of innovation* *Organisational Readiness Theory*

Facilitation	Social processes	**Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:** Breadth of expertise, social support	*Diffusion of innovation*
Identify and prepare champions; inform local opinion leaders	Social processes	**Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:** Social influence supporting change	*Diffusion of innovation* *Organisational Readiness Theory*
Involve executive boards; Obtain formal commitments	Social processes	**Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:** Trust, social support, legitimacy, accountability	*Social Cognitive Theory* *Diffusion of Innovation* *Organisational Readiness Theory*
Recruit, designate, and train for leadership	Social processes	**Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:** Social influence supporting change **Provide or facilitate practical support in the form of education and skill acquisition:**	*Social Cognitive Theory* *Diffusion of innovation*
Organize clinician implementation team meetings	Social processes	**Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:** Social influence supporting change, setting common goals and expectations	*Organisational Readiness Theory* *Theory of Planned Behaviour*

Conduct local consensus discussions	Social processes	**Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:** Social influence supporting the setting of clear objectives, building local trust, planning **Designed with adaptation to local settings in mind**	*Organisational Readiness Theory* *Partnership Synergy Theory* *Theory of Planned Behaviour*
Audit and provide feedback	Baseline assessment and planning Ongoing assessment	**Formal period of planning and needs assessment**: Setting up tension for change **Provide support for comparison across sites implementing the intervention:** Standardised collection of data sets up a tension for change, diagnoses areas for individual sites to work on, and tracks progress locally and across sites	*Organisational Readiness Theory*
Capture and share local knowledge	Social processes	**Support for comparison across sites implementing the intervention:** Increase the breadth of expertise, social support	*Social Cognitive Theory*
Develop and implement tools for quality monitoring	Baseline assessment and planning Ongoing assessment	**Support for implementation built into intervention**: Setting up conditions that foster change and decrease participant effort **Provide support for comparison across sites implementing the intervention**	*Organisational Readiness Theory*

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Table 6: Context-Mechanism-Outcome configurations for implementation strategies aligning with Organisational Readiness Theory. The broad context is for individual and collective implementers of large-scale hospital interventions.

Implementation strategy (ERIC wording)	**Context**	**Mechanism**	**Outcome**	**Component of Organisational Readiness Theory**	**Evidence from the literature on large-scale hospital projects**
Baseline audit results shared with implementers (Audit and provide feedback)	When implementers see their baseline audit results and perceive that current practice is not optimal	…a tension for change is developed leading to	… members being more likely to engage in the project	Appropriateness Personal valence	Support[10,43]
Clear evidence provided on effectiveness of intervention	When implementers see clear evidence that the intervention is effective and will improve patient care	… implementers value the change	… members are more likely to engage in the project	Appropriateness Personal valence	Support[44]

(Audit and provide feedback)	When implementers do not see clear evidence of the effectiveness of the intervention / do not see the link with improved outcomes for patients	… implementers do not value the change	… members are less likely to engage in the project	Appropriateness Personal valence	Limited support[45,46]
Sharing the positive experience of early adopters of the intervention (Create a learning collaborative)	When implementers are told of the success of early adopters at other sites	…a tension for change is developed and perceptions of feasibility at their own site will improve leading to	… members being more likely to engage in the project	Appropriateness Personal valence	Support[47]
A lead-in period is provided when local needs are assessed	When local needs of implementers are assessed before any proposed change	… confidence in capability rises, resulting in greater	… resulting in more effective implementation	Appropriateness Change-specific efficacy	Support [10,33,48-51] Not supported[52]

(Conduct local needs assessment)	When local needs are not accurately assessed (e.g., time needed for new practice underestimated)	levels of commitment and collaboration … confidence in capability falls, resulting in poorer levels of commitment and collaboration	… resulting in poor adoption and outcomes		Support[48]
Executive and management are engaged and support the intervention (Involve executive boards; Obtain formal commitments)	Executive /management support that is visible to the implementers Commitment to support the change from executive level is communicated to implementers Executive /management support is inadequate or not visible to the implementers	… increases perceptions of feasibility and organisational capacity … increases perceptions of feasibility and organisational capacity … decreases perceptions of feasibility and value of the change	… resulting in increased engagement … resulting in increased engagement … resulting in lack of engagement	Management support	Support[10,51,53-55] Support[30,44,49-51] Support[34,48]

					Supported[56]
	Executive /management support is inadequate or distant, but local or within team leadership is seen as strong and autonomous	… does not decrease perceptions of feasibility and value of the change	... and does not impact intention to commit		Supported[55]
	Executive /management support is inadequate, but local or within team leadership is seen as strong	… increases perceptions of siloed change, decreasing perceptions of feasibility	… resulting in lower staff buy-in and commitment		Supported[55]
	Executive /management support is inadequate, and local or within team leadership is	… decreases perceptions of feasibility and value of the change	… resulting in lack of engagement		

	also inadequate/ non participatory				
Support from external agencies / peak bodies for the intervention (Develop academic partnerships; use an implementation advisor; use advisory boards and workgroups)	When external support and/or endorsement of the proposed change is present	implementers may value the change more favourably or feel a greater tension for change	…resulting in increased engagement and commitment	Appropriateness	Support[10,29,44,49,53,57]
Clear and consistent communication with identified /designated leaders of the intervention	Consistent messages and actions from leaders, opinion leaders and champions	… increase perceptions of organisational capacity	… resulting in more effective engagement	Management support Appropriateness	Support[49,57]

(Identify and prepare champions; Recruit, designate, and train for leadership)	Mixed or missed information from leaders, opinion leaders and champions	… decrease perceptions of organisational capacity and disempowerment	… resulting in poorer engagement		Support[48,58]
Align intervention with other organisational priorities	When the proposed change aligns with other organisational or national priorities	… implementers may value the change more favourably and see their efforts as contributing to a larger, more significant program	… resulting in more effective engagement	Personal valence Appropriateness	Support[44,57]
	When the proposed change is part of a collaborative effort across multiple sites	… stakeholders' perceptions of the value of the change may increase	… resulting in greater commitment		Support[29,30,44,59]
Align with known concerns/priorities of implementers	When the proposed change aligns with the personal priorities of implementers	…the change is valued more highly by implementers	… resulting in more effective engagement	Personal valence	Support[34,50]

	When the proposed change does not align with personal or group priorities/ do not make sense	… the value of the change is discounted	…resulting in poor engagement	Individual and group valence	Support[58]
Provide opportunities for formal and informal planning and knowledge exchange around the intervention (Create a learning collaborative; Capture and share local knowledge)	When there is appropriate and timely information sharing through social interaction, and shared experience	… may increase collective vision and purpose	… resulting in greater engagement and persistence		Support[10,43,48,50,51,57]
Providing appropriate education	Development of educational packages appropriately pitched at key implementers	…… increase perceptions of feasibility and organisational capacity	… members are more likely to engage in the project	Change-specific efficacy	Support[33,43,50,57,59]

