

# BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email [info.bmjopen@bmj.com](mailto:info.bmjopen@bmj.com)

# BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-058158
Article Type:	Original research
Date Submitted by the Author:	11-Oct-2021
Complete List of Authors:	Long, Janet; Australian Institute of Health Innovation, Australian Institute of Health Innovation Sarkies, Mitchell N; Macquarie University, Australian Institute of Health Innovation Francis Auton, Emilie; Macquarie University, Australian Institute of Health Innovation Nguyen, Hoa Mi; Macquarie University, Australian Institute of Health Innovation Pomare, Chiara; Macquarie University, Australian Institute of Health Innovation, Centre for Healthcare Resilience and Implementation Science Hardwick, Rebecca; University of Exeter, Medical School Braithwaite, Jeffrey; Macquarie University, Australian Institute of Health Innovation
Keywords:	Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Change management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

SCHOLARONE™  
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1  
2  
3  
4  
5 1 Conceptualising contexts, mechanisms and outcomes for  
6  
7  
8  
9 2 implementing large-scale hospital improvement initiatives: a  
10  
11  
12  
13  
14 3 realist synthesis  
15  
16  
17  
18 4  
19  
20  
21 5 Authors  
22  
23  
24  
25 6 Janet C Long<sup>1\*</sup> PhD, MN, BSc (Hons)  
26  
27  
28 7 Mitchell Sarkies<sup>1</sup> PhD, BAppSc  
29  
30  
31 8 Emilie Francis-Auton<sup>1</sup> PhD, BA-BSc (Hons)  
32  
33  
34 9 Hoa Mi Nguyen<sup>1</sup> MIPH, BHIthSc  
35  
36  
37 10 Chiara Pomare<sup>1</sup> PhD, MRes, BPsych(Hons)  
38  
39  
40 11 Rebecca Hardwick<sup>2</sup> PhD, MSc, BSc (Hons)  
41  
42  
43 12 Jeffrey Braithwaite<sup>1</sup> PhD, MBA, BA, MIR (Hons I), DipLR  
44  
45  
46 13 Affiliations  
47  
48  
49 14 <sup>1</sup>Australian Institute of Health Innovation, Faculty of Medicine, Health and Human Sciences,  
50  
51 15 Macquarie University, North Ryde, Australia  
52  
53  
54 16 <sup>2</sup>Peninsula Medical School, Faculty of Health, University of Plymouth, Plymouth, United Kingdom  
55  
56  
57 17  
58  
59  
60

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

18 \*Corresponding author

19 [janet.long@mq.edu.au](mailto:janet.long@mq.edu.au)

20 AIHI, Level 6

21 75 Talavera Road,

22 North Ryde, NSW, 2109

23 Australia

24 +61 2 98502225

For peer review only

## 25 Abstract

### 26 Objectives:

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

### 31 Design:

32 Realist synthesis.

### 33 Setting

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

### 39 Methods

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

## 46 Results

47 We found 51 relevant articles (from a total of 381) from which concepts were identified. Large-scale  
48 hospital interventions are characterised by a top-down approach, support from both outside  
49 agencies and internal management, and use of high-quality evidence-based interventions. We found  
50 302 reports of 28 different implementation strategies. Formal theories proposed for the  
51 implementation strategies included Diffusion of Innovation, Theory of Planned Behaviour, and  
52 Organisational Readiness Theory. Initial program theories were then hypothesised, based on  
53 configurations of context-mechanism-outcomes for implementation strategies associated with  
54 planning and assessment activities. Evidence from the published literature supported the  
55 hypothesised program theories and were consistent with the tenets of Organisational Readiness  
56 Theory.

## 57 Conclusion

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

## 61 Key words

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

1  
2  
3  
4 635  
6  
7 64 **Article Summary**8  
9 65 **Strengths and limitations of this study**

- 10  
11  
12 66 • This realist synthesis examines the literature to define contextual features and concepts  
13  
14 67 pertinent to large-scale improvement initiatives affecting how implementation strategies  
15  
16 68 work  
17  
18 69 • It then identifies 28 different implementation strategies that have been deployed for such  
19  
20 70 programs and unpicks how these work in nuanced site contexts to produce intended or  
21  
22 71 unintended outcomes.  
23  
24 72 • An iterative process was used to search, extract data, validate and analyse results using  
25  
26 73 evidence and expertise from researchers and partners.  
27  
28 74 • RAMESES Reporting Standards were used to ensure rigour of each staged step.  
29  
30  
31  
32  
33

34 75 **Funding statement**

35 76 This systematic review was funded by the Medical Research Future Fund (MRFF) (APP1178554, CI  
36  
37 77 Braithwaite). The funding arrangement ensured there was no role of the study funder in study  
38  
39 78 design, collection, management, analysis, and interpretation of data; drafting the manuscript, and  
40  
41 79 decision to submit for publication.  
42  
43  
44

45 80 **Competing interests statement**

46 81 The authors declare they have no conflicting or competing interests.  
47  
48  
49 82

50  
51 83 **Word count: 4411**  
52  
53 84  
54  
55  
56  
57  
58  
59  
60



85

## 86 Introduction

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

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

1  
2  
3 110 In recent years, implementation strategies have been compiled, described and categorised<sup>9</sup>  
4  
5 111 but research has failed to explain why strategies that work as intended in one context,<sup>e.g., 10</sup> may be a  
6  
7 112 failure in another.<sup>e.g., 11</sup> Results suggest that those designing implementation strategies have failed to  
8  
9 113 take into account local contextual features,<sup>12</sup> and the underlying mechanism of action, which implies  
10  
11 114 the way strategies work is poorly understood. A program theory that lies beneath the  
12  
13 115 implementation program and that articulates how the strategies are thought to work is often not  
14  
15 116 explicitly stated. Davies and colleagues showed in their review of 235 guideline dissemination and  
16  
17 117 improvement projects in health care, only 23% used theory of any kind to inform the development  
18  
19 118 of the implementation strategies.<sup>13</sup> This, they argue, can result in a poor choice of implementation  
20  
21 119 strategy for the context (e.g., settling for a “default strategy” such as an education session<sup>14</sup>) and  
22  
23 120 corresponding poor results.

24  
25  
26  
27  
28 121 Realist approaches take a deep dive into why programs work as intended some of the time  
29  
30 122 but not all of the time.<sup>15</sup> A realist approach asserts that all programs have an underlying program  
31  
32 123 theory that explains how the strategies bring about intended or unintended results. This holds the  
33  
34 124 promise of unpicking the link between the context and outcomes. A realist synthesis is the ideal  
35  
36 125 approach to understand implementation programs for large-scale hospital interventions, as it  
37  
38 126 explores the links between strategies, mechanisms of action, contexts, the responses of clinicians,  
39  
40 127 and outcomes. Terms used in this synthesis referring to types of theories are defined in Box 1.

41  
42  
43  
44  
45 Formal theories: here, this refers to general implementation science theories that have been used  
46  
47 to explain how implementation strategies work broadly and for which there is some empirical  
48  
49 support. Also called mid-range theories<sup>16</sup>

50  
51 Program theory: a theory that explains how and why particular types of interventions work to  
52  
53 generate the outcome/s of interest<sup>16</sup>

54  
55  
56 Initial program theory: a program theory that is hypothesised, tested and refined as a result of the  
57  
58 realist synthesis to explain how the focal type of intervention generates the outcome/s of interest  
59  
60

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

128 *Box 1: Types of theories referred to in this paper*

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

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

## 152 Methods

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

### 162 *Step 1: Conceptualising large-scale hospital interventions*

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

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

1  
2  
3 176 for evidence to support or refute our list and to look for other concepts and features we had not  
4  
5 177 considered. We searched Medline, PubMed, Embase and CINAHL, using the search string: *health*  
6  
7 178 *AND (((implementation OR driver) OR change) AND large-scale) AND ((innovation OR intervention)*  
8  
9 179 *OR program))*. No date limits were set. We snowballed papers from the reference lists, added known

10  
11  
12  
13 180 **[INSERT TABLE 1 HERE]**

14  
15  
16 181 key papers not captured by the search, and included individual studies reported in reviews. We  
17  
18 182 assessed whether each of the concepts and features on our list were supported by the literature,  
19  
20 183 noting each as being reported “always”, “nearly always,” “often,” “sometimes”, “rarely” or “not at  
21  
22 184 all”.

23  
24  
25 185 Using an iterative approach, we refined our definition of large-scale hospital interventions as  
26  
27 186 we built up the list of associated concepts and features. Finally, antecedents and intended outcomes  
28  
29 187 of the features as a whole and individually were developed and considered to further explore  
30  
31 188 possible mechanisms that may be relevant. Articles that we included involved implementation  
32  
33 189 across multiple hospital sites for interventions aimed at improving patient safety or quality of care.  
34  
35 190 We did not include programs situated outside the hospital setting (e.g., implemented solely in  
36  
37 191 community-based health services), interventions at only one site, locally driven interventions (e.g.,  
38  
39 192 internally developed, ward-based improvements) or tightly controlled research trials that were not  
40  
41 193 considered “real world interventions” (e.g., randomised controlled trials). We did consider pragmatic  
42  
43 194 trials if they met other parts of our definition. A data extraction sheet was used to organise concepts  
44  
45 195 described in the papers found. Papers not reporting implementation strategies or activities were not  
46  
47 196 included.

48  
49  
50  
51  
52  
53 197 *Step 2: Scoping suites of implementation strategies*

54  
55  
56 198 Our next task was to identify and collate all implementation strategies that were reported as  
57  
58 199 part of these types of large-scale interventions. Together with the concepts and features of the  
59  
60

1  
2  
3 200 initiatives found in Step 1, this list of strategies and any information reported on how they were  
4  
5 201 intended to work, were needed to understand possible contexts and mechanisms leading to  
6  
7 202 outcomes.  
8  
9

10 203 We started our search for implementation strategies with the papers found in Step 1. Next  
11  
12 204 we scanned papers found in an existing systematic review of implementation strategies used in  
13  
14 205 hospital avoidance interventions for people with chronic conditions, choosing projects that met our  
15  
16 206 large-scale, multi-site criteria.<sup>20</sup> We also searched more broadly for systematic reviews looking at  
17  
18 207 implementation strategies targeting other cohorts of patients (Web of Science: “implementation”  
19  
20 208 AND “systematic review”). We included protocol papers hoping these might provide a fuller  
21  
22 209 rationale for their choice of strategies. We also included selected grey literature from a targeted  
23  
24 210 search of implementation materials from agencies known to actively support large-scale  
25  
26 211 implementation programs: United Kingdom’s National Health Service, Canada’s Advance Care  
27  
28 212 Planning, NSW Agency for Clinical Innovation, Australian Medical Research Council, Enhanced  
29  
30 213 Recovery After Surgery Society, and World Health Organization. We set up a data extraction matrix,  
31  
32 214 recording reported implementation strategies for each project. We also ran a Google search on  
33  
34 215 ‘implementation guide’ and ‘implementation healthcare guides.’ Implementation strategies were  
35  
36 216 collated and reviewed in each source.  
37  
38  
39  
40

41  
42 217 Initially, we used our own descriptors for the strategies, but then aggregated similar  
43  
44 218 strategies and mapped them to the Expert Recommendations for Implementing Change (ERIC)<sup>9</sup>  
45  
46 219 taxonomy of 68 implementation strategies. Any strategies that did not map to an ERIC strategy were  
47  
48 220 still included but noted.  
49  
50

### 51 52 221 *Step 3: Identifying potential initial program theories*

53  
54

55 222 In this next step, the research team workshopped ideas towards identifying potential initial  
56  
57 223 program theories<sup>18</sup> by considering all the data generated so far in the project as well as searching  
58  
59 224 published literature around known formal theories; in particular, we examined together the  
60

1  
2  
3 225 concepts identified in Step 1 and the implementation strategies identified in Step 2. That is, we  
4  
5 226 considered what existing formal theories or types of theories might be relevant to explain particular  
6  
7 227 implementation strategies given the concepts and putative mechanisms we had identified. For  
8  
9 228 example, an implementation strategy of *conducting a local needs assessment*, fitted with the  
10  
11 229 concept of *facilitation through provision of resources* and the feature *ensuring a formal period of*  
12  
13 230 *planning*. Organisational Readiness Theory was identified as a formal theory that promised to  
14  
15 231 explain how this implementation strategy of *conducting a local needs assessment* would work across  
16  
17 232 different contexts. These formal theories became the basis for our initial program theories and were  
18  
19 233 matched with implementation strategies using this process. The initial program theories were  
20  
21 234 general enough to describe what was happening, how and why across a range of contexts, and a  
22  
23 235 range of levels (micro, meso and macro).  
24  
25  
26  
27  
28

#### 29 236 *Step 4: Further scoping and focus on a key strategy*

30  
31 237 As realist syntheses aim to explain how and why a program works and have the potential to  
32  
33 238 generate vast amounts of data to do this well, it was necessary to carefully scope the results  
34  
35 239 generated and narrow our focus. Following the example of other realist syntheses,<sup>18,21-23</sup> we looked  
36  
37 240 for a single set of implementation strategies and their accompanying initial program theory that (a)  
38  
39 241 was deemed highly important in informing our parallel tranche of work - the realist evaluation of the  
40  
41 242 *Leading Better Value Care* projects in NSW, Australia - and (b) had not already been researched using  
42  
43 243 realist methodology.  
44  
45  
46  
47

## 48 244 **Results**

49  
50  
51 245 Results of the activities used to synthesise evidence and generate initial program theories  
52  
53 246 that explain how implementation strategies work in large-scale hospital interventions are outlined  
54  
55 247 below. The process was driven by the fortnightly research team meetings and iterative refinements.  
56  
57 248 Table 2 summarises the results from the four steps.  
58  
59  
60

249 *Concepts associated with large-scale hospital intervention implementation programs (Step*

250 *1)*

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

256 **[INSERT TABLE 2 HERE]**

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

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



1  
2  
3 272 *Evidence-based interventions:* All interventions were identified by the authors as being  
4  
5 273 evidence-based, although the evidence (e.g., the randomised control trial on which the intervention  
6  
7 274 was built) itself was rarely cited. Contrary to the expectations of our research team, de-  
8  
9  
10 275 implementation of processes and practices that presumably were no longer “best practice” was  
11  
12 276 rarely reported. This applied even to upgraded Information Technology systems where legacy  
13  
14 277 systems were allowed to remain alongside the new programs.<sup>31</sup>

16  
17 278 *Safety and quality focus:* A clear aim of improving patient outcomes was consistently found,  
18  
19 279 often by making a case for change from baseline data. Implicit in most programs was the assumption  
20  
21 280 that a positive safety culture, that saw improvement of patient outcomes as core business was  
22  
23 281 present at the site. Also implicit was that there was consensus at each site that the intervention was  
24  
25 282 needed, and that the implementation support provided would be acceptable.

26  
27  
28  
29 283 *Facilitation through provision of resources:* As well as implementation guides and  
30  
31 284 intervention resources, external support was seen in many projects in the form of new equipment,  
32  
33 285 customised forms for documentation, and care pathways. Project officers skilled in the intervention  
34  
35 286 and tasked with data collection or training were funded in some projects, often budgeted as part of  
36  
37 287 an associated research component (e.g.,<sup>32</sup>). Partnership agreements with external agencies  
38  
39 288 facilitated implementation by providing access to specialist advice. Funding for the projects was  
40  
41 289 often a mix of external (e.g., VA (USA)<sup>28</sup>), internal (e.g., Hornsby Ku-ring-gai District Hospital  
42  
43 290 (Australia)<sup>32</sup>), and research-based (e.g., National Institutes of Health grants (USA)<sup>33</sup>). Facilitation was  
44  
45 291 not always a feature. All studies relied on the goodwill of clinicians, and some did not factor in any  
46  
47 292 quarantined time for implementation activities such as audits. Interventions developed by clinical  
48  
49 293 collaboratives were often framed as partnerships, including access to practical support and expert  
50  
51 294 advice (in-kind) for the implementation and monitoring of outcomes, some allowing dissemination  
52  
53 295 of learnings from other sites, and benchmarking. Data was often provided to make a case for  
54  
55 296 change, and support for ongoing audit and feedback were common features.