(Develop educational materials)	Development of educational packages not tailored to specific group's knowledge base perceived as inappropriate	… decreases perceptions of capability	…members are less likely to engage or commit to the project		Support[48]
Providing appropriate implementation support (Facilitation: Develop a formal implementation blueprint)	Provision or preparation of implementation blueprints or plans	…… increase perceptions of feasibility and organisational capacity	… members are more likely to engage in the project	Change-specific efficacy	Support[33]
Appealing to past successes	In spite of previous successes and capabilities, if local needs and capabilities are not considered adequate by those enacting this specific change proposed ….	… collective capability will be seen as deficient	… levels of commitment will be poor	Change-specific efficacy	No evidence found

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Discussion

In this realist review of implementation strategies for large-scale hospital interventions we have used a four-step process to build a clearer picture of the nature and purpose of implementation and identify likely mechanisms driving intended and unintended outcomes. In the final step we focussed on early implementation strategies around baseline assessment and planning to define and test CMO statements explaining outcomes.

In Step 1, we articulated the key concepts associated with implementation programs of large-scale hospital interventions. Providing practical and social support figured prominently, as did establishing credibility, level of evidence and intended outcomes of the intervention through clear blueprints and collaborative learning and planning activities. While many of the interventions themselves were prescriptive (e.g., surgical checklists[10-12]), the need for implementation to include local needs assessments and tailored activities was also clear. In Step 2, we identified suites of implementation strategies for large-scale hospital interventions and found them to be multifaceted, directed at both individual and organisational levels, and often interdependent. For example, while nearly all the large-scale projects reported education and local leadership, these would only be successful as strategies if they were combined with executive support for the project, and a collective sense of the need for change. It can be argued that the precursor to all implementation strategies is the engagement of the implementers, as without their commitment to change, no substantive change can be achieved. The choice to use Organisational Readiness Theory to further develop the initial program theories was prompted by this observation.

Organisational Readiness Theory postulates that engagement and commitment to any proposed change will be strongly influenced by individual and collective perceptions around the need for the intervention, its quality and effectiveness, the level of support from management and executive that is apparent, and the feasibility of using it. Support for the hypothesised CMOs was

found across multiple projects providing strong evidence of the theory's applicability in large-scale hospital interventions.

Evidence found in our set of literature almost all supported CMOs that led to positive, desirable implementation outcomes of engagement and commitment. There was some refuting evidence that pointed to the interdependence of some factors, and that at times one contextual factor could interact and outweigh another. For example, Wyld and colleagues found that although all stakeholders involved with a new biobank highly valued the initiative, doctors tasked with collecting the samples felt early consultation, management support and consideration of the feasibility for them had been lacking.[52] In spite of this, the implementation of the program had been successful with almost universal adherence to the new processes by the doctors. Possibly, the patients' altruistic enthusiasm for the initiative, that was often voiced to the doctors during the informed consent process may have put greater value on the initiative, outweighing the doctors' difficulty.

Evidence for contextual factors that triggered mechanisms leading to poorer outcomes were also found. Bayley and colleagues note the mismatch in perceptions of feasibility found between managers and implementers, and between different healthcare professionals contributing to the multidisciplinary team effort of implementing stroke rehabilitation guidelines.[48] This same project found that perceptions of feasibility were also negatively affected by overly complicated statements of the intervention and called for a "plain English" version that would be more accessible for busy clinicians. Both contextual factors were considered barriers as this collective perception of lack of support and lack of feasibility triggered disengagement and lack of commitment to the change.

Some authors, lacking high quality evidence, suggested the cause of poor implementation outcomes might be linked to contextual factors. For example, Reames and colleagues suggest that the failure of their large-scale hospital intervention to effect change might be because it required staff to follow processes that were not strongly associated with clear patient improvements.[45] This

perception of lack of effectiveness would not trigger the mechanism of building a tension for change, but complacency leading to poor adoption of the intervention. Wand and colleagues found that disagreement voiced by a senior clinician in the early planning stages of an intervention was likely to adversely affect the project's success unless it could be resolved.[46] Here the perception of implementers would be that the intervention was not feasible or appropriate, and trigger disengagement. While these examples do not claim to be high level evidence, but rather the informed opinion of the authors, they are intuitively correct and consistent with the other evidence found in this study.

Strengths and Limitations

Our search for literature was systematic and thorough yet only resulted in 51 papers. This was because while large-scale hospital interventions abound, implementation activities and outcomes are not commonly reported.[60] This meant many articles reporting interventions were not relevant to the present study. Even for papers reporting implementation, reporting of these strategies and the contexts in which they were used was often not detailed enough to develop theories. Notable was the lack of accounts of patient involvement in implementation plans. Articles that were found were mostly reporting successful implementations and this is an acknowledged bias of published literature. While CMOs are useful in explaining single factors, multiple contextual factors may arise that modify how mechanisms work. Lack of detail in reporting meant the O (outcomes) in our CMO configurations were high level and dichotomous: implementers were engaged or implementers were not engaged. Another limitation was the need to constrain our search and inquiry to a subset of strategies and a single formal theory. Strengths included the expertise of the research team (including clinical and implementation science expertise) and the systematic four step iterative investigation.

Conclusions

Large-scale hospital interventions hold the promise of standardising high quality, evidence-based care for large numbers of patients but must be supported with appropriate implementation strategies to support and effect change. The study has used realist methodology to tease out how initial planning activities can drive engagement and commitment and delineate the contextual factors required to trigger mechanisms. These findings, using *Organisational Readiness Theory*, will add to understandings around why large-scale projects work some of the time but not all of the time. Evidence has been presented around a set of CMO hypotheses, showing the importance of implementers' perceptions around feasibility, support, and value in triggering engagement and commitment to the proposed change.

Abbreviations

CMO Context Mechanism Outcome

ERIC Expert Recommendations for Implementing Change

NSW New South Wales

Declarations

Ethics approval

Not applicable – using publicly available data.

Consent to participate

Not applicable as there were no participants.

Patient and public involvement

Patients and the public were not involved in this study.

Consent for publication

Not applicable.

Availability of data and materials

All data generated or analysed during this study are included in this published article [and its supplementary information files].

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

JCL conceptualised the synthesis, and JCL, CP, HMN, MS, EFA and RH contributed to the overall design. JCL, CP and HMN conducted the database search, article screening and data extraction. JCL conducted the synthesis and drafted the first manuscript. MS, EFA, RH and JB contributed to the final versions of the manuscript. All authors read and approved the manuscript.