1  
2  
3 297 *Harnessing local resources and encouraging adaptation:* The provision of a lead-in time for  
4  
5 298 each site to assess for readiness and local needs was sometimes reported, and internal support for  
6  
7 299 implementation from senior management was reported in most papers. Design amenable to  
8  
9 300 adaptation to fit different local practices, patient cohorts or workflows, developed by clinically based  
10  
11 301 implementation teams, was also frequently reported. Clinical leadership, mentoring, supervision and  
12  
13 302 in-house education were also key features.  
14  
15  
16

17 303 Following this, features were refined by determining their antecedents and intended  
18  
19 304 outcomes, to help with the next step of defining associated implementation strategies, mechanisms  
20  
21 305 and potential initial program theories. Supplementary File 2 shows the results of this step.  
22  
23  
24

### 25 306 *Collated suites of implementation strategies (Step 2)*

26  
27  
28 307 We found 302 reports of 28 different implementation strategies associated with large-scale  
29  
30 308 hospital interventions from 45 peer-reviewed papers and five sets of grey literature documents  
31  
32 309 (each linked to a single website). All of the strategies except one mapped to one or a combination of  
33  
34 310 strategies in the ERIC taxonomy.<sup>9</sup> The strategy that did not map was *Aligned with organisational/*  
35  
36 311 *District and Departmental priorities*. Some strategies that were similar were combined as  
37  
38 312 descriptions in the articles were not sufficient to determine exact details (e.g., *Involve executive*  
39  
40 313 *boards* was combined with *obtain formal commitments* as it was often the executive group which  
41  
42 314 was negotiating on behalf of the site. The 28 strategies are summarised in Table 3 and shown in full  
43  
44 315 in Supplementary File 3. Most frequently reported or recommended strategies were: *Promote*  
45  
46 316 *adaptability/purposely re-examine the implementation* (n=34); *Involve executive boards/obtain*  
47  
48 317 *formal commitments* (n=24); and *Assess for readiness and identify barriers and facilitators* (n=24).  
49  
50  
51  
52

53 318 **[INSERT TABLE 3 HERE]**  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 319 *Identify potential initial program theories (Step 3)*  
4  
5

6 320 The research team workshop started by considering both the concepts and features from  
7  
8 321 Step 1 and the strategies from Step 2 to identify high level domains in which our potential initial  
9  
10 322 program theories and their underlying mechanisms would be expected to work. Four of these  
11  
12 323 domains were identified: social processes and influences; assessment and planning; accessing  
13  
14 324 resources; and partnering outside the organisation. Domains were not seen as mutually exclusive  
15  
16 325 but connected and interdependent. A list of formal theories that addressed these domains was  
17  
18 326 compiled through researcher knowledge and discussion, searching other published realist studies,  
19  
20 327 literature on program theories, and online searches. Five formal theories that explained in a very  
21  
22 328 broad sense, how various strategies might be expected to work were selected through discussion.  
23  
24 329 The theories that were selected were: Organisational Readiness Theory, Social Cognitive Theory,  
25  
26 330 Partnership Synergy Theory, Diffusion of Innovation, and the Theory of Planned Behaviour. Table 4  
27  
28 331 summarises the selected formal theories. Table 5 shows the strategies, concepts, domains and their  
29  
30 332 matched theories.  
31  
32  
33  
34  
35

36 333 **[INSERT TABLE 4 HERE]**  
37  
38

39 334 *CMO statements from the Organisational Readiness Theory (Step 4)*  
40  
41

42 335 Weiner defines organisational readiness as multi-level and multi-faceted construct referring  
43  
44 336 to an organisational members' shared commitment to change - encompassing both willingness and  
45  
46 337 capacity.<sup>34</sup> This readiness for change is crucial in producing collective engagement; that is achieving  
47  
48 338 buy in and commitment from those at the front lines enacting the change. This engagement results  
49  
50 339 in valuable implementation outcomes: a collective commitment to initiate change, greater effort to  
51  
52 340 make the change successful, greater perseverance when barriers are encountered and an increase in  
53  
54 341 pro-social collaborative behaviours that promote the change.<sup>34</sup> Holt, Amenakis and colleagues,<sup>39</sup>  
55  
56 342 state the most potent mechanisms were shared perceptions and beliefs among stakeholders in the  
57  
58 343 organisation that (a) they are capable of implementing the proposed change (i.e., *change-specific*  
59  
60

1  
2  
3 344 *efficacy*), (b) the proposed change is appropriate for the organisation (i.e., *appropriateness*), (c)  
4  
5 345 leaders are committed to the proposed change (i.e., *management support*), and (d) the proposed  
6  
7 346 change is beneficial to organisational members (i.e., *personal valence*). Perceptions about resources  
8  
9  
10 347 are considered the active means to achieve readiness rather than the resources themselves.<sup>34</sup>  
11

12  
13 348 In an iterative process undertaken by the research team, CMOs were configured, to  
14  
15 349 understand what circumstances (context) needed to be present in an implementation strategy to  
16  
17 350 trigger an identified mechanism leading to an outcome. Since many of the strategies overlapped in  
18  
19 351 their mechanisms and outcomes, we considered them both together and separately. We limited our  
20  
21 352 enquiry to how the mechanisms worked on the implementers within an organisation; i.e., the people  
22  
23 353 delivering the intervention directly to patients, rather than the designers or facilitators of the  
24  
25 354 intervention. The outcomes associated with the Theory of Organisational Readiness were all around  
26  
27 355 engagement, buy-in and commitment to the change.  
28  
29  
30

31 356 At the same time as the CMO statements were being configured, articles that reported  
32  
33 357 enough detail on these strategies were reviewed for evidence. A further search specifically for  
34  
35 358 implementation projects across multiple sites that reported using organisational readiness theory  
36  
37 359 was also performed, yielding another three papers. The final column of Table 6 indicates the articles  
38  
39 360 that give evidence to support or not support the CMO configurations.  
40  
41  
42

43 361 **[INSERT TABLE 5 HERE]**  
44  
45

46 362  
47  
48

49 363 **[INSERT TABLE 6 HERE]**  
50  
51

52 364  
53  
54  
55  
56  
57  
58  
59  
60

## 365 Discussion

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

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

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

1  
2  
3 389 found across multiple projects providing strong evidence of the theory's applicability in large-scale  
4  
5 390 hospital interventions.  
6  
7

8 391 Evidence found in our set of literature almost all supported CMOs that led to positive,  
9  
10 392 desirable implementation outcomes of engagement and commitment. There was some refuting  
11  
12 393 evidence that pointed to the interdependence of some factors, and that at times one contextual  
13  
14  
15 394 factor could interact and outweigh another. For example, Wyld and colleagues found that although  
16  
17 395 all stakeholders involved with a new biobank highly valued the initiative, doctors tasked with  
18  
19 396 collecting the samples felt early consultation, management support and consideration of the  
20  
21 397 feasibility for them had been lacking.<sup>49</sup> In spite of this, the implementation of the program had been  
22  
23  
24 398 successful with almost universal adherence to the new processes by the doctors. Possibly, the  
25  
26 399 patients' altruistic enthusiasm for the initiative, that was often voiced to the doctors during the  
27  
28 400 informed consent process may have put greater value on the initiative, outweighing the doctors'  
29  
30 401 difficulty.  
31  
32

33 402 Evidence for contextual factors that triggered mechanisms leading to poorer outcomes were  
34  
35 403 also found. Bayley and colleagues note the mismatch in perceptions of feasibility found between  
36  
37 404 managers and implementers, and between different healthcare professionals contributing to the  
38  
39 405 multidisciplinary team effort of implementing stroke rehabilitation guidelines.<sup>45</sup> This same project  
40  
41 406 found that perceptions of feasibility were also negatively affected by overly complicated statements  
42  
43 407 of the intervention and called for a "plain English" version that would be more accessible for busy  
44  
45 408 clinicians. Both contextual factors were considered barriers as this collective perception of lack of  
46  
47 409 support and lack of feasibility triggered disengagement and lack of commitment to the change.  
48  
49  
50

51  
52 410 Some authors, lacking high quality evidence, suggested the cause of poor implementation  
53  
54 411 outcomes might be linked to contextual factors. For example, Reames and colleagues suggest that  
55  
56 412 the failure of their large-scale hospital intervention to effect change might be because it required  
57  
58 413 staff to follow processes that were not strongly associated with clear patient improvements.<sup>42</sup> This  
59  
60

1  
2  
3 414 perception of lack of effectiveness would not trigger the mechanism of building a tension for change,  
4  
5 415 but complacency leading to poor adoption of the intervention. Wand and colleagues found that  
6  
7 416 disagreement voiced by a senior clinician in the early planning stages of an intervention was likely to  
8  
9 417 adversely affect the project's success unless it could be resolved.<sup>43</sup> Here the perception of  
10  
11 418 implementers would be that the intervention was not feasible or appropriate, and trigger  
12  
13 419 disengagement. While these examples do not claim to be high level evidence, but rather the  
14  
15 420 informed opinion of the authors, they are intuitively correct and consistent with the other evidence  
16  
17 421 found in this study.  
18  
19  
20  
21

## 22 422 *Strengths and Limitations*

23  
24  
25 423 Our search for literature was systematic and thorough yet only resulted in 50 papers. This  
26  
27 424 was because while large-scale hospital interventions abound, implementation activities and  
28  
29 425 outcomes are not commonly reported.<sup>56</sup> This meant many articles reporting interventions were not  
30  
31 426 relevant to the present study. Even for papers reporting implementation, reporting of these  
32  
33 427 strategies and the contexts in which they were used was often not detailed enough to develop  
34  
35 428 theories. Articles that were found were mostly reporting successful implementations and this is an  
36  
37 429 acknowledged bias of published literature. While CMOs are useful in explaining single factors,  
38  
39 430 multiple contextual factors may arise that modify how mechanisms work. Lack of detail in reporting  
40  
41 431 meant the O (outcomes) in our CMO configurations were high level and dichotomous: implementers  
42  
43 432 were engaged or implementers were not engaged. Strengths included the expertise of the research  
44  
45 433 team (including clinical and implementation science expertise) and the systematic four step iterative  
46  
47 434 investigation.  
48  
49  
50  
51

## 52 435 *Conclusions*

53  
54  
55  
56 436 Large-scale hospital interventions hold the promise of standardising high quality, evidence-  
57  
58 437 based care for large numbers of patients but must be supported with appropriate implementation  
59  
60

1  
2  
3 438 strategies to support and effect change. The study has used realist methodology to tease out how  
4  
5 439 initial planning activities can drive engagement and commitment and delineate the contextual  
6  
7 440 factors required to trigger mechanisms. These findings, using *Organisational Readiness Theory*, will  
8  
9 441 add to understandings around why large-scale projects work some of the time but not all of the  
10  
11 442 time. Evidence has been presented around a set of CMO hypotheses, showing the importance of  
12  
13 443 implementers' perceptions around feasibility, support, and value in triggering engagement and  
14  
15 444 commitment to the proposed change.  
16  
17  
18  
19

## 20 445 Abbreviations

21  
22  
23 446 CMO Context Mechanism Outcome  
24  
25  
26 447 ERIC Expert Recommendations for Implementing Change  
27  
28  
29 448 NSW New South Wales  
30  
31

32 449

## 35 450 Declarations

### 37 451 Ethics approval

38  
39 452 Not applicable – using publicly available data.  
40  
41  
42

### 43 453 Consent to participate

44  
45  
46  
47 454 Not applicable as there were no participants.  
48  
49

### 50 455 Patient and public involvement

51 456

52  
53  
54 457 Not applicable as this was a review of the literature.  
55

### 56 458 Consent for publication

57  
58  
59 459 Not applicable.  
60



## 460 Availability of data and materials

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

## 463 Competing interests

464 The authors declare that they have no competing interests.

## 465 Funding

466 This systematic review was funded by the Medical Research Future Fund (MRFF) (APP1178554, CI  
467 Braithwaite). The funding arrangement ensured there was no role of the study funder in study  
468 design, collection, management, analysis, and interpretation of data; drafting the manuscript, and  
469 decision to submit for publication.

470

## 471 Authors' contributions

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

## 476 Acknowledgements

477 Not applicable.

478

479 **References**

- 480 1. Best A, Greenhalgh T, Lewis S, Saul JE, Carroll S, Bitz J. Large-System Transformation in  
481 Health Care: A Realist Review. *The Milbank Quarterly*. 2012;90(3):421-456.
- 482 2. Chaillet N, Dumont A, Abrahamowicz M, et al. A Cluster-Randomized Trial to Reduce  
483 Cesarean Delivery Rates in Quebec. *The New England Journal of Medicine*.  
484 2015;372(18):1710-1721.
- 485 3. Haynes A, Weiser T, Berry W, ; ea. A surgical safety checklist to reduce morbidity and  
486 mortality in a global population. *New England Journal of Medicine*. 2009;360:491-499.
- 487 4. de Vries EN, Prins HA, Crolla RMPH, et al. Effect of a Comprehensive Surgical Safety System  
488 on Patient Outcomes. *The New England Journal of Medicine*. 2010;363:1928-1937.
- 489 5. Greenhalgh T, Humphrey C, Hughes J, Macfarlane F, Butler C, Pawson RAY. How Do You  
490 Modernize a Health Service? A Realist Evaluation of Whole-Scale Transformation in London.  
491 *The Milbank Quarterly*. 2009;87(2):391-416.
- 492 6. Yamey G. What are the barriers to scaling up health interventions in low and middle income  
493 countries? A qualitative study of academic leaders in implementation science. *Globalization  
494 and health*. 2012;8(1):11.
- 495 7. Braithwaite J, Marks D, Taylor N. Harnessing implementation science to improve care quality  
496 and patient safety: a systematic review of targeted literature. *International Journal for  
497 Quality in Health Care*. 2014;26(3):321-329.
- 498 8. Rapport F, Clay-Williams R, Churrua K, Shih P, Hogden A, Braithwaite J. The struggle of  
499 translating science into action: Foundational concepts of implementation science. *Journal of  
500 Evaluation in Clinical Practice*. 2017; :1-10.
- 501 9. Powell BJ, Waltz TJ, Chinman MJ, et al. A refined compilation of implementation strategies:  
502 results from the Expert Recommendations for Implementing Change (ERIC) project.  
503 *Implementation Science*. 2015;10(1):21.

- 1  
2  
3 504 10. Haynes AB, Edmondson L, Lipsitz SR, et al. Mortality Trends After a Voluntary Checklist-  
4 based Surgical Safety Collaborative. *Annals of Surgery*. 2017;266(6):923-929.  
5 505  
6  
7 506 11. Urbach DR, Govindarajan A, Saskin R, Wilton AS, Baxter NN. Introduction of surgical safety  
8 checklists in Ontario, Canada. *N Engl J Med*. 2014;370(11):1029-1038.  
9 507  
10  
11 508 12. Molina G, Jiang W, Edmondson L, et al. Implementation of the Surgical Safety Checklist in  
12 South Carolina Hospitals Is Associated with Improvement in Perceived Perioperative Safety.  
13  
14 509  
15  
16 510 *Journal of the American College of Surgeons*. 2016;222(5):725-736.e725.  
17  
18  
19 511 13. Davies P, Walker AE, Grimshaw JM. A systematic review of the use of theory in the design of  
20 guideline dissemination and implementation strategies and interpretation of the results of  
21 512 rigorous evaluations. *Implementation Science*. 2010;5(1):14.  
22  
23  
24 513  
25 514 14. Fixsen D, Naoom S, Blase K, Friedman R, Wallace F. *Implementation Research: A Synthesis of*  
26 *the Literature*. Tamps, FL: University of South Florida, Louis de la Parte Florida Mental Health  
27 Institute, National Implementation Research Network;2005.  
28 515  
29  
30 516  
31  
32 517 15. Pawson R, Greenhalgh T, Harvey G, Walshe K. Realist review-a new method of systematic  
33 review designed for complex policy interventions. *Journal of Health Services Research &*  
34 518 *Policy*. 2005;10(1\_suppl):21-34.  
35  
36  
37 519  
38  
39 520 16. Kislov R, Pope C, Martin GP, Wilson PM. Harnessing the power of theorising in  
40 implementation science. *Implementation Science*. 2019;14(1):103.  
41 521  
42  
43 522 17. Wong G, Greenhalgh T, Westhorp G, Buckingham J, Pawson R. RAMESES publication  
44 standards: realist syntheses. In. Vol 692013:1005-1022.  
45 523  
46  
47 524 18. Shearn K, Allmark P, Piercy H, Hirst J. Building Realist Program Theory for Large Complex and  
48 Messy Interventions. *International Journal of Qualitative Methods*. 2017;16(1).  
49 525  
50  
51 526 19. Wong G, Greenhalgh T, Westhorp G, Buckingham J, Pawson R. RAMESES publication  
52 standards: realist syntheses. *BMC Medicine*. 2013;11(1):21.  
53 527  
54  
55  
56  
57  
58  
59  
60

- 1  
2  
3 528 20. Sarkies M, Long JC, Pomare C, et al. Avoiding unnecessary hospitalisation for patients with  
4  
5 529 chronic conditions: a systematic review of implementation determinants for hospital  
6  
7 530 avoidance programmes. *Implementation Science*. 2020;15(1):91.  
8  
9  
10 531 21. Cunningham U, Ward ME, De Brun A, McAuliffe E. Team interventions in acute hospital  
11  
12 532 contexts: a systematic search of the literature using realist synthesis. *BMC Health Serv Res*.  
13  
14 533 2018;18(1):536.  
15  
16 534 22. Rycroft-Malone J, McCormack B, Hutchinson AM, et al. Realist synthesis: illustrating the  
17  
18 535 method for implementation research. *Implementation Science*. 2012;7(1):33.  
19  
20  
21 536 23. Wong G, Greenhalgh T, Pawson R. Internet-based medical education: a realist review of  
22  
23 537 what works, for whom and in what circumstances. *BMC medical education*. 2010;10(1):12.  
24  
25  
26 538 24. Makene CL, Plotkin M, Currie S, et al. Improvements in newborn care and newborn  
27  
28 539 resuscitation following a quality improvement program at scale: results from a before and  
29  
30 540 after study in Tanzania. *BMC Pregnancy & Childbirth*. 2014;14:381.  
31  
32  
33 541 25. Cima R, Dankbar E, Lovely J, et al. Colorectal surgery surgical site infection reduction  
34  
35 542 program: a national surgical quality improvement program--driven multidisciplinary single-  
36  
37 543 institution experience. *J Am Coll Surg*. 2013;216(1):23-33.  
38  
39 544 26. Vu JV, Collins SD, Seese E, et al. Evidence that a Regional Surgical Collaborative Can  
40  
41 545 Transform Care: Surgical Site Infection Prevention Practices for Colectomy in Michigan. *J Am*  
42  
43 546 *Coll Surg*. 2018;226(1):91-99.  
44  
45  
46 547 27. Schwarzkopf D, Ruddel H, Grundling M, Putensen C, Reinhart K. The German Quality  
47  
48 548 Network Sepsis: study protocol for the evaluation of a quality collaborative on decreasing  
49  
50 549 sepsis-related mortality in a quasi-experimental difference-in-differences design.  
51  
52 550 *Implementation Science*. 2018;13(1):15.  
53  
54  
55 551 28. Maguire EM, Bokhour BG, Wagner TH, et al. Evaluating the implementation of a national  
56  
57 552 disclosure policy for large-scale adverse events in an integrated health care system:  
58  
59 553 identification of gaps and successes. *BMC Health Services Research*. 2016;16(1):648.  
60

- 1  
2  
3 554 29. Schweizer ML, Chiang HY, Septimus E, et al. Association of a bundled intervention with  
4  
5 555 surgical site infections among patients undergoing cardiac, hip, or knee surgery. *Jama*.  
6  
7 556 2015;313(21):2162-2171.  
8  
9  
10 557 30. Kourouche S, Buckley T, Van C, Munroe B, Curtis K. Designing strategies to implement a  
11  
12 558 blunt chest injury care bundle using the behaviour change wheel: a multi-site mixed  
13  
14 559 methods study. *BMC Health Services Research*. 2019;19(1):461.  
15  
16 560 31. Hendy J, Fulop N, Reeves BC, Hutchings A, Collin S. Implementing the NHS information  
17  
18 561 technology programme: qualitative study of progress in acute trusts. *BMJ*.  
19  
20 562 2007;334(7608):1360.  
21  
22  
23 563 32. Mudge AM, Banks MD, Barnett AG, et al. CHERISH (collaboration for hospitalised elders  
24  
25 564 reducing the impact of stays in hospital): protocol for a multi-site improvement program to  
26  
27 565 reduce geriatric syndromes in older inpatients. *BMC Geriatrics*. 2017;17(1):11.  
28  
29  
30 566 33. Marcus RK, Lillemoe HA, Rice DC, et al. Determining the Safety and Efficacy of Enhanced  
31  
32 567 Recovery Protocols in Major Oncologic Surgery: An Institutional NSQIP Analysis. *Annals of*  
33  
34 568 *Surgical Oncology*. 2019;26(3):782-790.  
35  
36  
37 569 34. Weiner BJ. A theory of organizational readiness for change. *Implementation Science*.  
38  
39 570 2009;4(1):67.  
40  
41 571 35. Bandura A. Social Cognitive Theory in Cultural Context. *Applied Psychology*. 2002;51(2):269-  
42  
43 572 290.  
44  
45  
46 573 36. Lasker RD, Weiss ES. Creating partnership synergy: the critical role of community  
47  
48 574 stakeholders. *J Health Hum Serv Adm*. 2003;26(1):119-139.  
49  
50 575 37. Rogers EM. *Diffusion of innovations*. New York : Free Press 1983.  
51  
52 576 38. Ajzen I. The theory of planned behavior. *Organizational behavior and human decision*  
53  
54 577 *processes*. 1991;50(2):179-211.  
55  
56  
57  
58  
59  
60

- 1  
2  
3 578 39. Holt DT, Armenakis AA, Feild HS, Harris SG. Readiness for Organizational Change: The  
4  
5 579 Systematic Development of a Scale. *The Journal of Applied Behavioral Science*.  
6  
7 580 2007;43(2):232-255.  
8  
9  
10 581 40. Palomar M, Alvarez-Lerma F, Riera A, et al. Impact of a national multimodal intervention to  
11  
12 582 prevent catheter-related bloodstream infection in the ICU: the Spanish experience. *Critical*  
13  
14 583 *Care Medicine*. 2013;41(10):2364-2372.  
15  
16 584 41. Pronovost P. Interventions to decrease catheter-related bloodstream infections in the ICU:  
17  
18 585 the Keystone Intensive Care Unit Project. *American Journal of Infection Control*.  
19  
20 586 2008;36(10):S171.e171-175.  
21  
22  
23 587 42. Reames BN, Krell RW, Campbell DA, Jr., Dimick JB. A checklist-based intervention to improve  
24  
25 588 surgical outcomes in Michigan: evaluation of the Keystone Surgery program. *JAMA Surg*.  
26  
27 589 2015;150(3):208-215.  
28  
29  
30 590 43. Wand T, Crawford C, Bell N, Murphy M, White K, Wood E. Documenting the pre-  
31  
32 591 implementation phase for a multi-site translational research project to test a new model  
33  
34 592 Emergency Department-based mental health nursing care. *International emergency nursing*.  
35  
36 593 2019;45:10-16.  
37  
38  
39 594 44. Morrow E, Robert G, Maben J, Griffiths P. Implementing large-scale quality improvement:  
40  
41 595 lessons from The Productive Ward: Releasing Time to Care. *International Journal of Health*  
42  
43 596 *Care Quality Assurance*. 2012;25(4):237-253.  
44  
45  
46 597 45. Bayley MT, Hurdowar A, Richards CL, et al. Barriers to implementation of stroke  
47  
48 598 rehabilitation evidence: findings from a multi-site pilot project. *Disability & Rehabilitation*.  
49  
50 599 2012;34(19):1633-1638.  
51  
52 600 46. Mansoori B, Erhard KK, Sunshine JL. Picture Archiving and Communication System (PACS)  
53  
54 601 implementation, integration & benefits in an integrated health system. *Academic Radiology*.  
55  
56 602 2012;19(2):229-235.  
57  
58  
59  
60

- 1  
2  
3 603 47. Pun BT, Gordon SM, Peterson JF, et al. Large-scale implementation of sedation and delirium  
4  
5 604 monitoring in the intensive care unit: a report from two medical centers. *Critical Care*  
6  
7 605 *Medicine*. 2005;33(6):1199-1205.
- 8  
9  
10 606 48. van Harten WH, Goedbloed N, Boekhout AH, Heintzbergen S. Implementing large scale fast  
11  
12 607 track diagnostics in a comprehensive cancer center, pre- and post-measurement data. *BMC*  
13  
14 608 *Health Services Research*. 2018;18(1):85.
- 15  
16 609 49. Wyld L, Smith S, Hawkins NJ, Long J, Ward RL. Introducing research initiatives into  
17  
18 610 healthcare: what do doctors think? *Biopreservation and Biobanking*. 2014;12(2):91-98.
- 19  
20  
21 611 50. Cuypers M, Al-Itejawi HHM, van Uden-Kraan CF, et al. Introducing Decision Aids into Routine  
22  
23 612 Prostate Cancer Care in The Netherlands: Implementation and Patient Evaluations from the  
24  
25 613 Multi-regional JIPPA Initiative. *Journal of Cancer Education*. 2019;5:05.
- 26  
27  
28 614 51. Sharma N, Herrnschmidt J, Claes V, et al. Organizational readiness for implementing change  
29  
30 615 in acute care hospitals: An analysis of a cross-sectional, multicentre study. *Journal of*  
31  
32 616 *Advanced Nursing*. 2018;74(12):2798-2808.
- 33  
34  
35 617 52. Rees GH. Organisational readiness and Lean Thinking implementation: Findings from three  
36  
37 618 emergency department case studies in New Zealand. *Health Services Management Research*.  
38  
39 619 2014;27(1-2):1-9.
- 40  
41  
42 620 53. Zapka J, Simpson K, Hiott L, Langston L, Fakhry S, Ford D. A mixed methods descriptive  
43  
44 621 investigation of readiness to change in rural hospitals participating in a tele-critical care  
45  
46 622 intervention. *BMC Health Services Research*. 2013;13(1):33.
- 47  
48  
49 623 54. Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related  
50  
51 624 bloodstream infections in the ICU. *N Engl J Med*. 2006;355(26):2725-2732.
- 52  
53  
54 625 55. Nocera M, Shanahan M, Murphy RA, et al. A statewide nurse training program for a hospital  
55  
56 626 based infant abusive head trauma prevention program. *Nurse Education in Practice*.  
57  
58 627 2016;16(1):e1-6.  
59  
60

1  
2  
3 628 56. Proctor EK, Powell BJ, McMillen JC. Implementation strategies: recommendations for  
4  
5 629 specifying and reporting. *Implementation Science*. 2013;8(1):139.  
6  
7

8 630  
9

10  
11 631  
12

13  
14 632  
15

16  
17 633  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

For peer review only



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

	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	

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

--	--	--	--	--

*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).*

For peer review only

<b>ERIC taxonomy</b>	<b>Implementation strategy</b>	<b>Frequency</b>
<b>ERIC,<sup>9</sup></b>		<b>(n=50 sources)</b>
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

1			
2			
3	Develop educational materials;	Education	18
4			
5	distribute educational materials		
6			
7	Develop resource sharing agreements	Resources shared	1
8			
9	Distribute educational materials	Clinical practice guidelines	8
10			
11	Facilitation	Problem solving	2
12			
13	Identify and prepare champions	Champion	4
14			
15	Inform local opinion leaders	Opinion leaders	7
16			
17	Involve executive boards; Obtain	Executive sponsorship/engagement with the	24
18			
19	formal commitments	state-wide collective	
20			
21	Organise clinician implementation	Quarantined time for skill acquisition	4
22			
23	team meetings		
24			
25	Promote adaptability; purposely re-	Local adaptation	34
26			
27	examine the implementation		
28			
29	Provide clinical supervision	Mentoring/ Supervision/ coaching	16
30			
31	Recruit, designate, and train for	Clinical leadership	10
32			
33	leadership		
34			
35	Use data experts	IT and communication support for new	6
36			
37		processes	
38			
39	(No ERIC equivalent)	Align with organisational/ District or	12
40			
41		Departmental priorities	
42			
43			
44	Total		302
45			

46 *Table 3: List of implementation strategies and their frequency, found in the set of 50 grey and black literature*  
47 *documents. (ERIC= Expert Recommendations for Implementing Change)*  
48  
49  
50

1 2 3 4	Theory	Overview (sources)
5 6 7 8 9 10 11	<b>Organisational Readiness Theory</b>	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). <sup>34</sup>
12 13 14 15 16 17 18 19 20	<b>Social Cognitive Theory</b>	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. <sup>35</sup>
21 22 23 24 25 26 27	<b>Partnership Synergy Theory</b>	Partners who effectively collaborate and share knowledge, skills and perspectives are able to achieve more value than the sum of the individual parts contributed. <sup>36</sup>
28 29 30 31 32 33 34 35 36 37 38 39 40	<b>Diffusion of Innovation</b>	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 averse "laggards" will be the last to adopt. <sup>37</sup>
41 42 43 44 45 46 47 48 49 50 51 52 53	<b>Theory of Planned Behaviour</b>	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. <sup>38</sup>

54  
55  
56  
57  
58  
59  
60

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

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

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

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

1 2 3 4 5 6 7 8	Identify and prepare champions; inform local opinion leaders	Social processes	<b>Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:</b> Social influence supporting change	<i>Diffusion of innovation</i> <i>Organisational Readiness Theory</i>
9 10 11 12 13 14	Involve executive boards; Obtain formal commitments	Social processes	<b>Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:</b> Trust, social support, legitimacy, accountability	<i>Social Cognitive Theory</i> <i>Diffusion of Innovation</i> <i>Organisational Readiness Theory</i>
15 16 17 18 19 20 21 22 23 24 25	Recruit, designate, and train for leadership	Social processes	<b>Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:</b> Social influence supporting change <b>Provide or facilitate practical support in the form of education and skill acquisition:</b>	<i>Social Cognitive Theory</i> <i>Diffusion of innovation</i>
26 27 28 29 30 31 32 33	Organize clinician implementation team meetings	Social processes	<b>Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:</b> Social influence supporting change, setting common goals and expectations	<i>Organisational Readiness Theory</i> <i>Theory of Planned Behaviour</i>
34 35 36 37 38 39 40	Conduct local consensus discussions	Social processes	<b>Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:</b> Social	<i>Organisational Readiness Theory</i> <i>Partnership Synergy Theory</i> <i>Theory of Planned Behaviour</i>

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

		influence supporting the setting of clear objectives, building local trust, planning	
		<b>Designed with adaptation to local settings in mind</b>	
Audit and provide feedback	Baseline assessment and planning	<b>Formal period of planning and needs assessment:</b> Setting up tension for change	<i>Organisational Readiness Theory</i>
	Ongoing assessment	<b>Provide support for comparison across sites implementing the intervention:</b> 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	
Capture and share local knowledge	Social processes	<b>Support for comparison across sites implementing the intervention:</b> Increase the breadth of expertise, social support	<i>Social Cognitive Theory</i>
Develop and implement tools for quality monitoring	Baseline assessment and planning	<b>Support for implementation built into intervention:</b> Setting up conditions that foster change and decrease participant effort	<i>Organisational Readiness Theory</i>
	Ongoing assessment	<b>Provide support for comparison across sites implementing the intervention</b>	

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 <sup>10,40</sup>
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 <sup>41</sup>

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

	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 <sup>42,43</sup>
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 <sup>44</sup>
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 <sup>49</sup>  Support <sup>45</sup>

	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 <sup>10,48,50-52</sup>  Support <sup>27,41,46-48</sup>  Support <sup>31,45</sup>  Supported <sup>53</sup>

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46



1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

	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 <sup>52</sup>
	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 <sup>52</sup>
	Executive /management support is inadequate, and local or within team leadership is also inadequate/ non participatory	... decreases perceptions of feasibility and value of the change	... resulting in lack of engagement		

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

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

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 <sup>41,54</sup>  Support <sup>26,27,41,55</sup>
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 <sup>31,47</sup>
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 <sup>10,40,45,47,48,54</sup>

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

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

(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, Ziml
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, Pi	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. Al	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. Pi	2019	Australia
Haynes, A. B., L. Edmondson, (	2017	USA

1		
2		
3	Hendy, J., N. Fulop, B. C. Reev	2007 UK
4		
5		
6	Keller, H. H., R. Valaitis, C. V. L	2019 Canada
7		
8		
9		
10	Kotagal, U. R., J. M. Robbins, M	2002 USA
11	Kourouche, S., T. Buckley, C. V	2019 Australia
12		
13	Luxton et al 2014, Caring lette	2014 USA
14		
15	Maguire et al 2016, Evaluating	2016 USA
16		
17		
18		
19	Makene, et al 2014 Improvem	2014 Africa
20		
21		
22		
23		
24		
25		
26	Mansoori et al 2012 Picture Ai	2012 USA
27	Marcus RK, Lillemoe HA, Rice I	2019 USA
28		
29	McCreight MS, Lambert-Kerzn	2019 USA
30	McFarland MS, Thomas AM, Y	2020 USA
31	McNeely J, Troxel AB, Kunins t	2019 USA
32		
33		
34		
35		
36		
37		
38		
39		
40		
41	Merry AF, Gargiulo DA, Bissett	2019 New Zealand
42		
43	Molina G, Jiang W, Edmondso	2016 USA
44		
45	Monico LB, Oros M, Smith S, N	2020 USA
46		
47		
48	Moore, J. E., A. Mascarenhas,	2014 Canada
49		
50		
51		
52		
53		
54		
55		
56		
57	Morrow, E., G. Robert, J. Mabr	2012 UK
58		
59	Mudge, A. M., M. D. Banks, A.	2017 Australia
60		

- 1  
2  
3  
4  
5 Nocera, M., M. Shanahan, R. A 2016 USA  
6  
7  
8 Palomar, M., F. Alvarez-Lerma 2013 Spain  
9  
10  
11 Pronovost, P. (2008). "Intervei 2008 USA  
12  
13  
14  
15 Pronovost, P., D. Needham, S. 2006 USA  
16  
17  
18  
19  
20 Pun, B. T., S. M. Gordon, J. F. F 2005 USA  
21 Reames BN, Krell RW,  
22 Campbell DA Jr, Dimick JB. A  
23 checklist-based  
24 intervention to improve  
25 surgical outcomes in  
26 Michigan: evaluation of the  
27 keystone surgery program.  
28 JAMA Surg.  
29 2015;150:208–15 2015 USA  
30  
31  
32  
33  
34  
35  
36 Schwarzkopf, D., H. Ruddel, M 2018 Germany  
37  
38 Schweizer, M. L., H. Y. Chiang, 2015 USA  
39  
40  
41  
42 Stollendorf, D. P., J. L. Schnipper, 2019 USA  
43 Terkola R, Czejka M, Berube J. 2017 Europe  
44  
45  
46  
47  
48  
49 Toltzis, P., M. O’Riordan, D. J. 2014 USA  
50  
51  
52  
53  
54  
55 van Harten WH, Goedbloed N, 2018 Netherlands  
56  
57  
58  
59  
60



1  
2 Vu JV, Collins SD, Seese E,  
3 Hendren S, Englesbe MJ,  
4 Campbell DA, Krapohl  
5 GL. Evidence that a regional  
6 surgical collaborative can  
7 transform care:  
8 surgical site infection  
9 prevention practices for  
10 colectomy in Michigan. J Am  
11 Coll Surg. 2018;226(Epub  
12 2017):91–9.) 2018 USA

16 Wand, T., C. Crawford, N. Bell, 2019 Australia

20 Wyld, L., S. Smith, N. J. Hawkir 2014 Australia

23 **Additional papers using Organistional Readiness Theory**

24 Zapka, J., K. Simpson, L. Hiott, 2013 USA

25 Sharma, N., J. Herrnschmidt, v 2018 Switzerland

27 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 ref
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: resulting in multiple interventions around SSI prevention	1 (but part 4 'early adc
Lorenzo software	33
International Patient Decision Aids Standards (IPDAS)	Protocol - n
Enhanced Recovery After Surgery but studying implementation strategies: breakthrough versus stepped	10
Time out procedure and debriefing in Operating theatres	46
QUARITE (quality of care, risk management, and technology in obstetrics) trial	9
Translating Research into Practice implementation model.	6
The transitional relationship model (TRM)	26 (all hosp
Tailored multi facteted strategy delivered by Scottish Programme for Clinical Effectiveness in Reproductive Health	16 trusts (6
The Feedback Intervention Trial (FIT) of a national cleanyourhands campaign	Not speciec
Aseptic technique policy	Not stated
A customized version of the WHO Surgical Safety Checklist - part of the Safe Surgery South Carolina program	14/58

1		
2	NHS information and technology (IT) programme	4 Trusts /al
3		
4		
5	More-2-Eat project	
6		5
7		
8		
9	Bronchiolitis clinical practice guidelines	
10		11
11	Blunt chest injury care bundle	2
12		
13	Caring Letters	6 Defence c
14	National disclosure policy after adverse events developed by	
15	Veterans' Affairs	All 150 VA c
16		
17		
18	Several interventions for newborns and maternal health	
19		251 facilitie
20		
21		
22		
23	Picture Archiving and Communication System (PACS)	
24		
25		
26		four special
27	Enhanced Recovery Protocols	One - across
28		
29	Anti-platelet therapy adherence	
30		20 VA medi
31	Pharmacist-to-Pharmacist Transitions of Care Initiative	2 VA medic
32	Consult for Addiction Treatment and Care in Hospitals (CATCH)	6
33		
34		
35		
36		
37	Anaesthetists Be Cleaner	
38		
39		
40		
41		5 hospitals
42	Safe Surgery 2015 initiative to implement SSCs in South Carolina	
43	hospitals	67 (reportir
44		
45	Screening, Brief Intervention, and Referral to Treatment (SBIRT)	
46		24 EDs
47		
48	Mobilization of Vulnerable Elders in Ontario (MOVE ON)	
49		26 hospital
50		
51		
52		
53	The Productive Ward: Releasing Time to Caree programme	
54		
55		
56		
57		5
58		
59	Eat Walk Engage	
60		4

1		
2		
3		
4	Period ofPURPLE Crying: Keeping Babies Safe in North Carolina,	
5		86
6		
7	The Bacteremia Zero study	
8		192 ICUs
9		
10	The Keystone Intensive Care Unit Project	
11		108 ICUs
12		
13	The Keystone Intensive Care Unit Project	
14		109 ICUs
15		
16		
17		
18	Society of Critical Care Medicine guidelines re sedation and	
19	monitoring	
20		2
21		
22		
23		
24		
25		
26	Keystone Surgery Program	
27		
28		
29		
30		29
31		
32		
33		
34	German Quality Network Sepsis	
35		75
36		
37	Study to Optimally Prevent Surgical Site Infections in Select	
38	Cardiac and Orthopedic Procedures (STOP SSI)	20
39		
40	Multi-Centre Medication Reconciliation Quality Improvement	
41	Study (MARQUIS2).	18
42		
43	Gravimetric workflow software systems	10 pharmaco
44		
45		
46		
47	Pediatric surgical site infection prevention bundle	
48		18
49		
50		
51		
52	Fast track cancer diagnostics	
53		
54		One large c
55		
56		
57		
58		
59		
60		