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Figures

Figure 1: PRISMA-style flowchart for data sources in Step 1

Figure 2: PRISMA-style flowchart for data sources in Step 2

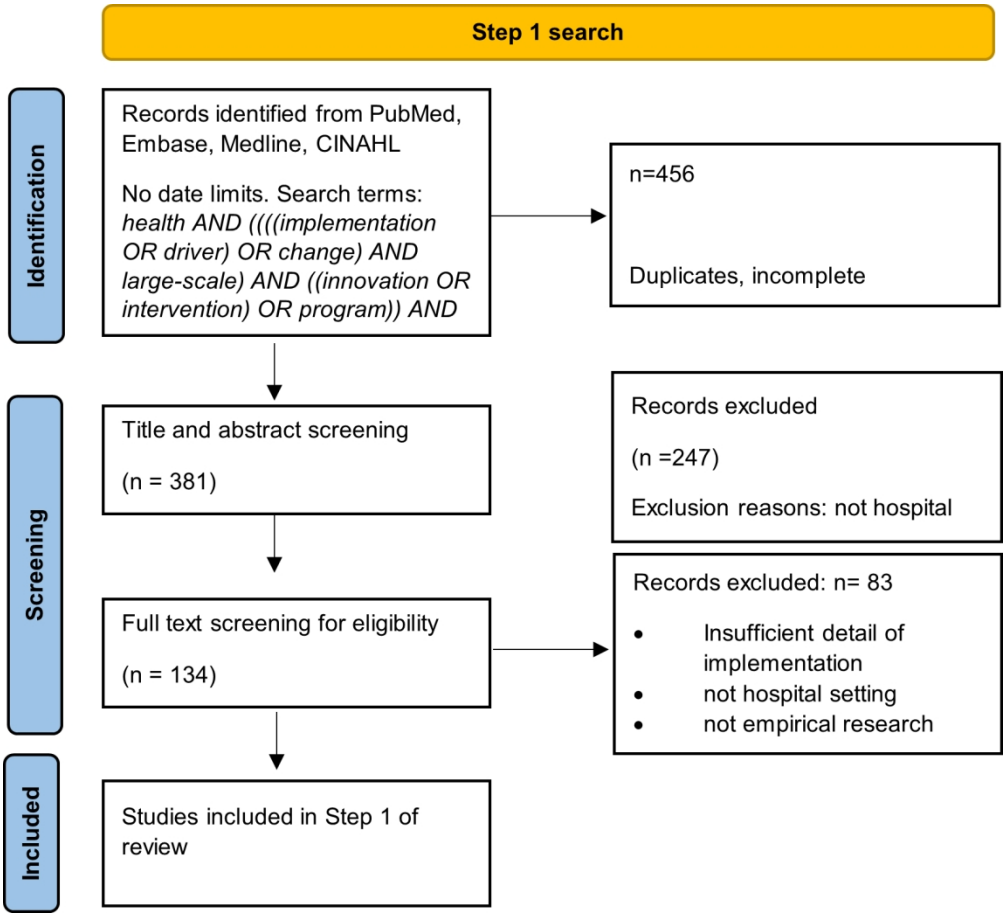

Figure 1: PRISMA-style flow cahrt for step 1. (Based on: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71)

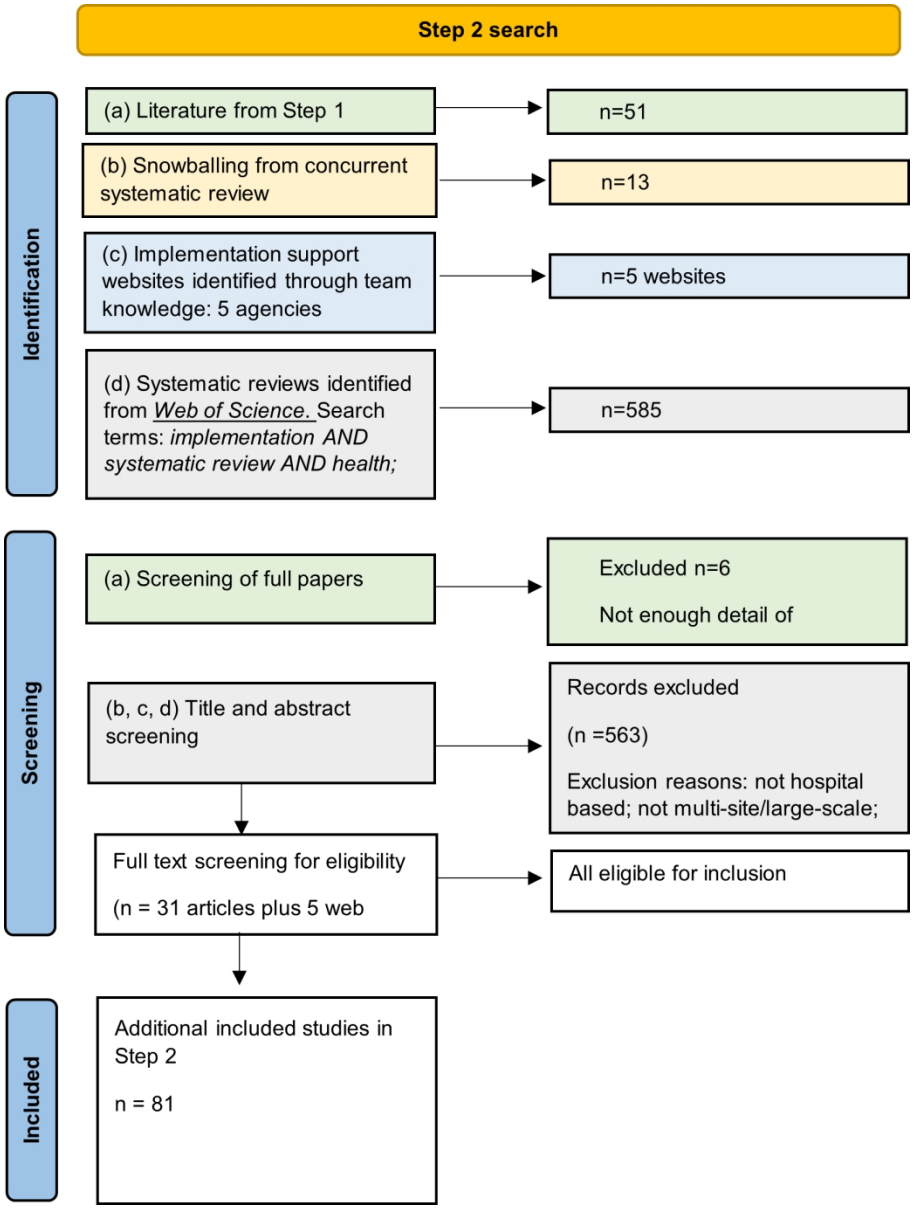

Figure 2: PRISMA-style flowchart for Step 2 (Based on: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71)