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

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  
Matching Registered Nurse Services with Changing Care Demands  
Lean thinking initiative

4

23

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 I=internal	External Support e.g., research ers 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	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 implementatio	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

1				
2				
3	the largest civilian IT programme in the world	E	N	E Y
4				
5				
6	implementation of an evidence-based nutritic	E	Y	E Y
7				
8				
9				
10	multisite implementation of an evidence-base	E	Y	Not report
11	implementation of a blunt chest injury care	E	Y	R Y
12				
13	National trial/ research	E	N	R Y
14				
15	National policy	E	N	I N
16				
17				
18				
19	large-scale quality improvement intervention	E	Y	E Y
20				
21				
22				
23				
24				
25				
26	Multisite implementation	E	Y	I Y
27	multispecialty implementation of ER protocol	E	Not clear	R,I, E Y
28				
29	multi-site randomized stepped wedge trial to	E	N	R, I Y
30	large-scale pharmacist-to-pharmacist TOC	mc	N	R, I Y
31	pragmatic trial at six hospitals; program	E	N	R, I Y
32				
33				
34				
35				
36				
37				
38				
39				
40				
41	an evidence-based bundle, stepped wedge, cl	E	Y	E Y
42				
43	state-wide/ large-scale implementation of sur	E	Y	E Y
44				
45	a state-wide effort in Maryland to expand SBI	E	N	E Y
46				
47				
48	a multi-site implementation intervention in a	E	Y	I, E, R Y
49				
50				
51				
52				
53				
54				
55				
56				
57	large-scale quality improvement	E	Y	Mixed Y
58				
59	a multi-site improvement program	E	Y	I, E, R Y
60				

1					
2					
3					
4					
5	statewide nurse training program	E	N	Mixed	Y
6					
7					
8	national multimedial intervention	E	Y	Mixed	Y
9					
10					
11	statewide quality improvement initiative	E	Y	Not clear	Y
12					
13					
14					
15	statewide quality improvement initiative	E	Y	Not clear	Y
16					
17					
18					
19					
20	a process-improvement project	E	N	R, I	Y
21					
22					
23					
24					
25					
26					
27					
28					
29					
30	Statewide, checklist-based quality improvement	E	Y	I	Y
31					
32					
33					
34					
35					
36	a quality collaborative	E	Y	I/E	Y
37					
38	the multisite pragmatic trial	E	Y	I	Y
39					
40					
41					
42	patient safety strategy that is widespread in U.S.	E	Y	I/E	Y
43	a large-scale, multicentre, multinational	E	N	Not clear	Not reported
44					
45					
46					
47					
48					
49	A quality improvement collaboration in Ohio	E	Y	I/E	Y
50					
51					
52					
53					
54					
55	Large scale implementation	E	Y	I	Y
56					
57					
58					
59					
60					



1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

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

	<b>Formal Internal Support for the project</b>	<b>Formal outcome measures collected. Y;N</b>	<b>Evidence of System Change (e.g., new forms,</b>	<b>Any mention of active de-implemen</b>	<b>Any mention of adaptabili ty? Or</b>
12	Y	Y		N	Y
14	Y	Y	Not really	N	Y
17	Y	Y	Y	N	Y
20	Y	Y	Y	N	Some
22	Y - implied	Y	Y poster	N	N
27	Y	Y	Y - resource	Y new proc	Y - more QI
28	Y	Y	Y	Not report	All tight
29	Not report	Y	Y	N	Y - some ne
32	Y	Y	protocol	protocol	Y
34	Y	Y	Yes	Yes some	Y
39	Y	Y	Y	N	N
43	Y	Y	Y	Not report	Y
45	Y	Y	Y	Not report	Y
49	Y	Y	N	N	Y
52	Y	Y	Y	N	N
56	Y	Y	Protocol	Protocol	Protocol
57	Y- implied	Y	Y	N	N
60	Y	Y	Y	Not report	Y

1					
2					
3	Y	Y	Y	Surprisingly	N
4					
5					
6	Y	Y	Y	No	Y
7					
8					
9					
10	Y	Y	Y	N	Y
11	Y - implied	Not reported	Y	N	Y
12					
13	Y	Y	Y, new ema	N	N
14					
15	Y	Y	Y new proc	N	Learning hc
16					
17					
18					
19	Y	Y	Y, new equi	Y	Y - each fac
20					
21					
22					
23					
24					
25					
26	Y	Y	Y; IT, proce	Y	N
27	Y	Y	Y, processe	N	N
28					
29	Y	Y	Y, processe	N	N (CT)
30	Y	Y	Y, processe	N	N
31	Y	Y	Y - extensiv	N	N
32					
33					
34					
35					
36					
37					
38					
39					
40					
41	Y	Y	Y, processe	N	Y
42					
43	Y	not reported	Y checklist	N	Not reported
44					
45	Y	Y	Y screening	N	N
46					
47					
48	Y	Not reported	Y	N	Y
49					
50					
51					
52					
53					
54					
55					
56					
57	Y	Y	Y	Y	Y
58					
59	Y	Y	Y	Protocol	Y
60					

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

5	Y	Y	Y	N	N
8	Y	Y	Y	N	Y
11	Y	Y	Y	N	Y
15	Y	Y	Y	N	Y
20	Y	Y	Y	N	N
30	Y	Y	Y	Y - checklist	Yes - local a
36	Y	Y	Y	N	N
38	Y	Y	Y	N	Y
42	Y	Y	Y	N	N
43	Y	Y	Y new softw	Y	Not report
49	Y	Y	Y	N	N
55	Y	Y	Y: new processes, new equipment		

For peer review only

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

Y	Y	Y	Not reported	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

For peer review only

1  
2  
3  
4 **Implementation strategies, frameworks named / discussed?**  
5  
6  
7  
8

9 Comprehensive Unit-based Safety Programme developed in the  
10 USA, is a five-step iterative process  
11

12  
13  
14 No

15  
16 Some

17  
18 Yes - Ubuntu philosophy 'I am what I am because of who we all are'  
19 to promote ownership  
20

21 Yes - based on poor knowledge of extent of SSI - not well reported  
22 across UK.  
23

24  
25 Lean Six Sigma  
26

27  
28 Yes - developing a framework for how to engage clinical staff  
29 Barriers  
30

31 The Model for Planning Change .  
32

33 Adaptive Design  
34

35  
36  
37 Yes  
38

39  
40 Healthcare Improvement Collaborative Model (HICM) based on  
41 Provonost and Johns Hosplins Implementation models. Really a QI  
42 process.  
43

44  
45 Yes at length - make their own Evidence-Based strategy.  
46

47 Yes theory-based analysis of barriers to implementation of  
48 guidelines  
49

50  
51 Yes  
52

53  
54 The Generic Implementation Framework and RE-AIM to evaluate  
55

56  
57 Lack of strategies discussed at length. Assessed using CFIR  
58

59 Yes  
60

1  
2 Staged implementation of components, support from Central IT  
3 service - focus here is on what didn't happen.

4 COM-B analysis, PDSA, sudit and feedback, MD imp Teams,  
5 clinical leaders/champions; engaing senior management  
6  
7

8 Yes  
9

10  
11 Only in terms of barriers / enablers using TDF and COM-B

12 Mostly based on pilot study

13  
14  
15 Analysis of barriers using CFIR

16  
17  
18 No  
19

20  
21  
22  
23 Yes  
24

25  
26  
27 No  
28

29 Yes  
30

31 No

32 Not clear  
33  
34  
35  
36

37 Yes - Table 1 shows their set of IS informed principles.  
38  
39  
40  
41

42  
43 Yes  
44

45 No  
46  
47

48 Yes mapped to context and barriers analysis with TDF  
49  
50  
51  
52

53 Yes - based on Diffusion of Innovation  
54  
55  
56  
57

58 integrated Promoting Action on Research Implementation in  
59 Health Services (i-PARIHS) framework  
60

1  
2  
3 Kirkpatrick's typology  
4  
5  
6

7 Yes "engage, educate, execute and evaluate"  
8  
9

10 Yes "engage, educate, execute and evaluate"  
11  
12

13 Yes "engage, educate, execute and evaluate"  
14  
15

16  
17  
18 A four-phase implementation process incorporated a planning  
19 phase, baseline phase, education phase, and maintenance phase  
20  
21

22  
23  
24  
25 Provonost et al's "translating evidence into practice" model and  
26 Comprehensive Unit-based Safety Program (CUSP)  
27  
28

29  
30  
31  
32  
33  
34 Yes  
35  
36

37  
38 N  
39

40 Yes - Framework used to evaluate factors that may have  
41 influenced implementation. Not always clear what the  
42 implementation at each site was.  
43

44 No  
45

46  
47 Yes  
48  
49

50  
51  
52 Elements from lean management, theory of constraints and  
53 mathematical analysis  
54  
55  
56  
57  
58  
59  
60



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; accountability 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 multi-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 auditors.

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.

1 Hospital exec engagement, clinical leadership, support from  
 2 external experts, harnessing tension for change,  
 3 implementation team, audit and feedback, champions, senior  
 4 management "educated" by champions, education, external  
 5 support  
 6  
 7 Hosp exec engaged to sponsor project, resources shared, support  
 8 from TRN collaborative, education, project coordinator, physician  
 9 champion.  
 10 Education, CPGs available,  
 11 Clear process to follow, education, coaching, exec sponsorship,  
 12 clear objectives  
 13  
 14 Not reported  
 15  
 16 Observational audits of quality of care, education and skills  
 17 assessment, coaching, external support, provision/help in  
 18 sourcing equipment  
 19 Consideration of physical infrastructure supporting the IT upgrade  
 20 (the intervention); training offered at multiple times and through  
 21 multiple formats -webinar/face to face/written , champions,  
 22 implementation team with clear responsibilities and roles;  
 23 comprehensive communication plan; problem solving by imp  
 24 team  
 25  
 26 Not reported  
 27  
 28 Readiness for change analysis, clinical champions, clear guidelines  
 29 to follow  
 30  
 31 Not reported  
 32  
 33 Not reported  
 34  
 35 Education: presentations, written material and illustrative videos;  
 36 co-designed bundle of interventions (so clinicians implementing  
 37 the bundle have ownership), collection of outcome data; engage  
 38 senior leadership, clinical champions. building a tension for  
 39 change, ensuring all interventions "make sense "and are  
 40 compatible with current workflow, "once intervention has been  
 41 agreed, compliance should not be negotiable".  
 42  
 43 Needs analysis/context mapping at start; education; tools to do  
 44 the intervention; multidisciplinary engagement  
 45  
 46 Not reported  
 47  
 48 Education, staff coaching tools, printed education materials,  
 49 reminders, huddles, posters etc.  
 50 Establishing a clear vision, success stories from "early adopters",  
 51 regional level support for education and planning, alignment of  
 52 program with organisational targets, dedicated project  
 53 leadership, senior support, external support, dedicated project  
 54 time for staff, good communication, and information, establishing  
 55 a need for change, valuing the initiative, access to modules,  
 56 voluntary enrolment in the project, sufficient resources, local  
 57 ownership emphasised.  
 58 Facilitator works with MDT to prioritise areas for improvement,  
 59 PDSA, project officer. Education  
 60

1 offered resources free of charge, diffusion of the course via senior  
 2 clinicians involved in a regional education network, MOU with  
 3 exec outlining the program/participation, resources and staff to  
 4 be freed to do program. Education  
 5 Engaged clinicians during meetings etc, audit and feedback via an  
 6 online tool, other tools, education, problem solving, analysis of  
 7 errors

8  
 9 Clinician change agents on each ICU, trained and shown the  
 10 evidence for the/need for change/  
 11

12 Engage: personally communicate, tell stories and share results  
 13 from other sites; educate - including skills, Execute: given skills on  
 14 managing behaviour of others / themselves, streamlining  
 15 processes, checklists; Evaluate: fidelity checked.  
 16 baseline assessment; utilization of existing personnel (e.g., nurse  
 17 educators, unit managers, charge nurses); education in the form  
 18 of lectures, posters, and one-on-one reminders; and evaluation of  
 19 compliance and impact  
 20  
 21  
 22  
 23  
 24

25 Education, collaboration, imp teams; interventions aimed at  
 26 increased safety knowledge and culture  
 27  
 28  
 29  
 30  
 31

32 Audit and feedback, collaborative - benchmarking, responding to  
 33 audits, link between collaborative and local clinical champions,  
 34 education, engage exec - must pay an annual participation fee and  
 35 publication of hospital mortality, expert advice  
 36  
 37

38 not reported  
 39  
 40

41 MD implementation teams, leadership support,  
 42

43 Not reported

44 common goal for improvement, engage and educate  
 45 multidisciplinary teams and senior leaders, simplify and  
 46 standardize care (bundles, protocols, policies, and briefings),  
 47 collect data and offer performance feedback, and to provide  
 48 opportunities for shared learning  
 49 Clinical leadership; executive sponsorship; audit and feedback;  
 50 process mapping/analysis; predefined plan with project officers;  
 51 inventory of barriers and facilitators; PDSA cycles to tweak the  
 52 processes; active involvement of clinicians; external input from  
 53 consultants to benchmark.  
 54  
 55  
 56  
 57  
 58  
 59  
 60

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

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
<b>External, top-down source</b>	Implementing externally developed interventions	Basic and applied research undertaken	Standardised, evidence-based practice used across sites	Always	Developed by quality or safety agencies, <sup>34</sup> research institutes / groups, <sup>24</sup> 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., <sup>35</sup> ), checklists (e.g., <sup>10</sup> ), or guidelines (e.g., <sup>36</sup> ). 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 <sup>12</sup>
	Incentives and disincentives for implementation are offered			Rarely	For one project a participation fee was charged for organisations, <sup>35</sup> for another, selected participants were paid <sup>37</sup>
<b>Evidence-based interventions</b>	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 <sup>38,39</sup>

	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 <sup>31</sup>
<b>Safety and quality focus</b>	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.
<b>Facilitation through assessment and provision of resources</b>	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., <sup>26,40</sup> ) 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 <sup>39</sup>
<b>Harnessing local resources and encouraging adaptation</b>	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	Alleganzi, 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
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 Community of practice / knowledge network of clinicians	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					



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

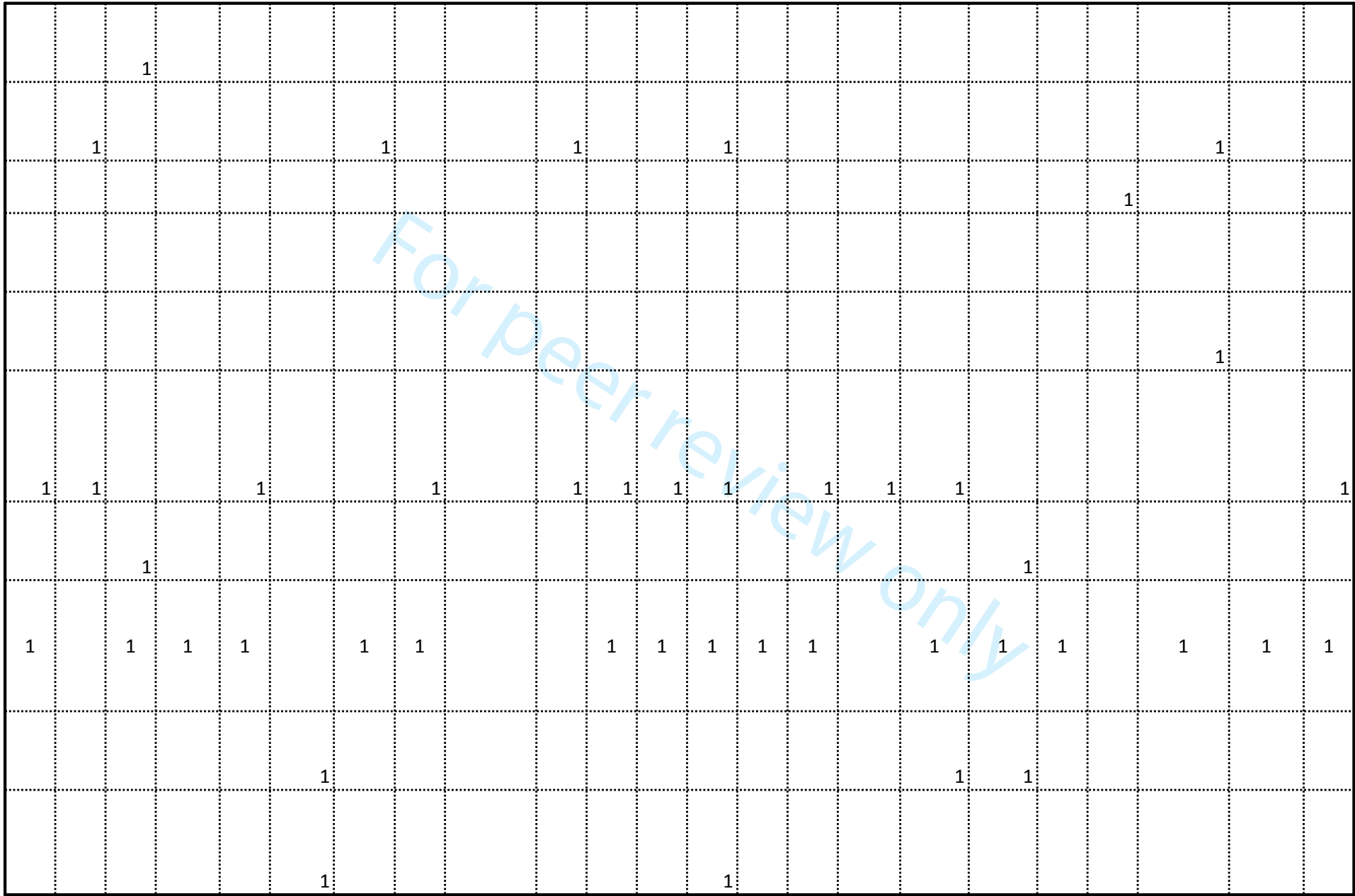


1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

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



1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46







1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

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

For peer review only







## 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

# BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-058158.R1
Article Type:	Original research
Date Submitted by the Author:	23-Feb-2022
Complete List of Authors:	Long, Janet; Australian Institute of Health Innovation, Australian Institute of Health Innovation Sarkies, Mitchell N; Macquarie University, Australian Institute of Health Innovation Francis Auton, Emilie; Macquarie University, Australian Institute of Health Innovation Nguyen, Hoa Mi; Macquarie University, Australian Institute of Health Innovation Pomare, Chiara; Macquarie University, Australian Institute of Health Innovation, Centre for Healthcare Resilience and Implementation Science Hardwick, Rebecca; University of Exeter, Medical School Braithwaite, Jeffrey; Macquarie University, Australian Institute of Health Innovation
<b>Primary Subject Heading</b>:	Health services research
Secondary Subject Heading:	Evidence based practice
Keywords:	Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Change management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

SCHOLARONE™  
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.



1  
2  
3  
4  
5 1 Conceptualising contexts, mechanisms and outcomes for  
6  
7  
8  
9 2 implementing large-scale, multi-site hospital improvement  
10  
11  
12  
13  
14 3 initiatives: a realist synthesis  
15  
16  
17  
18 4

19  
20  
21 5 Authors  
22  
23

24 6 Janet C Long<sup>1\*</sup> PhD, MN, BSc (Hons)  
25  
26

27 7 Mitchell N. Sarkies<sup>1</sup> PhD, BAppSc  
28  
29

30 8 Emilie Francis-Auton<sup>1</sup> PhD, BA-BSc (Hons)  
31  
32

33 9 Hoa Mi Nguyen<sup>1</sup> MIPH, BHIthSc  
34  
35

36 10 Chiara Pomare<sup>1</sup> PhD, MRes, BPsych(Hons)  
37  
38

39 11 Rebecca Hardwick<sup>2</sup> PhD, MSc, BSc (Hons)  
40  
41

42 12 Jeffrey Braithwaite<sup>1</sup> PhD, MBA, BA, MIR (Hons I), DipLR  
43  
44

45 13 Affiliations  
46  
47

48 14 <sup>1</sup>Australian Institute of Health Innovation, Faculty of Medicine, Health and Human Sciences,  
49  
50  
51 15 Macquarie University, North Ryde, Australia  
52  
53

54 16 <sup>2</sup>Peninsula Medical School, Faculty of Health, University of Plymouth, Plymouth, United Kingdom  
55  
56

57 17  
58  
59  
60

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

18 \*Corresponding author

19 [janet.long@mq.edu.au](mailto:janet.long@mq.edu.au)

20 AIHI, Level 6

21 75 Talavera Road,

22 North Ryde, NSW, 2109

23 Australia

24 +61 2 98502225

For peer review only

1  
2  
3  
4 25 **Abstract**  
5  
6  
7

8 26 **Design:**

9 27 Realist synthesis  
10  
11

12 28 **Study background:**  
13  
14

15 29 Large-scale hospital improvement initiatives can standardise healthcare across multiple sites but  
16  
17 30 results are contingent on the implementation strategies that complement them. The benefits of  
18  
19 31 these implemented interventions are rarely able to be replicated in different contexts. Realist  
20  
21 32 studies explore this phenomenon in depth by identifying underlying context-mechanism–outcome  
22  
23 33 interactions.  
24  
25

26  
27 34 **Objectives:**  
28  
29

30 35 To review implementation strategies used in large-scale hospital initiatives and hypothesise initial  
31  
32 36 program theories for how they worked across different contexts.  
33  
34  
35

36 37 **Methods**  
37  
38

38 38 An iterative, four-step process was applied. Step 1 explored the concepts inherent in large-scale  
39  
40 39 interventions using database searches and snowballing. Step 2 identified strategies used in their  
41  
42 40 implementation. Step 3 identified potential initial program theories that may explain strategies'  
43  
44 41 mechanisms. Step 4 focused on one strategy-theory pairing to develop and test context-mechanism-  
45  
46 42 outcome hypotheses. Data was drawn from searches (March-May 2020) of Medline, Embase,  
47  
48 43 PubMed and CINAHL, snowballed from key papers, implementation support websites, and the  
49  
50 44 expertise of the research team and experts. Inclusion criteria: reported implementation of a large-  
51  
52 45 scale, multisite hospital intervention. RAMESES reporting standards were followed.  
53  
54  
55  
56  
57  
58  
59  
60

## 46 Results

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

## 55 Conclusion

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

## 59 Key words

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

61

## 62 Article Summary

### 63 Strengths and limitations of this study

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

- 1  
2  
3 67       • In spite of a systematic and thorough search for literature, only 51 papers were found; while  
4  
5 68       large-scale hospital interventions abound, implementation activities and outcomes are not  
6  
7 69       commonly reported.  
8  
9  
10 70       • The wealth of data constrained our study to consider only a single formal theory, and a  
11  
12 71       subset of implementation strategies.  
13  
14

## 15 72 Funding statement

16 73 This realist review was funded by the Medical Research Future Fund (MRFF) (APP1178554, CI  
17  
18 74 Braithwaite). The funding arrangement ensured there was no role of the study funder in study  
19  
20 75 design, collection, management, analysis, and interpretation of data; drafting the manuscript, and  
21  
22 76 decision to submit for publication.  
23  
24  
25

## 26 77 Competing interest statement

27 78 The authors declare they have no conflicting or competing interests.  
28  
29  
30  
31  
32  
33  
34

## 35 81 Introduction

36  
37  
38  
39 82       The implementation of large-scale, multi-site, hospital-based improvement initiatives,  
40  
41 83 developed from high quality evidence have the potential to standardise practice, improve safety,  
42  
43 84 continuity and quality of care for patients, reduce unnecessary, unwarranted treatments and  
44  
45 85 provide better value for money.<sup>1</sup> Large-scale hospital interventions, as discussed here, are projects  
46  
47 86 that are typically intended to be implemented across multiple hospitals (e.g., all public hospitals in a  
48  
49 87 region). They are usually “top down” in nature, in contrast to local, clinician-initiated “grass-roots”  
50  
51 88 projects. The mandate to implement these initiatives is typically from the hospitals’ funding or  
52  
53 89 governing bodies (e.g., State Health Departments, or local health networks), or high-level clinical  
54  
55 90 agencies (e.g., a national Quality and Safety Commission). Such interventions may be supported by  
56  
57  
58  
59  
60

1  
2  
3 91 additional staff and resources and align with other high-level health system priorities. The focus of  
4  
5 92 these initiatives is improvement of care and did not include mandated, enforceable health orders.  
6  
7

8 93 The QUARISMA intervention in Quebec, Canada, for example, was implemented in 32  
9  
10 94 hospitals.<sup>2</sup> The intervention was based on best practice guidelines derived from recommendations  
11  
12 95 of the Society of Obstetricians and Gynaecologists. The hospitals that implemented it, successfully  
13  
14 96 and safely reduced the rates of clinically unwarranted caesarean sections in low risk mothers.<sup>2</sup>  
15  
16 97 Another example of a large-scale hospital intervention is the World Health Organisation's surgical  
17  
18 98 safety check-list<sup>3</sup> which was successfully adopted in six high performing hospitals in The Netherlands.  
19  
20 99 This significantly reduced surgical complications and mortality.<sup>4</sup>  
21  
22  
23

24 100 Large-scale interventions are expensive and time consuming to implement.<sup>5</sup> Their success is  
25  
26 101 contingent on the implementation programs that accompany them<sup>6</sup>; that is, the suite of individual  
27  
28 102 implementation strategies designed to prepare the hospitals for change, and equip the focal  
29  
30 103 stakeholders to adopt new practices and adapt or discard old ones. Recent systematic reviews have  
31  
32 104 identified a range of strategies linked to successful implementation programs, such as conducting a  
33  
34 105 needs assessment, recruitment of champions or opinion leaders, use of audit and feedback,  
35  
36 106 engaging organisational leaders, and developing implementation teams.<sup>e.g.,7,8</sup> For large-scale  
37  
38 107 interventions, these implementation programs are often required to fit a range of hospitals of  
39  
40 108 different size, geographic and socio-demographic contexts, and health consumer needs.  
41  
42  
43  
44

45 109 In recent years, implementation strategies have been compiled, described and categorised<sup>9</sup>  
46  
47 110 but research has failed to explain why strategies that work as intended in one context,<sup>e.g., 10</sup> may be a  
48  
49 111 failure in another.<sup>e.g., 11</sup> Results suggest that those designing implementation strategies have failed to  
50  
51 112 take into account local contextual features,<sup>12</sup> and that contextual features are poorly conceptualised  
52  
53 113 and defined in reporting.<sup>13</sup> Moreover, the underlying mechanism of action, working within that  
54  
55 114 context, is only rarely defined, implying that the way strategies work is poorly understood. A  
56  
57 115 program theory that lies beneath the implementation program and that articulates how the  
58  
59  
60

1  
2  
3 116 strategies are thought to work is often not explicitly stated. Davies and colleagues showed in their  
4  
5 117 review of 235 guideline dissemination and improvement projects in health care, only 23% used  
6  
7 118 theory of any kind to inform the development of the implementation strategies.<sup>14</sup> This, they argue,  
8  
9 119 can result in a poor choice of implementation strategy for the context (e.g., settling for a “default  
10  
11 strategy” such as an education session<sup>15</sup>) and corresponding poor results.  
12  
13  
14

15 121 Realist approaches take a deep dive into why programs work as intended some of the time  
16  
17 122 but not all of the time.<sup>16</sup> A realist approach asserts that all programs have an underlying program  
18  
19 123 theory that explains how the strategies bring about intended or unintended results. This holds the  
20  
21 124 promise of unpicking the link between the context and outcomes. A realist synthesis is the ideal  
22  
23 125 approach to understand implementation programs for large-scale hospital interventions, as it  
24  
25 126 explores the links between strategies, mechanisms of action, contexts, the responses of clinicians,  
26  
27 127 and outcomes. Terms used in this synthesis referring to types of theories are defined in Box 1.  
28  
29  
30

31  
32 Formal theories: here, this refers to general implementation science theories that have been used  
33  
34 to explain how implementation strategies work broadly and for which there is some empirical  
35  
36 support. Also called mid-range theories<sup>17</sup>  
37

38 Program theory: a theory that explains how and why particular types of interventions work to  
39  
40 generate the outcome/s of interest<sup>16</sup>  
41

42 Initial program theory: a program theory that is hypothesised, tested and refined as a result of the  
43  
44 realist synthesis to explain how the focal type of intervention generates the outcome/s of interest  
45  
46

47 Potential initial program theories: a suite of program theories being considered as an initial  
48  
49 program theory  
50

51  
52 128 *Box 1: Types of theories referred to in this paper*  
53

54 129 A realist synthesis is a generative process, first understanding the nature of the  
55  
56 130 implementation program and then proposing potential initial program theories around the way a  
57  
58 131 program works. These initial program theories, configured as *contexts* (circumstances under which  
59  
60

1  
2  
3 132 the program works), *mechanisms* (generative causes of how programs elicit results), and *outcomes*  
4  
5 133 (the results of the program), are then tested using published literature.<sup>16</sup> The *context-mechanism-*  
6  
7 134 *outcome* configurations (CMOs) that are found through analysis of the literature can be explored  
8  
9  
10 135 and used to formulate and refine initial program theories which explain how and under what  
11  
12 136 circumstances programs achieve different outcomes. Consequently, realist research does not apply  
13  
14 137 value judgements on program outcomes such as “successful” or “unsuccessful”. Instead, it  
15  
16 138 acknowledges that programs produce intended and unintended outcomes.<sup>18</sup>

19  
20 139 The aim of this realist synthesis was to synthesise evidence and generate initial program  
21  
22 140 theories that explain how implementation strategies work in large-scale hospital interventions; in  
23  
24 141 other words, to gather evidence on what works as intended for whom, in what circumstances, and  
25  
26 142 why. This realist synthesis is divided into two parts. First, we scope the literature seeking to  
27  
28 143 understand the concepts and features of implementation programs for large-scale hospital  
29  
30 144 interventions to understand the sorts of formal theories that may be relevant here. Second, we  
31  
32 145 focus on a single group of implementation strategies and generate initial program theories<sup>19</sup> and  
33  
34 146 CMO configurations to test against the literature.

37  
38 147 Both parts of the synthesis are part of a larger project<sup>20</sup> examining seven *Leading Better*  
39  
40 148 *Value Care* projects implemented in metropolitan, remote and regional-based hospitals (n=100)  
41  
42 149 across New South Wales (NSW), Australia between 2016 and 2018.<sup>20</sup> These projects are based on a  
43  
44 150 value-based care paradigm and address unwarranted clinical variation, and preventable  
45  
46 151 hospitalisations across seven high impact conditions.<sup>21</sup> Early results from this project showed that  
47  
48 152 implementation strategies accompanying the projects were variably successful across sites at  
49  
50 153 eliciting buy-in and adoption of the interventions. This current study is informing a realist evaluation  
51  
52 154 of the implementation strategies used to build a nuanced model to support future large-scale  
53  
54 155 hospital implementations; specifically, by defining relevant concepts and proposing initial program  
55  
56 156 theories.



## 157 Methods

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

### 167 *Step 1: Conceptualising large-scale hospital interventions*

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

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

179 First we built a list of concepts and associated features characterising implementation  
180 programs for large-scale hospital interventions from key articles, e.g.,<sup>1</sup> our own research, and clinical

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

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

196 *Table 1: The four iterative steps used to search, find, extract and synthesise evidence to generate*  
 197 *initial program theories that explain how implementation strategies work in large-scale hospital*  
 198 *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

		<p>What mechanisms might these suggest are key to driving the program?</p>	<p>Consider antecedents and outcomes of each feature to identify putative relevant mechanisms</p>
<p>2</p>	<p>To scope suites of implementation strategies used with large-scale hospital interventions</p>	<p>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?</p>	<p>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</p>
<p>3</p>	<p>Identify potential initial program theories</p>	<p>What formal theories might explain the mechanisms of action for the strategies listed?</p>	<p>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</p>
<p>4</p>	<p>Focus on a promising implementation</p>	<p>What context-mechanism-outcome configurations can we</p>	<p>Research team workshop to develop initial CMO statements</p>

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

	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
--	--	--	--

199

For peer review only

1  
2  
3 200 Using an iterative approach, the research team refined our definition of large-scale hospital  
4  
5 201 interventions as we built up the list of associated concepts and features. Finally, antecedents and  
6  
7 202 intended outcomes of the features as a whole and individually were developed and considered to  
8  
9 203 further explore possible mechanisms that may be relevant. Articles that we included involved  
10  
11 204 implementation across multiple hospital sites for interventions aimed at improving patient safety or  
12  
13 205 quality of care. We did not include programs situated outside the hospital setting (e.g., implemented  
14  
15 206 solely in community-based health services), interventions at only one site, locally driven  
16  
17 207 interventions (e.g., internally developed, ward-based improvements) or tightly controlled research  
18  
19 208 trials that were not considered “real world interventions” (e.g., randomised controlled trials). We did  
20  
21 209 consider pragmatic trials if they met other parts of our definition. A data extraction sheet was used  
22  
23 210 to organise concepts described in the papers found. Papers not reporting implementation strategies  
24  
25 211 or activities were not included.  
26  
27  
28  
29  
30

### 31 212 *Step 2: Scoping suites of implementation strategies*

32  
33  
34 213 Our next task was to identify and collate all implementation strategies that were reported as  
35  
36 214 part of these types of large-scale interventions. Together with the concepts and features of the  
37  
38 215 initiatives found in Step 1, this list of strategies and any information reported on how they were  
39  
40 216 intended to work, were needed to understand possible contexts and mechanisms leading to  
41  
42 217 outcomes.  
43  
44

45 218 We started our search for implementation strategies with the papers found in Step 1. Next  
46  
47 219 we scanned papers found in an existing systematic review of implementation strategies used in  
48  
49 220 hospital avoidance interventions for people with chronic conditions, choosing projects that met our  
50  
51 221 large-scale, multi-site criteria.<sup>23</sup> We also searched more broadly for systematic reviews looking at  
52  
53 222 implementation strategies targeting other cohorts of patients (Web of Science (all databases  
54  
55 223 selected): “implementation” AND “systematic review”). We included protocol papers hoping these  
56  
57 224 might provide a fuller rationale for their choice of strategies. We also included selected grey  
58  
59  
60

1  
2  
3 225 literature from a targeted search of implementation materials from agencies known to actively  
4  
5 226 support large-scale implementation programs: United Kingdom's National Health Service, Canada's  
6  
7 227 Advance Care Planning, NSW Agency for Clinical Innovation, Australian Medical Research Council,  
8  
9  
10 228 Enhanced Recovery After Surgery Society, and World Health Organization. We set up a data  
11  
12 229 extraction matrix, recording reported implementation strategies for each project. We also ran a  
13  
14 230 Google search on 'implementation guide' and 'implementation healthcare guides.' Implementation  
15  
16 231 strategies were collated and reviewed in each source.

17  
18  
19 232 Initially, we used our own descriptors for the strategies, but then aggregated similar  
20  
21 233 strategies and mapped them to the Expert Recommendations for Implementing Change (ERIC)<sup>9</sup>  
22  
23 234 taxonomy of 73 implementation strategies. Any strategies that did not map to an ERIC strategy were  
24  
25 235 still included but noted.

### 26 27 28 29 236 *Step 3: Identifying potential initial program theories*

30  
31  
32 237 In this next step, the research team held two, two-hour meetings to workshop ideas towards  
33  
34 238 identifying potential initial program theories.<sup>19</sup> Many theories were proposed in the workshop,  
35  
36 239 mainly from our prior research experience and discussed one by one. We also read up on theories  
37  
38 240 proposed by other realist researchers and added them for consideration. This work was being done  
39  
40 241 in parallel with the realist evaluation of the actual state-wide initiative so this also guided our  
41  
42 242 thinking. This resulted in a short list of promising theories.