Reference	Year	Source	Country	Name of the Intervention (e.g., WHO Surgical Checklist, QARISMA)	No. of hospitals involved (N)
Allegranzi B, Aiken AM, Zeynep K	2018	Database search	Kenya, Uganda, Zimba	African Surgical Unit-based Safety Programme (based on WHO guidelines)	5
Bayley MT, Hurdowar A, Richards	2012	Database search	Canada	The Stroke Canada Optimization of Rehabilitation by Evidence project (SCORE project)	5 stroke rehab centres
Borchert M, Goufodji S, Alihonou	2012	Database search	Benin, W Africa	Obstetric near-miss case reviews	5
Brink AJ, Messina AP, Maslo C, et	2020	Database search	South Africa	Hand hygiene informed by Cochrane reviews	50
Cameron M, Jones S, Adedeji O. A	2015	Database search	UK	Traffic light antibiotic prophylaxis poster based on Scottish Intercollegiate Guidelines Network guidelines	3
Cima R, Dankbar E, Lovely J, Penc	2013	Database search	USA	American College of Surgeons National Surgical Quality Improvement Program: rsulting in multiple interventions around SSI prevention	1 (but part of a national program)
Cresswell K, Morrison Z, Crowe S,	2011	Database search	UK	Lorenzo software	4 'early adopter' sites
Cuypers M, Al-Itejawi HHM, van I	2019	Database search	Netherlands	International Patient Decision Aids Standards (IPDAS)	33
de Groot JJ, Maessen JM, Slanger	2015	Database search	Netherlands	Enhanced Recovery After Surgery but studying implementation strategies: breakthrough versus stepped	Protocol - not given
Dekker-van Doorn C, Wauben L,	2020	Database search	Netherlands	Time out procedure and debriefing in Operating theatres	10

Dumont, A., P. Fournier, M. Abra	2013	Database search	Senegal and Mali	QUARITE (quality of care, risk management, and technology in obstetrics) trial	46
Edward, K. L., K. Walker and J. Du	2017	Database search	Australia	Translating Research into Practice implementation model.	9
Forchuk, C., M. L. Martin, E. Jens	2013	Database search	Canada	The transitional relationship model (TRM)	6
Foy, R., G. C. Penney, J. M. Grims	2004	Database search	Scotland	Tailored multi facteted strategy delivered by Scottish Programme for Clinical Effectiveness inReproductive Health	26 (all hospital gyanecology units in Scotland)
Fuller, C., S. Michie, J. Savage, J. M	2012	Database search	England and Wales	The Feedback Intervention Trial (FIT) of a national cleanyourhands campaign	16 trusts (60 wards)
Grazioli, V. S., J. C. Moullin, M. Ka	2019	Database search	Switzerland	Case Management of frequent users of Emergency departments	Not specied but over a large Canton
Havers, S. M., P. L. Russo, K. Page	2019	Database search	Australia	Aseptic technique policy	Not stated
Haynes, A. B., L. Edmondson, S. R	2017	Database search	USA	A customized version of the WHO Surgical Safety Checklist - part of the Safe Surgery South Carolina program	14/58
Hendy, J., N. Fulop, B. C. Reeves,	2007	Database search	UK	NHS information and technology (IT) programme	4 Trusts /all in UK
Keller, H. H., R. Valaitis, C. V. Laur	2019	Database search	Canada	More-2-Eat project	5

Kotagal, U. R., J. M. Robbins, N. M	2002	Database search	USA	Bronchiolitis clinical practice guidelines	11
Kourouche, S., T. Buckley, C. Van,	2019	Database search	Australia	Blunt chest injury care bundle	2
Luxton et al 2014, Caring letters f	2014	Database search	USA	Caring Letters	6 Defence department hospitals with acute psych units
Maguire et al 2016, Evaluating th	2016	Database search	USA	National disclosure policy after adverse events developed by Veterans' Affairs	All 150 VA administered hospitals
Makene, et al 2014 Improvement	2014	Database search	Africa	Several interventions for newborns and maternal health	251 facilities; 52 in evaluation

Mansoori et al 2012 Picture Arch	2012	Database search	USA	Picture Archiving and Communication System (PACS)	four specialty hospitals, six additional community hospitals, and in all associated outpatient clinics
Marcus RK, Lillemoe HA, Rice DC,	2019	Database search	USA	Enhanced Recovery Protocols	One - across multiple oncology specialties
McCreight MS, Lambert-Kerzner ,	2019	Database search	USA	Anti-platelet therapy adherence	20 VA medical centres
McFarland MS, Thomas AM, Your	2020	Database search	USA	Pharmacist-to-Pharmacist Transitions of Care Initiative	2 VA medical centers, 18 community-based outpatient clinics
McNeely J, Troxel AB, Kunins HV,	2019	Database search	USA	Consult for Addiction Treatment and Care in Hospitals (CATCH)	6

	2019	Database search		Anaesthetists Be Cleaner	5 hospitals x 5 departments
Merry AF, Gargiulo DA, Bissett I,			New Zealamd		
Molina G, Jiang W, Edmondson L	2016	Database search	USA	Safe Surgery 2015 initiative to implement SSCs in South Carolina hospitals	67 (reporting on 13)
Monico LB, Oros M, Smith S, Mit	2020	Database search	USA	Screening, Brief Intervention, and Referral to Treatment (SBIRT)	24 EDs
Moore, J. E., A. Mascarenhas, C. I	2014	Database search	Canada	Mobilization of Vulnerable Elders in Ontario (MOVE ON)	26 hospital units
	2012	Database search		The Productive Ward: Releasing Time to Caree programme	
Morrow, E., G. Robert, J. Maben			UK		5
Mudge, A. M., M. D. Banks, A. G.	2017	Database search	Australia	Eat Walk Engage	4
Nocera, M., M. Shanahan, R. A. M	2016	Database search	USA	Period ofPURPLE Crying: Keeping Babies Safe in North Carolina,	86
Palomar, M., F. Alvarez-Lerma, A.	2013	Database search	Spain	The Bacteremia Zero study	192 ICUs
Pronovost, P. (2008). "Interventic	2008	Database search	USA	The Keystone Intensive Care Unit Project	108 ICUs

Pronovost, P., D. Needham, S. Be	2006	Database search	USA	The Keystone Intensive Care Unit Project	109 ICUs
Pun, B. T., S. M. Gordon, J. F. Pete	2005	Database search	USA	Society of Critical Care Medicine guidelines re sedation and monitoring	2
Reames BN, Krell RW, Campbell D	2015	Database search	USA	Keystone Surgery Program	29
Schwarzkopf, D., H. Ruddel, M. G	2018	Database search	Germany	German Quality Network Sepsis	75
Schweizer, M. L., H. Y. Chiang, E.	2015	Database search	USA	Study to Optimally Prevent Surgical Site Iinfections in Select Cardiac and Orthopedic Procedures (STOP SSI)	20
Stolldorf, D. P., J. L. Schnipper, A.	2019	Database search	USA	Multi-Centre Medication Reconciliation Quality Improvement Study (MARQUIS2).	18
Terkola R, Czejka M, Berube J. Ev	2017	Database search	Europe	Gravimetric workflow software systems	10 pharmacy services in 5 European countries
Toltzis, P., M. O'Riordan, D. J. Cur	2014	Database search	USA	Pediatric surgical site infection prevention bundle	18

	2018	Database search	Netherlands	Fast track cancer diagnostics	One large cancer centre across 18 tumour types
Vu JV, Collins SD, Seese E, Hendre	2018	Database search	USA	Michigan Surgical Quality Collaborative (MSQC) Surgical Site Infection bundle	52
Wand, T., C. Crawford, N. Bell, M	2019	Database search	Australia	Mental health model of Care for patient in ED	3
Wyld, L., S. Smith, N. J. Hawkins,	2014	Database search	Australia	Institutional biobanking	2
Additional papers using Organistional Readiness Theory					
Zapka, J., K. Simpson, L. Hiott, L. I	2013		USA	Telemedicine outreach service for underserved rural hospitals	4
Sharma, N., J. Herrnschmidt, V. C	2018		Switzerland	Matching Registered Nurse Services with Changing Care Demands	23
Rees, G. H. (2014). "Organisation	2014		New Zealand	Lean thinking initiative	3
Website search					
ACI Redesign		health.nsw	Australia	See supplemenatary file 3	
Advance care planning		w.canada.c	Canada		
NHMRC Implementation Guideline		w.nhmrc.g	Australia		
NHS NICE Chronic heart failure		w.nice.org.	UK		
WHO Surgical Checklist		w.who.int/	Global		

How is it characterised by the authors? (National, multisite, policy /research /trial /package/ directive/ priority	Source of the intervention I=developed in-house by the team implementing it; E=developed	Evidence of local adaptation? Y; N	Initiative funding: E=external funding; I=internal funding;	External Support e.g., researchers from Universit	Formal Internal Support for the project (e.g.,	Formal outcome measures collected. Y;N	Evidence of System Change (e.g., new forms, new IT, new	Any mention of active de-implementation of usual care	Any mention of adaptability? Or ownership ?
multimodal infection control intervention / a mult	E	Y	E	Y	Y	Y		N	Y
a pilot implementation study across 5 diverse site	E	Y	Not stated	Y	Y	Y	Not really	N	Y
a quality assurance intervention suitable for hospi	E	Y	E	Y	Y	Y	Y	N	Y
a five-phase multi-faceted HH management syster	E	Y	I	Y	Y	Y	Y	N	Some
Intervention	E	Y	R	Y	Y - implied	Y	Y poster	N	N
nationally validated system that uses clinically abs	E	Y	Not stated	Y	Y	Y	Y - resource	Y new proce	Y - more QI
the implementation of Lorenzo as a complex type	E	N	E	N	Y	Y	Y	Not reporte	All tight
multi-regional implementation	E	Y	E, R	Y	Not reporte	Y	Y	N	Y - some ne
multi-regional implementation	E	Protocol	I	Y	Y	Y	protocol	protocol	Y
multi-site study using participatory action researcl	E	Y	Not stated	Y	Y	Y	Yes	Yes some	Y

multifaceted intervention / a cluster-randomised t	E	Y	I/R	Y	Y	Y	Y	N	N
Trial of the implementation intervention: addressi	E	Y	E, R	Y	Y	Y	Y	Not reporte	Y
quasi-experimental testing of implementation of T	E	Y	R	Y	Y	Y	Y	Not reporte	Y
a tailored multifaceted strategy implementa=ing g	E	Y	R	Y	Y	Y	N	N	Y
Three year stepped wedge cluster RCT of a feedba	E	Y	I/R	Y	Y	Y	Y	N	N
effectiveness-implementation hybrid trial	E	Protocol	R	Y	Y	Y	Protocol	Protocol	Protocol
the implementation of aseptic technique policy re	E	N	I	N	Y- implied it	Y	Y	N	N
The Safe Surgery 2015 South Carolina program	E	Y	E	Y	Y	Y	Y	Not reporte	Y
the largest civilian IT programme in the world	E	N	E	Y	Y	Y	Y	Surprisingly	N
implementation of an evidence-based nutrition ca	E	Y	E	Y	Y	Y	Y	No	Y

multisite implementation of an evidence-based cli	E	Y	Not reporte	Y	Y	Y	Y	N	Y
implementation of a blunt chest injury care bundl	E	Y	R	Y	Y - implied	Not reporte	Y	N	Y
National trial/ research	E	N	R	Y	Y	Y	Y, new emai	N	N
National policy	E	N	I	N	Y	Y	Y new proce	N	Learning ho
large-scale quality improvement intervention	E	Y	E	Y	Y	Y	Y, new equi	Y	Y - each faci

Multisite implementation	E	Y	I	Y	Y	Y	Y; IT, proces	Y	N
multispecialty implementation of ER protocols at ;	E	Not clear	R,I, E	Y	Y	Y	Y , processe	N	N
multi-site randomized stepped wedge trial to test	E	N	R, I	Y	Y	Y	Y, processes	N	N (CT)
large-scale pharmacist-to-pharmacist TOC model p	E	N	R, I	Y	Y	Y	Y, processes	N	N
pragmatic trial at six hospitals; program	E	N	R, I	Y	Y	Y	Y - extensive	N	N

an evidence-based bundle, stepped wedge, cluste	E	Y	E	Y	Y	Y	Y, processes	N	Y
state-wide/ large-scale implementation of surgical	E	Y	E	Y	Y	not reporte	Y checklist	N	Not reporte
a state-wide effort in Maryland to expand SBIRT ir	E	N	E	Y	Y	Y	Y screening	N	N
a multi-site implementation intervention in acute	E	Y	I, E, R	Y	Y	Not reporte	Y	N	Y
large-scale quality improvement	E	Y	Mixed	Y	Y	Y	Y	Y	Y
a multi-site improvement program	E	Y	I, E, R	Y	Y	Y	Y	Protocol	Y
statewide nurse training program	E	N	Mixed	Y	Y	Y	Y	N	N
national mulitmodal intervention	E	Y	Mixed	Y	Y	Y	Y	N	Y
statewide quality improvement initiative	E	Y	Not clear	Y	Y	Y	Y	N	Y

statewide quality improvement initiative	E	Y	Not clear	Y	Y	Y	Y	N	Y
a process-improvement project	E	N	R, I	Y	Y	Y	Y	N	N
Statewide, checklist-based quality improvement ir	E	Y	I	Y	Y	Y	Y	Y - checklist	Yes - local a
a quality collaborative	E	Y	I/E	Y	Y	Y	Y	N	N
the multisite pragmatic trial	E	Y	I	Y	Y	Y	Y	N	Y
patient safety strategy that is widespread in US hc	E	y	I/E	Y	Y	Y	Y	N	N
a large-scale, multicentre, multinational	E	N	Not clear	Not report	Y	Y	Y new softw	Y	Not reporte
A quality improvement collaboration in Ohio com	E	Y	I/E	Y	Y	Y	Y	N	N