43  
44  
45  
46 243 The process included consideration of all the data generated so far in the project as well as  
47  
48 244 searching published literature around known formal theories; in particular, we examined together  
49  
50 245 the concepts identified in Step 1 and the implementation strategies identified in Step 2. That is, we  
51  
52 246 considered what existing formal theories or types of theories might be relevant to explain particular  
53  
54 247 implementation strategies given the concepts and putative mechanisms we had identified. For  
55  
56 248 example, an implementation strategy of *conducting a local needs assessment*, fitted with the  
57  
58 249 concept of *facilitation through provision of resources* and the feature *ensuring a formal period of*

1  
2  
3 250 *planning*. Organisational Readiness Theory was identified as a formal theory that promised to  
4  
5 251 explain how this implementation strategy of *conducting a local needs assessment* would work across  
6  
7 252 different contexts. These formal theories became the basis for our initial program theories and were  
8  
9 253 matched with implementation strategies using this process. Theories were retained or excluded on  
10  
11 254 their ability to broadly describe what was happening in one or more implementation strategies, how  
12  
13 255 and why across a range of contexts, and a range of levels (micro, meso and macro).  
14  
15  
16

#### 17 256 *Step 4: Further scoping and focus on a key strategy*

18  
19  
20 257 As realist syntheses aim to explain how and why a program works and have the potential to  
21  
22 258 generate vast amounts of data to do this well, it was necessary to carefully scope the results  
23  
24 259 generated and narrow our focus. Following the example of other realist syntheses,<sup>19,24-26</sup> we looked  
25  
26 260 for a single set of implementation strategies and their accompanying initial program theory that (a)  
27  
28 261 was deemed highly important in informing our parallel tranche of work - the realist evaluation of the  
29  
30 262 *Leading Better Value Care* projects in NSW, Australia - and (b) had not already been researched using  
31  
32 263 realist methodology.  
33  
34  
35  
36

## 37 264 Results

38  
39  
40 265 Results of the activities used to synthesise evidence and generate initial program theories  
41  
42 266 that explain how implementation strategies work in large-scale hospital interventions are outlined  
43  
44 267 below. The process was driven by the fortnightly research team meetings, separate two-hour  
45  
46 268 workshops, validation by other authors and stakeholders, and iterative refinements. Table 2  
47  
48 269 summarises the results from the four steps. Figures 1 and 2 show the PRISMA-style flow diagrams  
49  
50 270 for steps 1 and 2 respectively.  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

271 *Concepts associated with large-scale hospital intervention implementation programs (Step*

272 *1)*

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

278 *Table 2: Summary of search strategy, activities and results at each of the four steps. (ERIC = Expert*  
 279 *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	<p>Extracted data from Step 1 literature that report implementation strategies</p> <p>Search for published literature on implementation and screen for large-scale hospital criteria. Include known literature. Individual studies extracted from reviews</p> <p>Search of targeted websites and other grey literature</p> <p>Strategies aggregated and sorted then mapped to ERIC implementation strategies</p>	<p>45 articles</p> <p>585 reviews found: 31 found to include relevant studies some reporting on multiple implementation strategies</p> <p>Data extracted from 5 sets of documents</p>	<p>302 reports of 28 different implementation strategies identified and collated</p> <p>28 implementation strategies mapped to ERIC taxonomy, 1 did not map</p>
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

280

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

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

1  
2  
3 287 institutes (e.g., WHO,<sup>27</sup> American College of Surgeons<sup>28</sup>), quality collaboratives (e.g., Michigan  
4  
5 288 Surgical Quality Collaborative,<sup>29</sup> German Quality Network<sup>30</sup>), or in one case, mandated, evidence-  
6  
7 289 informed policy (e.g., US Veterans' Affairs (VA) National Disclosure Policy<sup>31</sup>). Support for  
8  
9  
10 290 implementation for the intervention itself was frequently built into this package by the external  
11  
12 291 source: interventions were often presented as a "bundle" of interventions all aimed at addressing a  
13  
14 292 single issue (e.g., surgical site infections,<sup>32</sup> treatment of blunt chest injury<sup>33</sup>). Checklists and  
15  
16 293 implementation guides may also be provided by the external agency that developed the  
17  
18 294 intervention. Contrary to our expectations, the offer of incentives or disincentives for  
19  
20  
21 295 implementation was rarely reported.

22  
23  
24 296 *Evidence-based interventions:* All interventions were identified by the authors as being  
25  
26 297 evidence-based, although the evidence (e.g., the randomised control trial on which the intervention  
27  
28 298 was built) itself was rarely cited. Contrary to the expectations of our research team, de-  
29  
30 299 implementation of processes and practices that presumably were no longer "best practice" was  
31  
32  
33 300 rarely reported. This applied even to upgraded Information Technology systems where legacy  
34  
35 301 systems were allowed to remain alongside the new programs.<sup>34</sup>

36  
37  
38 302 *Safety and quality focus:* A clear aim of improving patient outcomes was consistently found,  
39  
40 303 often by making a case for change from baseline data. Implicit in most programs was the assumption  
41  
42 304 that a positive safety culture, that saw improvement of patient outcomes as core business was  
43  
44 305 present at the site. Also implicit was that there was consensus at each site that the intervention was  
45  
46 306 needed, and that the implementation support provided would be acceptable.

47  
48  
49  
50 307 *Facilitation through provision of resources:* As well as implementation guides and  
51  
52 308 intervention resources, external support was seen in many projects in the form of new equipment,  
53  
54 309 customised forms for documentation, and care pathways. Project officers skilled in the intervention  
55  
56 310 and tasked with data collection or training were funded in some projects, often budgeted as part of  
57  
58 311 an associated research component (e.g.,<sup>35</sup>). Partnership agreements with external agencies  
59  
60

1  
2  
3 312 facilitated implementation by providing access to specialist advice. Funding for the projects was  
4  
5 313 often a mix of external (e.g., VA (USA)<sup>31</sup>), internal (e.g., Hornsby Ku-ring-gai District Hospital  
6  
7 314 (Australia)<sup>35</sup>), and research-based (e.g., National Institutes of Health grants (USA)<sup>36</sup>). Facilitation was  
8  
9  
10 315 not always a feature. All studies relied on the goodwill of clinicians, and some did not factor in any  
11  
12 316 quarantined time for implementation activities such as audits. Interventions developed by clinical  
13  
14 317 collaboratives were often framed as partnerships, including access to practical support and expert  
15  
16 318 advice (in-kind) for the implementation and monitoring of outcomes, some allowing dissemination  
17  
18  
19 319 of learnings from other sites, and benchmarking. Data was often provided to make a case for  
20  
21 320 change, and support for ongoing audit and feedback were common features.

22  
23  
24 321 *Harnessing local resources and encouraging adaptation:* The provision of a lead-in time for  
25  
26 322 each site to assess for readiness and local needs was sometimes reported, and internal support for  
27  
28 323 implementation from senior management was reported in most papers. Design amenable to  
29  
30 324 adaptation to fit different local practices, patient cohorts or workflows, developed by clinically based  
31  
32  
33 325 implementation teams, was also frequently reported. Clinical leadership, mentoring, supervision and  
34  
35 326 in-house education were also key features.

36  
37  
38 327 Following this, features were refined by determining their antecedents and intended  
39  
40 328 outcomes, to help with the next step of defining associated implementation strategies, mechanisms  
41  
42 329 and potential initial program theories. Supplementary File 2 shows the results of this step.

#### 43 44 45 330 *Collated suites of implementation strategies (Step 2)*

46  
47  
48 331 We found 302 reports of 28 different implementation strategies associated with large-scale  
49  
50 332 hospital interventions from 45 peer-reviewed papers and five sets of grey literature documents  
51  
52 333 (each linked to a single website). Figure 2 shows the PRISMA flow diagram for this step. All of the  
53  
54 334 strategies except one mapped to one or a combination of strategies in the ERIC taxonomy.<sup>9</sup> The  
55  
56 335 strategy that did not map was *Aligned with organisational/ District and Departmental priorities*.  
57  
58  
59 336 Some strategies that were similar were combined as descriptions in the articles were not sufficient

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

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

ERIC taxonomy	Implementation strategy	Frequency
ERIC, <sup>9</sup>		(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

1			
2			
3	Develop a formal implementation	Implementation guides	14
4			
5	blueprint (a)		
6			
7	Develop a formal implementation	Intervention Toolkit	10
8			
9	blueprint (b)		
10			
11	Develop academic partnerships; use	Support from external experts/ external	14
12			
13	an implementation advisor; use	support	
14			
15	advisory boards and workgroups		
16			
17	Develop and implement tools for	Monitoring	6
18			
19	quality monitoring		
20			
21	Develop educational materials;	Education	18
22			
23	distribute educational materials		
24			
25	Develop resource sharing agreements	Resources shared	1
26			
27	Distribute educational materials	Clinical practice guidelines	8
28			
29	Facilitation	Problem solving	2
30			
31	Identify and prepare champions	Champion	4
32			
33	Inform local opinion leaders	Opinion leaders	7
34			
35	Involve executive boards; Obtain	Executive sponsorship/engagement with the	24
36			
37	formal commitments	state-wide collective	
38			
39	Organise clinician implementation	Quarantined time for skill acquisition	4
40			
41	team meetings		
42			
43	Promote adaptability; purposely re-	Local adaptation	34
44			
45	examine the implementation		
46			
47	Provide clinical supervision	Mentoring/ Supervision/ coaching	16
48			
49	Recruit, designate, and train for	Clinical leadership	10
50			
51	leadership		
52			
53	Use data experts	IT and communication support for new	6
54			
55		processes	
56			
57			
58			
59			
60			

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

345

### 346 *Identify potential initial program theories (Step 3)*

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

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

Theory	Overview (sources)
<b>Organisational Readiness Theory</b>	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). <sup>37</sup>

<b>Social Cognitive Theory</b>	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. <sup>38</sup>
<b>Partnership Synergy Theory</b>	Partners who effectively collaborate and share knowledge, skills and perspectives are able to achieve more value than the sum of the individual parts contributed. <sup>39</sup>
<b>Diffusion of Innovation</b>	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 averse "laggards" will be the last to adopt. <sup>40</sup>
<b>Theory of Planned Behaviour</b>	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. <sup>41</sup>

362

363 *CMO statements from the Organisational Readiness Theory (Step 4)*

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



1  
2  
3 368 in valuable implementation outcomes: a collective commitment to initiate change, greater effort to  
4  
5 369 make the change successful, greater perseverance when barriers are encountered and an increase in  
6  
7 370 pro-social collaborative behaviours that promote the change.<sup>37</sup> Holt, Amenakis and colleagues,<sup>42</sup>  
8  
9 371 state the most potent mechanisms were shared perceptions and beliefs among stakeholders in the  
10  
11 372 organisation that (a) they are capable of implementing the proposed change (i.e., *change-specific*  
12  
13 373 *efficacy*), (b) the proposed change is appropriate for the organisation (i.e., *appropriateness*), (c)  
14  
15 374 leaders are committed to the proposed change (i.e., *management support*), and (d) the proposed  
16  
17 375 change is beneficial to organisational members (i.e., *personal valence*). Perceptions about resources  
18  
19 376 are considered the active means to achieve readiness rather than the resources themselves.<sup>37</sup>  
20  
21  
22  
23

24 377 In an iterative process undertaken by the research team, CMOs were configured, to  
25  
26 378 understand what circumstances (context) needed to be present in an implementation strategy to  
27  
28 379 trigger an identified mechanism leading to an outcome. Since many of the strategies overlapped in  
29  
30 380 their mechanisms and outcomes, we considered them both together and separately. We limited our  
31  
32 381 enquiry to how the mechanisms worked on the implementers within an organisation; i.e., the people  
33  
34 382 delivering the intervention directly to patients, rather than the designers or facilitators of the  
35  
36 383 intervention. The outcomes associated with the Theory of Organisational Readiness were all around  
37  
38 384 engagement, buy-in and commitment to the change.  
39  
40  
41

42 385 At the same time as the CMO statements were being configured, articles that reported  
43  
44 386 enough detail on these strategies were reviewed for evidence looking for specific contextual factors  
45  
46 387 (external, organisational or individual<sup>13</sup>) and mechanisms. A further search specifically for  
47  
48 388 implementation projects across multiple sites that reported using organisational readiness theory  
49  
50 389 was also performed, yielding another four papers. The final column of Table 6 indicates the articles  
51  
52 390 that give evidence to support or not support the CMO configurations.  
53  
54

55  
56 391 Supplementary file 4 shows the RAMESES checklist for this synthesis. Supplementary file 5  
57  
58 392 shows the full search string used in the early steps.  
59  
60

393 Table 5: Theory areas associated with implementation strategies

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

1				
2				
3	use advisory boards and			
4				
5	workgroups			
6				
7	Align with other priorities	Social processes	<b>Formal period of planning and needs assessment:</b> Assess the fit	<i>Organisational Readiness Theory</i>
8			with current workflow, personal and organisational goals aligned	<i>Social Cognitive Theory</i>
9				
10				
11	Conduct local needs	Baseline assessment	<b>Formal period of planning and needs assessment:</b> Assessing	<i>Organisational Readiness Theory</i>
12			readiness; understanding implications of change on workflow and	
13	assessment	and planning	practice	
14				
15			<b>Designed with adaptation to local settings in mind</b>	
16				
17				
18				
19	Assess for readiness and	Baseline assessment	<b>Formal period of planning and needs assessment:</b> Setting up	<i>Organisational Readiness Theory</i>
20			conditions that support change	
21	identify barriers and	and planning		
22				
23	facilitators			
24				
25				
26	Change physical structure	Accessing resources	<b>Provide or facilitate practical support in the form of resources</b>	<i>Partnership Synergy Theory</i>
27			<b>and equipment:</b> Aligning structure with process	
28	and equipment			
29				
30	Use data experts	Partnering	<b>Provide data support for new or changed IT systems, baseline</b>	<i>Partnership Synergy Theory</i>
31			<b>audits and ongoing monitoring:</b> Partnership with experts to	
32			support change	
33				
34				
35				
36	Develop resource sharing	Partnering	<b>Provide or facilitate practical support in the form of resources</b>	<i>Partnership Synergy Theory</i>
37			<b>and equipment:</b> Working with others to effect change	
38	agreements			
39				
40				
41				
42				
43				
44				
45				
46				

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

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

1 2 3 4 5 6 7 8	Facilitation	Social processes	<b>Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:</b> Breadth of expertise, social support	<i>Diffusion of innovation</i>
9 10 11 12 13 14	Identify and prepare champions; inform local opinion leaders	Social processes	<b>Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:</b> Social influence supporting change	<i>Diffusion of innovation</i> <i>Organisational Readiness Theory</i>
15 16 17 18 19 20	Involve executive boards; Obtain formal commitments	Social processes	<b>Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:</b> Trust, social support, legitimacy, accountability	<i>Social Cognitive Theory</i> <i>Diffusion of Innovation</i> <i>Organisational Readiness Theory</i>
21 22 23 24 25 26 27 28 29 30 31	Recruit, designate, and train for leadership	Social processes	<b>Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:</b> Social influence supporting change <b>Provide or facilitate practical support in the form of education and skill acquisition:</b>	<i>Social Cognitive Theory</i> <i>Diffusion of innovation</i>
32 33 34 35 36 37 38 39 40	Organize clinician implementation team meetings	Social processes	<b>Provide social support from executive sponsorship, supervised practice, project officers, opinion leaders or champions:</b> Social influence supporting change, setting common goals and expectations	<i>Organisational Readiness Theory</i> <i>Theory of Planned Behaviour</i>

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

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

394

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

<b>Implementation strategy (ERIC wording)</b>	<b>Context</b>	<b>Mechanism</b>	<b>Outcome</b>	<b>Component of Organisational Readiness Theory</b>	<b>Evidence from the literature on large-scale hospital projects</b>
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 <sup>10,43</sup>
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 <sup>44</sup>

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

(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 <sup>45,46</sup>
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 <sup>47</sup>
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 <sup>10,33,48-51</sup> Not supported <sup>52</sup>



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

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

		... does not decrease			Supported <sup>56</sup>
	Executive /management support is inadequate or distant, but local or within team leadership is seen as strong and autonomous	perceptions of feasibility and value of the change	... and does not impact intention to commit		
	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 <sup>55</sup>
	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		Supported <sup>55</sup>

	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 <sup>10,29,44,49,53,57</sup>
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 <sup>49,57</sup>

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

(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 <sup>48,58</sup>
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 <sup>44,57</sup>
	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 <sup>29,30,44,59</sup>
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 <sup>34,50</sup>

	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 <sup>58</sup>
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 <sup>10,43,48,50,51,57</sup>
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 <sup>33,43,50,57,59</sup>

(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 <sup>48</sup>
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 <sup>33</sup>
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

397

## 398 Discussion

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

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

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

1  
2  
3 422 found across multiple projects providing strong evidence of the theory's applicability in large-scale  
4  
5 423 hospital interventions.  
6  
7

8 424 Evidence found in our set of literature almost all supported CMOs that led to positive,  
9  
10 425 desirable implementation outcomes of engagement and commitment. There was some refuting  
11  
12 426 evidence that pointed to the interdependence of some factors, and that at times one contextual  
13  
14  
15 427 factor could interact and outweigh another. For example, Wyld and colleagues found that although  
16  
17 428 all stakeholders involved with a new biobank highly valued the initiative, doctors tasked with  
18  
19 429 collecting the samples felt early consultation, management support and consideration of the  
20  
21 430 feasibility for them had been lacking.<sup>52</sup> In spite of this, the implementation of the program had been  
22  
23  
24 431 successful with almost universal adherence to the new processes by the doctors. Possibly, the  
25  
26 432 patients' altruistic enthusiasm for the initiative, that was often voiced to the doctors during the  
27  
28 433 informed consent process may have put greater value on the initiative, outweighing the doctors'  
29  
30 434 difficulty.  
31  
32

33 435 Evidence for contextual factors that triggered mechanisms leading to poorer outcomes were  
34  
35 436 also found. Bayley and colleagues note the mismatch in perceptions of feasibility found between  
36  
37 437 managers and implementers, and between different healthcare professionals contributing to the  
38  
39 438 multidisciplinary team effort of implementing stroke rehabilitation guidelines.<sup>48</sup> This same project  
40  
41 439 found that perceptions of feasibility were also negatively affected by overly complicated statements  
42  
43 440 of the intervention and called for a "plain English" version that would be more accessible for busy  
44  
45 441 clinicians. Both contextual factors were considered barriers as this collective perception of lack of  
46  
47 442 support and lack of feasibility triggered disengagement and lack of commitment to the change.  
48  
49  
50

51  
52 443 Some authors, lacking high quality evidence, suggested the cause of poor implementation  
53  
54 444 outcomes might be linked to contextual factors. For example, Reames and colleagues suggest that  
55  
56 445 the failure of their large-scale hospital intervention to effect change might be because it required  
57  
58 446 staff to follow processes that were not strongly associated with clear patient improvements.<sup>45</sup> This  
59  
60



1  
2  
3 447 perception of lack of effectiveness would not trigger the mechanism of building a tension for change,  
4  
5 448 but complacency leading to poor adoption of the intervention. Wand and colleagues found that  
6  
7 449 disagreement voiced by a senior clinician in the early planning stages of an intervention was likely to  
8  
9 450 adversely affect the project's success unless it could be resolved.<sup>46</sup> Here the perception of  
10  
11 451 implementers would be that the intervention was not feasible or appropriate, and trigger  
12  
13 452 disengagement. While these examples do not claim to be high level evidence, but rather the  
14  
15 453 informed opinion of the authors, they are intuitively correct and consistent with the other evidence  
16  
17 454 found in this study.

### 22 455 *Strengths and Limitations*

25 456 Our search for literature was systematic and thorough yet only resulted in 51 papers. This  
26  
27 457 was because while large-scale hospital interventions abound, implementation activities and  
28  
29 458 outcomes are not commonly reported.<sup>60</sup> This meant many articles reporting interventions were not  
30  
31 459 relevant to the present study. Even for papers reporting implementation, reporting of these  
32  
33 460 strategies and the contexts in which they were used was often not detailed enough to develop  
34  
35 461 theories. Notable was the lack of accounts of patient involvement in implementation plans. Articles  
36  
37 462 that were found were mostly reporting successful implementations and this is an acknowledged bias  
38  
39 463 of published literature. While CMOs are useful in explaining single factors, multiple contextual  
40  
41 464 factors may arise that modify how mechanisms work. Lack of detail in reporting meant the O  
42  
43 465 (outcomes) in our CMO configurations were high level and dichotomous: implementers were  
44  
45 466 engaged or implementers were not engaged. Another limitation was the need to constrain our  
46  
47 467 search and inquiry to a subset of strategies and a single formal theory. Strengths included the  
48  
49 468 expertise of the research team (including clinical and implementation science expertise) and the  
50  
51 469 systematic four step iterative investigation.

## 470 Conclusions

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

## 480 Abbreviations

481 CMO Context Mechanism Outcome

482 ERIC Expert Recommendations for Implementing Change

483 NSW New South Wales

484

## 485 Declarations

### 486 Ethics approval

487 Not applicable – using publicly available data.

## 488 Consent to participate

489 Not applicable as there were no participants.

## 490 Patient and public involvement

491

492 Patients and the public were not involved in this study.

## 493 Consent for publication

494 Not applicable.

## 495 Availability of data and materials

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

## 498 Competing interests

499 The authors declare that they have no competing interests.

## 500 Funding

501 This systematic review was funded by the Medical Research Future Fund (MRFF) (APP1178554, CI  
502 Braithwaite). The funding arrangement ensured there was no role of the study funder in study  
503 design, collection, management, analysis, and interpretation of data; drafting the manuscript, and  
504 decision to submit for publication.

505

## 506 Authors' contributions

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

1  
2  
3  
4 511 **Acknowledgements**  
5  
6

7 512 Not applicable.  
8  
9

10 513  
11  
12

13 514 **References**  
14  
15

- 16 515 1. Best A, Greenhalgh T, Lewis S, Saul JE, Carroll S, Bitz J. Large-System Transformation in  
17 516 Health Care: A Realist Review. *The Milbank Quarterly*. 2012;90(3):421-456.  
18 517 2. Chaillet N, Dumont A, Abrahamowicz M, et al. A Cluster-Randomized Trial to Reduce  
19 518 Cesarean Delivery Rates in Quebec. *The New England Journal of Medicine*.  
20 519 2015;372(18):1710-1721.  
21 520 3. Haynes A, Weiser T, Berry W, ; ea. A surgical safety checklist to reduce morbidity and  
22 521 mortality in a global population. *New England Journal of Medicine*. 2009;360:491-499.  
23 522 4. de Vries EN, Prins HA, Crolla RMPH, et al. Effect of a Comprehensive Surgical Safety System  
24 523 on Patient Outcomes. *The New England Journal of Medicine*. 2010;363:1928-1937.  
25 524 5. Greenhalgh T, Humphrey C, Hughes J, Macfarlane F, Butler C, Pawson RAY. How Do You  
26 525 Modernize a Health Service? A Realist Evaluation of Whole-Scale Transformation in London.  
27 526 *The Milbank Quarterly*. 2009;87(2):391-416.  
28 527 6. Yamey G. What are the barriers to scaling up health interventions in low and middle income  
29 528 countries? A qualitative study of academic leaders in implementation science. *Globalization  
30 529 and health*. 2012;8(1):11.  
31 530 7. Braithwaite J, Marks D, Taylor N. Harnessing implementation science to improve care quality  
32 531 and patient safety: a systematic review of targeted literature. *International Journal for  
33 532 Quality in Health Care*. 2014;26(3):321-329.  
34 533 8. Rapport F, Clay-Williams R, Churruca K, Shih P, Hogden A, Braithwaite J. The struggle of  
35 534 translating science into action: Foundational concepts of implementation science. *Journal of  
36 535 Evaluation in Clinical Practice*. 2017; :1-10.  
37 536 9. Powell BJ, Waltz TJ, Chinman MJ, et al. A refined compilation of implementation strategies:  
38 537 results from the Expert Recommendations for Implementing Change (ERIC) project.  
39 538 *Implementation Science*. 2015;10(1):21.  
40 539 10. Haynes AB, Edmondson L, Lipsitz SR, et al. Mortality Trends After a Voluntary Checklist-  
41 540 based Surgical Safety Collaborative. *Annals of Surgery*. 2017;266(6):923-929.  
42 541 11. Urbach DR, Govindarajan A, Saskin R, Wilton AS, Baxter NN. Introduction of surgical safety  
43 542 checklists in Ontario, Canada. *N Engl J Med*. 2014;370(11):1029-1038.  
44 543 12. Molina G, Jiang W, Edmondson L, et al. Implementation of the Surgical Safety Checklist in  
45 544 South Carolina Hospitals Is Associated with Improvement in Perceived Perioperative Safety.  
46 545 *Journal of the American College of Surgeons*. 2016;222(5):725-736.e725.  
47 546 13. Rogers L, De Brún A, McAuliffe E. Defining and assessing context in healthcare  
48 547 implementation studies: a systematic review. *BMC Health Services Research*.  
49 548 2020;20(1):591.  
50 549 14. Davies P, Walker AE, Grimshaw JM. A systematic review of the use of theory in the design of  
51 550 guideline dissemination and implementation strategies and interpretation of the results of  
52 551 rigorous evaluations. *Implementation Science*. 2010;5(1):14.  
53 552 15. Fixsen D, Naoom S, Blase K, Friedman R, Wallace F. *Implementation Research: A Synthesis of  
54 553 the Literature*. Tamps, FL: University of South Florida, Louis de la Parte Florida Mental Health  
55 554 Institute, National Implementation Research Network;2005.

- 1  
2  
3 555 16. Pawson R, Greenhalgh T, Harvey G, Walshe K. Realist review-a new method of systematic  
4 556 review designed for complex policy interventions. *Journal of Health Services Research &*  
5 557 *Policy*. 2005;10(1\_suppl):21-34.
- 6 558 17. Kislov R, Pope C, Martin GP, Wilson PM. Harnessing the power of theorising in  
7 559 implementation science. *Implementation Science*. 2019;14(1):103.
- 8 560 18. Wong G, Greenhalgh T, Westhorp G, Buckingham J, Pawson R. RAMESES publication  
9 561 standards: realist syntheses. In. Vol 692013:1005-1022.
- 10 562 19. Shearn K, Allmark P, Piercy H, Hirst J. Building Realist Program Theory for Large Complex and  
11 563 Messy Interventions. *International Journal of Qualitative Methods*. 2017;16(1).
- 12 564 20. Sarkies MN, Francis-Auton E, Long JC, et al. Implementing large-system, value-based  
13 565 healthcare initiatives: a realist study protocol for seven natural experiments. *BMJ Open*.  
14 566 2020;10(12):e044049.
- 15 567 21. Koff E, Lyons N. Implementing value-based health care at scale: the NSW experience. *Med J*  
16 568 *Aust*. 2020;212(3):104-106 e101.
- 17 569 22. Wong G, Greenhalgh T, Westhorp G, Buckingham J, Pawson R. RAMESES publication  
18 570 standards: realist syntheses. *BMC Medicine*. 2013;11(1):21.
- 19 571 23. Sarkies M, Long JC, Pomare C, et al. Avoiding unnecessary hospitalisation for patients with  
20 572 chronic conditions: a systematic review of implementation determinants for hospital  
21 573 avoidance programmes. *Implementation Science*. 2020;15(1):91.
- 22 574 24. Cunningham U, Ward ME, De Brun A, McAuliffe E. Team interventions in acute hospital  
23 575 contexts: a systematic search of the literature using realist synthesis. *BMC Health Serv Res*.  
24 576 2018;18(1):536.
- 25 577 25. Rycroft-Malone J, McCormack B, Hutchinson AM, et al. Realist synthesis: illustrating the  
26 578 method for implementation research. *Implementation Science*. 2012;7(1):33.
- 27 579 26. Wong G, Greenhalgh T, Pawson R. Internet-based medical education: a realist review of  
28 580 what works, for whom and in what circumstances. *BMC medical education*. 2010;10(1):12.
- 29 581 27. Makene CL, Plotkin M, Currie S, et al. Improvements in newborn care and newborn  
30 582 resuscitation following a quality improvement program at scale: results from a before and  
31 583 after study in Tanzania. *BMC Pregnancy & Childbirth*. 2014;14:381.
- 32 584 28. Cima R, Dankbar E, Lovely J, et al. Colorectal surgery surgical site infection reduction  
33 585 program: a national surgical quality improvement program--driven multidisciplinary single-  
34 586 institution experience. *J Am Coll Surg*. 2013;216(1):23-33.
- 35 587 29. Vu JV, Collins SD, Seese E, et al. Evidence that a Regional Surgical Collaborative Can  
36 588 Transform Care: Surgical Site Infection Prevention Practices for Colectomy in Michigan. *J Am*  
37 589 *Coll Surg*. 2018;226(1):91-99.
- 38 590 30. Schwarzkopf D, Ruddel H, Grundling M, Putensen C, Reinhart K. The German Quality  
39 591 Network Sepsis: study protocol for the evaluation of a quality collaborative on decreasing  
40 592 sepsis-related mortality in a quasi-experimental difference-in-differences design.  
41 593 *Implementation Science*. 2018;13(1):15.
- 42 594 31. Maguire EM, Bokhour BG, Wagner TH, et al. Evaluating the implementation of a national  
43 595 disclosure policy for large-scale adverse events in an integrated health care system:  
44 596 identification of gaps and successes. *BMC Health Services Research*. 2016;16(1):648.
- 45 597 32. Schweizer ML, Chiang HY, Septimus E, et al. Association of a bundled intervention with  
46 598 surgical site infections among patients undergoing cardiac, hip, or knee surgery. *Jama*.  
47 599 2015;313(21):2162-2171.
- 50 600 33. Kourouche S, Buckley T, Van C, Munroe B, Curtis K. Designing strategies to implement a  
51 601 blunt chest injury care bundle using the behaviour change wheel: a multi-site mixed  
52 602 methods study. *BMC Health Services Research*. 2019;19(1):461.
- 53 603 34. Hendy J, Fulop N, Reeves BC, Hutchings A, Collin S. Implementing the NHS information  
54 604 technology programme: qualitative study of progress in acute trusts. *BMJ*.  
55 605 2007;334(7608):1360.

- 1  
2  
3 606 35. Mudge AM, Banks MD, Barnett AG, et al. CHERISH (collaboration for hospitalised elders  
4 607 reducing the impact of stays in hospital): protocol for a multi-site improvement program to  
5 608 reduce geriatric syndromes in older inpatients. *BMC Geriatrics*. 2017;17(1):11.  
6 609 36. Marcus RK, Lillemoe HA, Rice DC, et al. Determining the Safety and Efficacy of Enhanced  
7 610 Recovery Protocols in Major Oncologic Surgery: An Institutional NSQIP Analysis. *Annals of*  
8 611 *Surgical Oncology*. 2019;26(3):782-790.  
9 612 37. Weiner BJ. A theory of organizational readiness for change. *Implementation Science*.  
10 613 2009;4(1):67.  
11 614 38. Bandura A. Social Cognitive Theory in Cultural Context. *Applied Psychology*. 2002;51(2):269-  
12 615 290.  
13 616 39. Lasker RD, Weiss ES. Creating partnership synergy: the critical role of community  
14 617 stakeholders. *J Health Hum Serv Adm*. 2003;26(1):119-139.  
15 618 40. Rogers EM. *Diffusion of innovations*. New York : Free Press 1983.  
16 619 41. Ajzen I. The theory of planned behavior. *Organizational behavior and human decision*  
17 620 *processes*. 1991;50(2):179-211.  
18 621 42. Holt DT, Armenakis AA, Feild HS, Harris SG. Readiness for Organizational Change: The  
19 622 Systematic Development of a Scale. *The Journal of Applied Behavioral Science*.  
20 623 2007;43(2):232-255.  
21 624 43. Palomar M, Alvarez-Lerma F, Riera A, et al. Impact of a national multimodal intervention to  
22 625 prevent catheter-related bloodstream infection in the ICU: the Spanish experience. *Critical*  
23 626 *Care Medicine*. 2013;41(10):2364-2372.  
24 627 44. Pronovost P. Interventions to decrease catheter-related bloodstream infections in the ICU:  
25 628 the Keystone Intensive Care Unit Project. *American Journal of Infection Control*.  
26 629 2008;36(10):S171.e171-175.  
27 630 45. Reames BN, Krell RW, Campbell DA, Jr., Dimick JB. A checklist-based intervention to improve  
28 631 surgical outcomes in Michigan: evaluation of the Keystone Surgery program. *JAMA Surg*.  
29 632 2015;150(3):208-215.  
30 633 46. Wand T, Crawford C, Bell N, Murphy M, White K, Wood E. Documenting the pre-  
31 634 implementation phase for a multi-site translational research project to test a new model  
32 635 Emergency Department-based mental health nursing care. *International emergency nursing*.  
33 636 2019;45:10-16.  
34 637 47. Morrow E, Robert G, Maben J, Griffiths P. Implementing large-scale quality improvement:  
35 638 lessons from The Productive Ward: Releasing Time to Care. *International Journal of Health*  
36 639 *Care Quality Assurance*. 2012;25(4):237-253.  
37 640 48. Bayley MT, Hurdowar A, Richards CL, et al. Barriers to implementation of stroke  
38 641 rehabilitation evidence: findings from a multi-site pilot project. *Disability & Rehabilitation*.  
39 642 2012;34(19):1633-1638.  
40 643 49. Mansoori B, Erhard KK, Sunshine JL. Picture Archiving and Communication System (PACS)  
41 644 implementation, integration & benefits in an integrated health system. *Academic Radiology*.  
42 645 2012;19(2):229-235.  
43 646 50. Pun BT, Gordon SM, Peterson JF, et al. Large-scale implementation of sedation and delirium  
44 647 monitoring in the intensive care unit: a report from two medical centers. *Critical Care*  
45 648 *Medicine*. 2005;33(6):1199-1205.  
46 649 51. van Harten WH, Goedbloed N, Boekhout AH, Heintzbergen S. Implementing large scale fast  
47 650 track diagnostics in a comprehensive cancer center, pre- and post-measurement data. *BMC*  
48 651 *Health Services Research*. 2018;18(1):85.  
49 652 52. Wyld L, Smith S, Hawkins NJ, Long J, Ward RL. Introducing research initiatives into  
50 653 healthcare: what do doctors think? *Biopreservation and Biobanking*. 2014;12(2):91-98.  
51 654 53. Cuypers M, Al-Itejawi HHM, van Uden-Kraan CF, et al. Introducing Decision Aids into Routine  
52 655 Prostate Cancer Care in The Netherlands: Implementation and Patient Evaluations from the  
53 656 Multi-regional JIPPA Initiative. *Journal of Cancer Education*. 2019;5:05.



- 1  
2  
3 657 54. Sharma N, Herrnschmidt J, Claes V, et al. Organizational readiness for implementing change  
4 658 in acute care hospitals: An analysis of a cross-sectional, multicentre study. *Journal of*  
5 659 *Advanced Nursing*. 2018;74(12):2798-2808.  
6 660 55. Rees GH. Organisational readiness and Lean Thinking implementation: Findings from three  
7 661 emergency department case studies in New Zealand. *Health Services Management Research*.  
8 662 2014;27(1-2):1-9.  
9 663 56. Zapka J, Simpson K, Hiott L, Langston L, Fakhry S, Ford D. A mixed methods descriptive  
10 664 investigation of readiness to change in rural hospitals participating in a tele-critical care  
11 665 intervention. *BMC Health Services Research*. 2013;13(1):33.  
12 666 57. Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related  
13 667 bloodstream infections in the ICU. *N Engl J Med*. 2006;355(26):2725-2732.  
14 668 58. Flynn R, Rotter T, Hartfield D, Newton AS, Scott SD. A realist evaluation to identify contexts  
15 669 and mechanisms that enabled and hindered implementation and had an effect on  
16 670 sustainability of a lean intervention in pediatric healthcare. *BMC Health Services Research*.  
17 671 2019;19(1):912.  
18 672 59. Nocera M, Shanahan M, Murphy RA, et al. A statewide nurse training program for a hospital  
19 673 based infant abusive head trauma prevention program. *Nurse Education in Practice*.  
20 674 2016;16(1):e1-6.  
21 675 60. Proctor EK, Powell BJ, McMillen JC. Implementation strategies: recommendations for  
22 676 specifying and reporting. *Implementation Science*. 2013;8(1):139.