Large scale implementation	E	Y	I	Y	Y	Y	Y: new processes, new equipment		
a “bundle” of care processes	E	Y	I	Y	Y	Y	Y	Not reporte	N
multi-site translation research project to impleme	E	Y	I/R	Y	Y	Y	NA pre-impl	N	Y
modern, large-scale research initiative	E	Y	I/R	Y	Y	Y	Y	N	Y
academic-clinician partnership	E	Y	E	Y	Y, N	Y	NA pre-impl	N	Y
a cross-sectional multicentre study	E	N	E	Y	Y	Y	Y	N	N
Lean management philosophy and activities	E	Y	E	Y	Y	Y	Y	N	N

Implementation strategies, frameworks named / discussed?	Implementation Strategies
Comprehensive Unit-based Safety Programme developed in the USA, is a five-step iterative process	Formation of implementation teams to oversee; senior executive sponsorship; clinical leads; education; audit and feedback; assess safety culture; accountabiity for senior staff and leaders; tools to improve communication; expertise and mentorship from the US experts.
No	Local facilitator - clinician; salary support for 1 day/week; education and gap analysis;
Some	Audit and case review; paid clinical lead for the audits; Multidisciplinary Team
Yes - Ubuntu pholisphy 'I am what I am because of who we all are' to promote ownership	Targeted activities for different groups (eg exec vs clinical); audit and feedback; education/retraining; resources such as alcohol rub
Yes - based on poor knowledge of extent of SSI - not well reported across UK.	Audit and feedback x 2; education as part of M&M meeting; posters
Lean Six Sigma	Multidisciplinary Teams, literature review and process mapping; work flow analysis to standardise practice; audit and feedback (using a mulit-institutional data set); new resources; education; Community of Practice
Yes - developing a framework for how to engage clinical staff	Boundary spanner/ clinical champions; national champions
Barriers	Discussion of fitting into workflow
The Model for Planning Change .	Education, PDSA cycles, audits, process audits, cost effectiveness, digital tool; opinion leaders; outreach visit
Adaptive Design	Education and successive learning cycles; including all professionals, monitoring.

Yes	Developing opinion leaders; undertaking educational clinically-oriented, and evidence-based outreach visits focused on emergency obstetric care; clinical audits (maternal death reviews)
Healthcare Improvement Collaborative Model (HICM) based on Provonost and Johns Hosplins Implementation models. Really a QI process.	PDSA, audit and Feedback, Education, workshops, CoP team support, champions, and expert advisors, map processes, barriers analysis and mitigation strategy, online support and discussion boards, baseline audit.
Yes at length - make their own Evidence-Based strategy.	Education, on-site champions, supportive documentation systems
Yes theory-based analysis of barriers to implementation of guidelines	Audit and feedback, unit educational meetings, dissemination of structured case records and promotion of a patient information booklet.
Yes	Observational audit then constructive feedback and planning for improvement; audit and feedback at ward meetings, education for auditers.
The Generic Implementation Framework and RE-AIM to evaluate	Needs and interest assessment, hospital orientation / engagement with research support team, intervention toolkit, imp team, coaching, education
Lack of strategies discussed at length. Assessed using CFIR	Focus on barriers
Yes	Executive sponsorship/engagement with the state-wide collective, coaching, teleconferences, site visits, promotional materials, implementation "leadership" team.
Staged implementation of components, support from Central IT service - focus here is on what didn't happen.	Hospital exec engagement, clinical leadership, support from external experts, harnessing tension for change,
COM-B analysis, PDSA, sudit and feedback, MD imp Teams, clinical leaders/champions; engaing senior management	implementation team, audit and feedback, champions, senior management "educated" by champions, education, externalk support

Yes	Hosp exec engaged to sponsor project, resources shared, support from TRN collaborative, education, project coordinator, physician champion.
Only in terms of barriers / enablers using TDF and COM-B	Education, CPGs available,
Mostly based on pilot study	Clear process to follow, education, coaching, exec sponsorship, clear objectives
Analysis of barriers using CFIR	Not reported
No	Observational audits of quality of care, education and skills assessment, coaching, external support, provision/help in sourcing equipment

Yes	Consideration of physical infrastructure supporting the IT upgrade (the intervention); training offered at multiple times and through multiple formats -webinar/face to face/written , champions, implementation team with ckear responsibilities and roles; comprehensive communication plan; problem solving by imp team	
No	Not reported	
Yes	Readiness for change analysis, clinical champions, clear guidelines to follow	
No	Not reported	
Not clear	Not reported	

Yes - Table 1 shows their set of IS informed principles.	Education: presentations, written material and illustrative videos; co-designed bundle of interventions (so clinicians implementing the bundle have ownership), collection of outcome data; engage senior leadership, clinical champions. building a tension for change, ensuring all interventions"make sense "and are compatible with current workflow, "once intervention has been agreed, compliance should not be negotiable".
Yes	Needs analysis/context mapping at start; education; tools to do the intervention; multidisciplinary engagement
No	Not reported
Yes mapped to context and barriers analysis with TDF	Education, staff coaching tools, printed education materials, reminders, huddles, posters etc.
Yes - based on Diffusion of Innovation	Establishing a clear vision, success stories from "early adopters", regional level support for education and planning, alignment of program with organisational targets, dedicated project leadership, senior support, external support, dedicated project time for staff, good communication, and information, establishing a need for change, valuing the initiative, access to modules, voluntary enrolment in the project, sufficient resources, local ownership emphasised.
integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) framework	Facilitator works with MDT to prioritise areas for improvement, PDSA, project officer. Education
Kirkpatrick's typology	offered resources free of charge, diffusion of the course via senior clinicians involved in a regional education network, MOU with exec outlining the program/participation, resources and staff to be freed to do program. Education
Yes "engage, educate, execute and evaluate"	Engaged clinicians during meetings etc, audit and feedback via an online tool, other tools, education, problem solving, analsysis of errors
Yes "engage, educate, execute and evaluate"	Clinician change agents on each ICU, trained and shown the evidence for the/need for change/

Yes "engage, educate, execute and evaluate"	Engage: personally communicate, tell stories and share results from other sites; educate - including skills, Execute: given skills on managing behaviour of others / themselves, streamlining processes, checklists; Evaluate: fidelity checked.
A four-phase implementation process incorporated a planning phase, baseline phase, education phase, and maintenance phase	baseline assessment; utilization of existing personnel (e.g., nurse educators, unit managers, charge nurses); education in the form of lectures, posters, and one-on-one reminders; and evaluation of compliance and impact
Provonost et al's "translating evidence into practice" model and Comprehensive Unit-based Safety Program (CUSP)	Education, collaboration, imp teams; interventions aimed at increased safety knowledge and culture
Yes	Audit and feedback, collaborative - benchmarking, responding to audits, link between collaborative and local clinical champions, education, engage exec - must pay an annual particpation fee and publication of hospital mortality, expert advice
N	not reported
Yes - Framework used to evaluate factors that may have influenced implementation. Not always clear what the implementation at each site was.	MD implementation teams, leadership support,
No	Not reported
Yes	common goal for improvement, engage and educate multidisciplinary teams and senior leaders, simplify and standardize care (bundles, protocols, policies, and briefings), ollect data and offer performance feedback, and to provide opportunities for shared learning

Elements from lean management, theory of constraints and mathematical analysis	Clinical leadership; executive sponsorship; audit and feedback; process mapping/analysis; predefined plan with project officers; inventory of barriers and facilitators; PDSA cycles to tweak the processes; active involvement of clinicians; external input from consultants to benchmark.
Promoted by a regional quality improvement collaborative	audit-andfeedback system for adherence, face-to-face meetings, and support for quality improvement projects at participating hospitals
Realistic evaluation of the pre-implementation	Engage with each site, assess willingness for change, identify resources required and flag potential barriers.
Analysis of barriers	Implementation team, clinical leadership, no extra resources/time given, case for change clear especially to patients
Organisational Readiness Theory	Organisational Readiness assessment
Organisational Readiness Theory	Organisational Readiness assessment
Organisational Readiness Theory	Organisational Readiness exploration

Supplementary File

Concepts and features associated with implementation of large-scale hospital interventions. (denotes concepts added after literature review)*

Concept	Associated Features	Antecedents	Intended Outcome	Supported by the literature?	Comments and examples
External, top-down source	Implementing externally developed interventions	Basic and applied research undertaken	Standardised, evidence-based practice used across sites	Always	Developed by quality or safety agencies,[34] research institutes / groups,[24] professional colleges
	Support for implementation built into intervention	Current locally held resources may be inadequate for effective implementation; knowledge and skills deficits	Social and practical support and relevant knowledge and skills acquisition assist implementation of intervention with high fidelity	Often	Intervention designed to provide implementation support through tools (e.g.,[35]), checklists (e.g.,[10]), or guidelines (e.g.,[36]). Education and skills building key elements
	Aligns with organisational or state/nation-wide priorities	Clear, coherent intentions developed and presented	Adoption of intervention through collective understanding of a clear intention	Often	Often synonymous with the large-scale intervention model[12]
	Incentives and disincentives for implementation are offered			Rarely	For one project a participation fee was charged for organisations,[35] for another, selected participants were paid[37]
Evidence-based interventions	Implementing evidence-based interventions	Basic and applied research undertaken	Standardised, evidence-based practice used across sites	Always	Usually based on Level 1 evidence; sometimes informed by a pilot at a subset of sites[38,39]

	De-implementation of previous practices	Current practices have been updated/outmoded	New interventions	Rarely	Rarely reported explicitly. Even for implementation of new IT systems, legacy software may be kept alongside the new [31]
Safety and quality focus	Clear aim of improving patient outcomes*	Clear, coherent intentions developed and presented	Adoption of intervention through collective understanding of a clear intention	Always	With or without baseline data setting up a case for change, consistent understanding that intervention is needed to improve patient outcomes
	Sites harness their positive safety culture	Work of improving patient outcomes seen as core business	Higher adoption and engagement through collective competencies and intentions	Rarely	Rarely reported explicitly. Assumption made in most that positive safety culture exists.
Facilitation through assessment and provision of resources	External funding	Current locally held resources may be inadequate for effective implementation; knowledge and skills deficits	Social and practical support and relevant knowledge and skills acquisition assist implementation of intervention with high fidelity	Sometimes	Mix of external, internal or research funding
	Support for comparison across sites implementing the intervention*	Siloed working may hide need for change	Benchmarking and social support allow implementation of intervention with high fidelity	Sometimes	Often included in research-based design or collaborative groups
	Support for planning and implementation activities from	Current locally held resources may be inadequate for effective implementation;	Social and practical support and relevant knowledge and skills	Sometimes	Research-based projects and those involving a collaborative group

	external agencies*	knowledge and skills deficits	acquisition assist implementation of intervention with high fidelity		were most likely to give support; (e.g.,[26,40]) often given in-kind
	Case for change made through data	Limited or no understanding of the need for change; complacency	Tension for change fosters adoption of the intervention	Always	Baseline data and local audit and feedback were common implementation strategies
	Sites given a lead-in time to assess for readiness and local needs*	Naïve site, unprepared (even if willing) for change	Participants more likely to adopt change, exert greater effort, exhibit greater persistence, and display more cooperative behaviour	Sometimes	Formal needs/readiness assessments were sometimes reported[39]
Harnessing local resources and encouraging adaptation	Executive support/ sponsorship	Social and practical support for work of implementation not initially explicit	Intervention driven by local organisational ownership, active support, accountability and responsibility	Always	While commonly reported, it was only implied in some papers Variable use of the terms "support" and "sponsorship"
	Local adaptation encouraged / expected	Diversity of sites and contextual factors	Both implementation and intervention can be tailored to suit local context without loss of fidelity	Often	Assumed step, often based on a quality assurance / improvement model
	Clinical leadership	Social and practical support for work of implementation not initially explicit	Intervention driven by local organisational ownership, active support, accountability and responsibility	Often	Involvement of clinical leads gave credibility, accountability to implementation efforts. Social influence through mentorship, leading by example.

ERIC implementation strategy	Our listed strategies	Allegranzi, 2018	Bayley, 2012	Borchert, 2012	Brink, 2020	Cameron, 2015	Cima, 2013	Cresswell, 2011	Cuypers, 2019	de Groot, 2015	Dekker-van Doorn, 2020	Dumont, 2013	Edward, 2017	Forchuk, 2013	Foy, 2004	Fuller, 2012	Grazioli, 2019)	Havers, 201	Ha
Access new funding	Extra staffing as needed; salary support; monetary incentives		1						1									1	
Assess for readiness and identify barriers and facilitators	Readiness / give sites planning or lead-in time		1						1	1							1		1
Audit and provide feedback	Audit and Feedback											1							
Build a coalition; create new clinical teams; create a learning collaborative	Multidisciplinary involvement	1					1					1	1				1		
Capture and share local knowledge	Community of practice / knowledge network of clinicians	1												1	1	1			1
Change physical structure and equipment	Funding for equipment									1		1							
Change physical structure and equipment	Tools to improve communication						1					1							

Conduct cyclical small tests of change	**PDSA Cycle**									1			1					
Conduct local consensus discussions; Facilitator	**Local facilitator / project officer**	1	1							1		1						
Conduct local needs assessment	**Identify resources required**	1	1									1						
Create a learning collaborative	**Engaging stakeholders**																	1
Develop a formal implementation blueprint	**Implementation guides**	1			1												1	
Develop a formal implementation blueprint	**Intervention Toolkit**				1						1						1	
Develop academic partnerships; use implementation advisor; use advisory boards and workgroups	**Support from external experts/ external support**										1			1	1		1	1	1
Develop and implement tools for quality monitoring	**Monitoring**										1					1			

Develop educational materials; distribute educational materials	**Education**	1	1			1	1					1	1		1	1			
Develop resource sharing agreements	**Resources shared**																		
Distribute educational materials	**Clinical practice guidelines**				1	1													
Facilitation	**Problem solving**																		
Identify and prepare champions	**Champions**									1									
Inform local opinion leaders	**Opinion leaders; fostering positive safety culture**	1		1	1														1
Involve executive boards; Obtain formal commitments	**Executive sponsorship/engagement with the state-wide collective**	1			1		1	1	1	1			1						
Organize clinician implementation team meetings	**Quarantined time for skill acquisition**																		1
Promote adaptability; purposely re-examine the implementation	**Evidence of local adaptation**	1	1	1	1	1	1		1		1	1	1		1	1			

Provide clinical supervision	**Mentoring/ Supervision/ coaching**	1		1	1		1		1	1				1					
Recruit, designate, and train for leadership	**Clinical leadership**		1	1									1						
Use data experts	**IT and communication support for new processes**						1				1					1			
(No ERIC strategy)	**Align with organisational/ District and Departmental priorities**	1																	
Footnotes																			
[1] https://aci.health.nsw.gov.au/__data/assets/pdf_file/0007/291742/Clinical_Innovation_Program_Implementation_Guide.pdf																			
[2] https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/hcs-sss/alt_formats/pdf/pubs/palliat/2008-acp-guide-pps/acp-guide-pps-eng.pdf																			
[3] https://www.nhmrc.gov.au/sites/default/files/images/a-guide-to-the-development-and-evaluation-of-clinical-practice-guidelines.pdf																			
[4] https://www.nice.org.uk/guidance/ng106/resources/chronic-heart-failure-in-adults-diagnosis-and-management-pdf-66141541311685																			
[5] https://www.who.int/patientsafety/safesurgery/checklist_implementation/en/																			

9 ynes, 2017

	Hendy, 2007	Keller, 2019	Kotagal, 2002	Kourouche, 2019	Luxton, 2014	Makene, 2014	Mansoori, 2012	Marcus, 2019	McCreight, 2019	Merry, 2019	Molina, 2016	Moore, 2014	Morrow, 2012	Mudge, 2017	Nocera, 2016	Palomar, 2013	Pronovost, 2006	Pronovost, 2008	Pun, 2005	Reames, 2015	Schwarzkopf, 2018	Stolldorf, 2019	To
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tzis, 2014	van Harten, 2018	Vu , 2018	Wand, 2019	Wyld, 2014	ACI Redesign [1]	Advance care planning (Canada)[2] NHMRC	Implementation Guideline [3]	NHS NICE Chronic heart failure [4]	WHO Surgical Checklist [5]	Sum
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Supplementary file 4: RAMESES publication standards checklist

1	Title, identifies the document as a realist synthesis or review.	Yes	Page 1
2	Abstracts should ideally contain brief details of the study's background, review question or objectives; search strategy; methods of selection, appraisal, analysis and synthesis of sources; main results; and implications for practice.	Yes	Page 3-4
3	Explain why the review is needed and what it is likely to contribute to existing understanding of the topic area.	Yes	Page 7-8
4	State the objective(s) of the review and/or the review question(s). Define and provide a rationale for the focus of the review.	Yes	Page 8
5	Any changes made to the review that was initially planned should be briefly described and justified.	NA	
6	Explain why realist synthesis was considered the most appropriate method to use.	Yes	Page 7
7	Describe and justify the initial process of exploratory scoping of the literature.	Yes	Page 9
8	State and provide a rationale for how the iterative searching was done. Provide details on all the sources accessed for information in the synthesis. For example, where electronic databases have been searched, details should include, for example, the name of the database, search terms, dates of coverage and date last searched. If individuals familiar with the relevant literature and/or topic area were contacted, indicate how they were identified and selected.	Yes	Page 9 and 10
9	Explain how judgements were made about including and excluding data from documents, and justify these.	Yes	Page 10
10	Describe and explain which data or information were extracted from the included documents and justify this selection.	Yes	Page 10, 11, Supplementary files 1 and 3
11	Describe the analysis and synthesis processes in detail. This section should include information on the constructs analysed and describe the analytic process.	Yes	Page 11, 12 and 15,16
12	Provide details on the number of documents assessed for eligibility and included in the review with reasons for exclusion at each stage, as well as an indication of their source	Yes	Abstract briefly, Table 2

	of origin (for example, from searching databases, reference lists and so on).		
13	Provide information on the characteristics of the documents included in the synthesis.	Yes	Supplementary file 1
14	Present the key findings with a specific focus on theory building and testing.	Yes	Pages 15, 16 and 17
15	Summarize the main findings, taking into account the synthesis' objective(s), research question(s), focus and intended audience(s).	Yes	Pages 17-18
16	Discuss both the strengths of the review and its limitations. These should include (but need not be restricted to) (a) consideration of all the steps in the synthesis process and (b) comment on the overall strength of evidence supporting the explanatory insights that emerged. The limitations identified may point to areas where further work is needed.	Yes	Page 20
17	Where applicable, compare and contrast the synthesis' findings with the existing literature (for example, other reviews) on the same topic.	Yes	Page 19
18	List the main implications of the findings and place these in the context of other relevant literature. If appropriate, offer recommendations for policy and practice.	Yes	Page 20
19	Provide details of funding source (if any) for the synthesis, the role played by the funder (if any) and any conflicts of interests of the reviewers.	Yes	Page 5

Search terms for Step 1

PubMed

health [Title/Abstract] AND ((((implementation [Title/Abstract] OR driver [Title/Abstract]) OR change [Title/Abstract]) AND large-scale [Title/Abstract]) AND ((innovation [Title/Abstract] OR intervention [Title/Abstract]) OR program [Title/Abstract])) AND hospital [Title/Abstract]

Limits: English language
No date limits

Medline, Embase (Ovid)

health [keyword] AND ((((implementation [keyword] OR driver [keyword]) OR change [keyword]) AND large-scale [keyword]) AND ((innovation [keyword] OR intervention [keyword]) OR program [keyword])) AND hospital [keyword]

Limits: English language
No date limits

CINAHL (Ebscohost)

health [Abstract] AND ((((implementation [Abstract] OR driver [Abstract]) OR change [Abstract]) AND large-scale [Abstract]) AND ((innovation [Abstract] OR intervention [Abstract]) OR program [Abstract])) AND hospital [Abstract]

Limits: English language
No date limits

Search terms for Step 2

Web of Science.

systematic review [title] AND Implementation [title] AND health [topic heading]

Limits: English language
No date limits