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## Figures

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

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

For peer review only



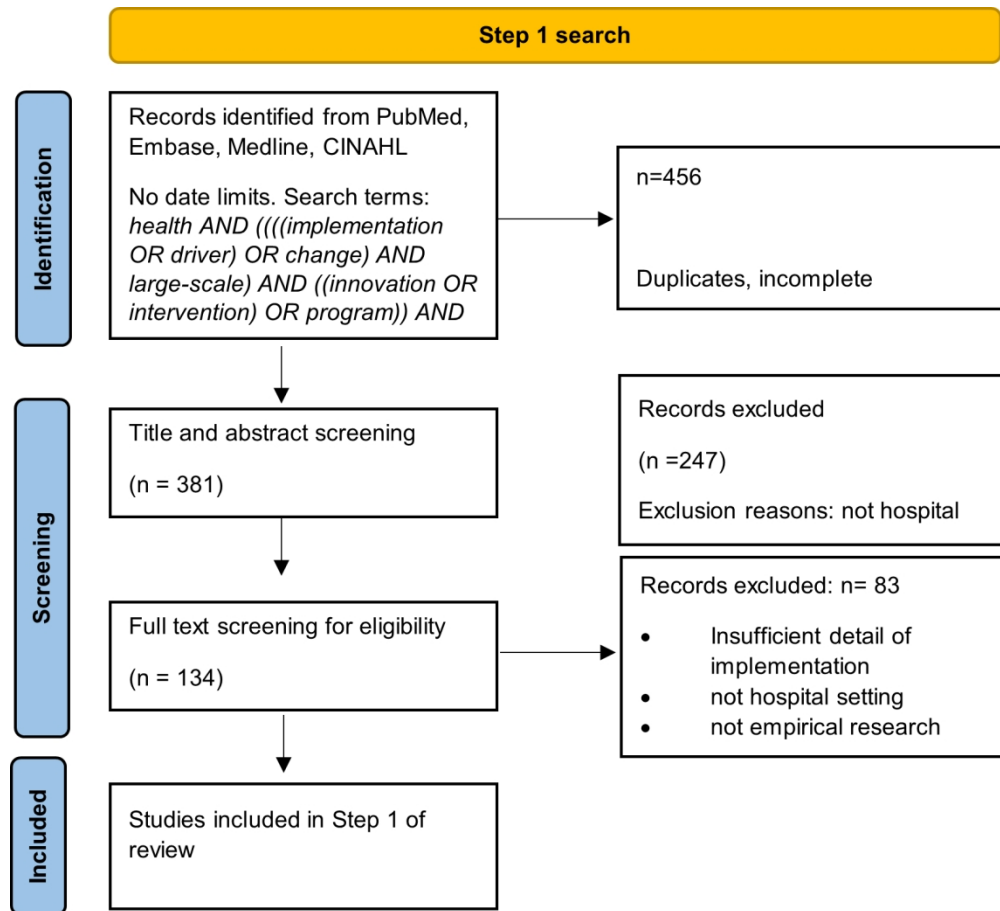
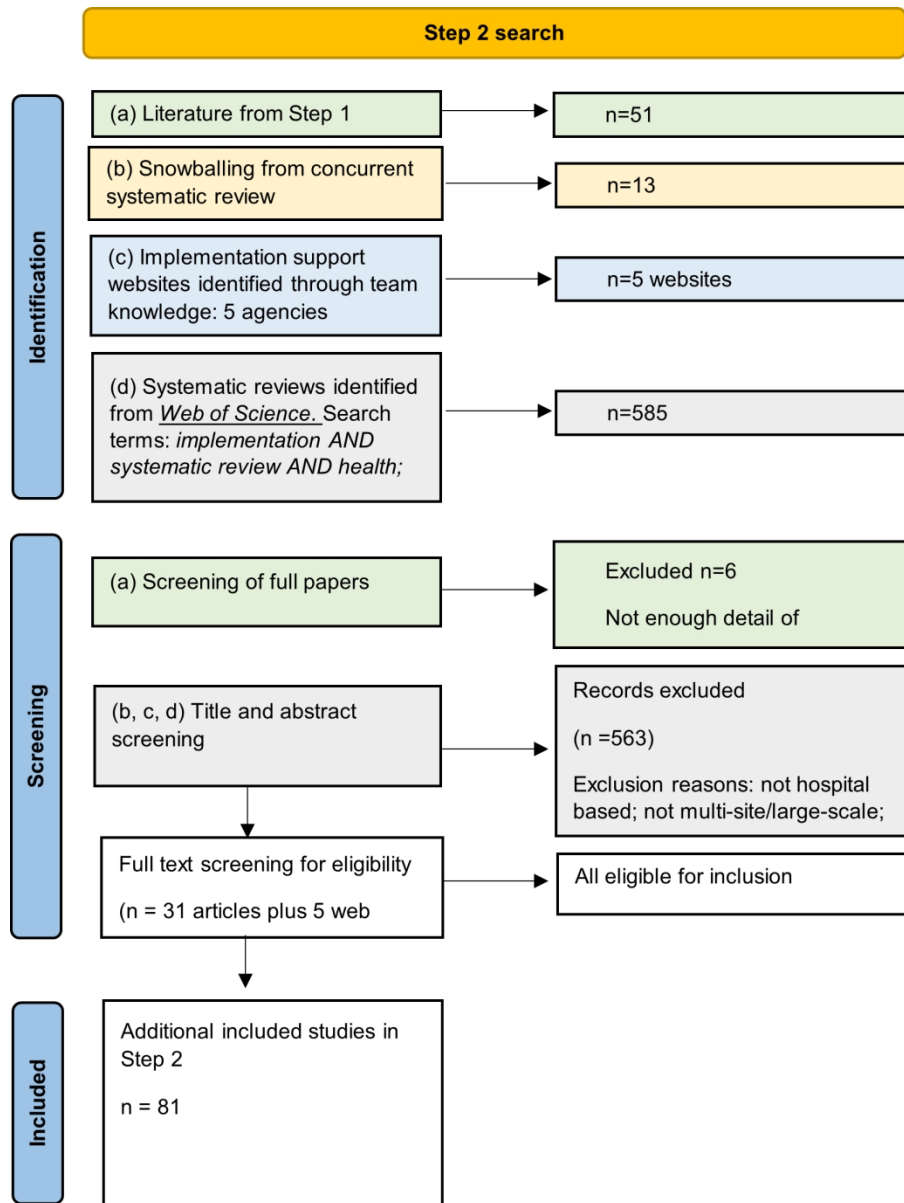


Figure 1: PRISMA-style flow chart for step 1. (Based on: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. doi: 10.1136/bmj.n71)



45 Figure 2: PRISMA-style flowchart for Step 2 (Based on: Page MJ, McKenzie JE, Bossuyt PM, Boutron I,  
46 Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic  
47 reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71)  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

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. /	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: resulting 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 l	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, v	2020	Database search	Netherlands	Time out procedure and debriefing in Operating theatres	10

1						
2						
3		2013	Database search		QUARITE (quality of care, risk management, and technology in	
4	Dumont, A., P. Fournier, M. Abra			Senegal and Mali	obstetrics) trial	46
5						
6						
7		2017	Database search		Translating Research into Practice implementation model.	
8	Edward, K. L., K. Walker and J. Du			Australia		9
9						
10		2013	Database search		The transitional relationship model (TRM)	6
11	Forchuk, C., M. L. Martin, E. Jens			Canada		
12						
13						
14						26 (all
15		2004	Database search		Tailored multi facteted strategy delivered by Scottish Programme for	hospital
16					Clinical Effectiveness inReproductive Health	gyanecolog
17						y units in
18	Foy, R., G. C. Penney, J. M. Grims			Scotland		Scotland)
19						
20		2012	Database search		The Feedback Intervention Trial (FIT) of a national cleanyourhands	16 trusts
21	Fuller, C., S. Michie, J. Savage, J. I			England and Wales	campaign	(60 wards)
22						
23						Not
24						specied but
25		2019	Database search		Case Management of frequent users of Emergency departments	over a
26						large
27	Grazioli, V. S., J. C. Moullin, M. Ka			Switzerland		Canton
28						
29		2019	Database search		Aseptic technique policy	Not stated
30	Havers, S. M., P. L. Russo, K. Page			Australia		
31						
32		2017	Database search		A customized version of the WHO Surgical Safety Checklist - part of the	
33	Haynes, A. B., L. Edmondson, S. R			USA	Safe Surgery South Carolina program	14/58
34						
35		2007	Database search		NHS information and technology (IT) programme	4 Trusts
36	Hendy, J., N. Fulop, B. C. Reeves,			UK		/all in UK
37						
38		2019	Database search		More-2-Eat project	
39	Keller, H. H., R. Valaitis, C. V. Laur			Canada		5
40						
41						
42						
43						
44						
45						
46						

1						
2						
3		2002	Database search		Bronchiolitis clinical practice guidelines	
4	Kotagal, U. R., J. M. Robbins, N. N		USA			11
5						
6		2019	Database search	Australia	Blunt chest injury care bundle	2
7	Kourouche, S., T. Buckley, C. Van,					
8						
9						
10						
11		2014	Database search		Caring Letters	6 Defence department hospitals with acute psych units
12						
13						
14						
15	Luxton et al 2014, Caring letters f		USA			
16						
17						
18		2016	Database search		National disclosure policy after adverse events developed by Veterans' Affairs	All 150 VA administered hospitals
19						
20						
21	Maguire et al 2016, Evaluating th		USA			
22						
23						
24		2014	Database search		Several interventions for newborns and maternal health	251 facilities; 52 in evaluation
25						
26						
27	Makene, et al 2014 Improvement		Africa			
28						
29						
30						
31						
32						
33						
34						
35						
36						
37						
38						
39						
40						
41						
42						
43						
44						
45						
46						

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

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

1						
2						
3						
4						
5		2019	Database search		Anaesthetists Be Cleaner	5 hospitals
6						x 5
7						departmen
8	Merry AF, Gargiulo DA, Bissett I, et al.			New Zealand		ts
9						67
10						(reporting
11		2016	Database search		Safe Surgery 2015 initiative to implement SSCs in South Carolina hospitals	on 13)
12	Molina G, Jiang W, Edmondson L			USA		
13						
14		2020	Database search	USA	Screening, Brief Intervention, and Referral to Treatment (SBIRT)	24 EDs
15	Monico LB, Oros M, Smith S, Mitchell					
16						
17		2014	Database search		Mobilization of Vulnerable Elders in Ontario (MOVE ON)	26 hospital
18	Moore, J. E., A. Mascarenhas, C. I.			Canada		units
19						
20						
21						
22						
23		2012	Database search		The Productive Ward: Releasing Time to Caree programme	
24						
25						
26						
27	Morrow, E., G. Robert, J. Maben			UK		5
28						
29		2017	Database search	Australia	Eat Walk Engage	4
30	Mudge, A. M., M. D. Banks, A. G.					
31						
32						
33		2016	Database search		Period ofPURPLE Crying: Keeping Babies Safe in North Carolina,	
34	Nocera, M., M. Shanahan, R. A. N			USA		86
35						
36						
37		2013	Database search		The Bacteremia Zero study	
38	Palomar, M., F. Alvarez-Lerma, A.			Spain		192 ICUs
39						
40	Pronovost, P. (2008). "Interventive	2008	Database search	USA	The Keystone Intensive Care Unit Project	108 ICUs
41						
42						
43						
44						
45						
46						

1					
2					
3					
4		2006	Database search	The Keystone Intensive Care Unit Project	
5	Pronovost, P., D. Needham, S. Be		USA		109 ICUs
6					
7					
8		2005	Database search	Society of Critical Care Medicine guidelines re sedation and monitoring	
9					
10	Pun, B. T., S. M. Gordon, J. F. Petr		USA		2
11					
12	Reames BN, Krell RW, Campbell C	2015	Database search	Keystone Surgery Program	29
13					
14					
15		2018	Database search	German Quality Network Sepsis	
16					
17	Schwarzkopf, D., H. Ruddel, M. G		Germany		75
18					
19	Schweizer, M. L., H. Y. Chiang, E.	2015	Database search	Study to Optimally Prevent Surgical Site linfections in Select Cardiac and Orthopedic Procedures (STOP SSI)	20
20					
21					
22		2019	Database search	Multi-Centre Medication Reconciliation Quality Improvement Study (MARQUIS2).	
23	Stolldorf, D. P., J. L. Schnipper, A.		USA		18
24					
25					10
26					pharmacy
27		2017	Database search	Gravimetric workflow software systems	services in
28					5 European
29					countries
30	Terkola R, Czejka M, Berube J. Ev		Europe		
31					
32					
33		2014	Database search	Pediatric surgical site infection prevention bundle	
34					
35	Toltzis, P., M. O'Riordan, D. J. Cur		USA		18
36					
37					
38					
39					
40					
41					
42					
43					
44					
45					
46					



1					
2					One large
3					cancer
4					centre
5		2018	Database search	Fast track cancer diagnostics	across 18
6					tumour
7					types
8	van Harten WH, Goedbloed N, Bc		Netherlands		
9					
10		2018	Database search	Michigan Surgical Quality Collaborative (MSQC) Surgical Site Infection bundle	
11	Vu JV, Collins SD, Seese E, Hendre		USA		52
12					
13		2019	Database search	Mental health model of Care for patient in ED	
14	Wand, T., C. Crawford, N. Bell, M		Australia		3
15					
16		2014	Database search	Institutional biobanking	
17	Wyld, L., S. Smith, N. J. Hawkins, .		Australia		2
18					
19	<b>Additional papers using Organistional Readiness Theory</b>				
20					
21	Zapka, J., K. Simpson, L. Hiott, L. I	2013	USA	Telemedicine outreach service for underserved rural hospitals	4
22					
23	Sharma, N., J. Herrnschmidt, V. C	2018	Switzerland	Matching Registered Nurse Services with Changing Care Demands	23
24					
25		2014			
26	Rees, G. H. (2014). "Organisation		New Zealand	Lean thinking initiative	3
27					
28					
29	<b>Website search</b>				
30					
31	ACI Redesign		<a href="http://health.nsw.gov.au">health.nsw.gov.au</a> Australia	See supplementary file 3	
32	Advance care planning		<a href="http://w.canada.ca">w.canada.ca</a> Canada		
33					
34	NHMRC Implementation Guideline		<a href="http://w.nhmrc.gov.au">w.nhmrc.gov.au</a> Australia		
35	NHS NICE Chronic heart failure		<a href="http://w.nice.org.uk">w.nice.org.uk</a> UK		
36					
37	WHO Surgical Checklist		<a href="http://w.who.int/">w.who.int/</a> Global		
38					
39					
40					
41					
42					
43					
44					
45					
46					

	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., research ers from Universit	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 ?
1 2 3 4 5 6 7	How is it characterised by the authors? (National, multisite, policy /research /trial /package/ directive/ priority								
8 9 10 11 12 13 14 15	multimodal infection control intervention / a mult E	Y	E	Y	Y	Y	N	Y	
16 17 18 19 20 21 22	a pilot implementation study across 5 diverse site E	Y	Not stated	Y	Y	Y	Not really	N	Y
23 24 25 26 27 28 29 30	a quality assurance intervention suitable for hospi E	Y	E	Y	Y	Y	Y	N	Y
31 32 33 34 35 36 37	a five-phase multi-faceted HH management system E	Y	I	Y	Y	Y	Y	N	Some
38 39 40 41 42 43 44 45 46	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 research E	Y	Not stated	Y	Y	Y	Yes	Yes some	Y

1									
2									
3									
4	multifaceted intervention / a cluster-randomised trial	Y	I/R	Y	Y	Y	Y	N	N
5									
6									
7									
8	Trial of the implementation intervention: addressing	Y	E, R	Y	Y	Y	Y	Not reported	Y
9									
10	quasi-experimental testing of implementation of	Y	R	Y	Y	Y	Y	Not reported	Y
11									
12									
13									
14									
15									
16									
17									
18	a tailored multifaceted strategy implementing	Y	R	Y	Y	Y	N	N	Y
19									
20									
21	Three year stepped wedge cluster RCT of a feedback	Y	I/R	Y	Y	Y	Y	N	N
22									
23									
24									
25									
26									
27	effectiveness-implementation hybrid trial	E	Protocol	R	Y	Y	Y	Protocol	Protocol
28									
29	the implementation of aseptic technique policy	E	N	I	N	Y- implied it	Y	N	N
30									
31									
32									
33	The Safe Surgery 2015 South Carolina program	E	Y	E	Y	Y	Y	Y	Not reported
34									
35	the largest civilian IT programme in the world	E	N	E	Y	Y	Y	Y	Surprisingly
36									
37									
38									
39	implementation of an evidence-based nutrition care	E	Y	E	Y	Y	Y	Y	No
40									
41									
42									
43									
44									
45									
46									

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

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

For peer review only

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

For peer review only

Multisite implementation	E	Y	I	Y	Y	Y	Y; IT, proces	Y	N
multispecialty implementation of ER protocols at 3 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 4 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 - extensiv	N	N

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

an evidence-based bundle, stepped wedge, cluster	E	Y	E	Y	Y	Y	Y, processes	N	Y
state-wide/ large-scale implementation of surgical	E	Y	E	Y	Y	not reported	Y checklist	N	Not reported
a state-wide effort in Maryland to expand SBIRT in	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 reported	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 multimodal intervention	E	Y	Mixed	Y	Y	Y	Y	N	Y
statewide quality improvement initiative	E	Y	Not clear	Y	Y	Y	Y	N	Y

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

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

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

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

For peer review only



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; accountability 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 philosophy '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 multi-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.

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

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 auditors.

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

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

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

For peer review only

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

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

For peer review only

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

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, analysis of errors

Yes "engage, educate, execute and evaluate"

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

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

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 participation 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), collect data and offer performance feedback, and to provide opportunities for shared learning

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

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
<b>External, top-down source</b>	Implementing externally developed interventions	Basic and applied research undertaken	Standardised, evidence-based practice used across sites	Always	Developed by quality or safety agencies, <sup>34</sup> research institutes / groups, <sup>24</sup> 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., <sup>35</sup> ), checklists (e.g., <sup>10</sup> ), or guidelines (e.g., <sup>36</sup> ). 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 <sup>12</sup>
	Incentives and disincentives for implementation are offered			Rarely	For one project a participation fee was charged for organisations, <sup>35</sup> for another, selected participants were paid <sup>37</sup>
<b>Evidence-based interventions</b>	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 <sup>38,39</sup>



	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 <sup>31</sup>
<b>Safety and quality focus</b>	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.
<b>Facilitation through assessment and provision of resources</b>	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

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

	external agencies*	knowledge and skills deficits	acquisition assist implementation of intervention with high fidelity		were most likely to give support; (e.g., <sup>26,40</sup> ) 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 <sup>39</sup>
<b>Harnessing local resources and encouraging adaptation</b>	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	Cuyppers, 2019	de Groot, 2015	Dekker-van Doorn, 2020	Dumont, 2013	Edward, 2017	Forchuk, 2013	Foy, 2004	Fuller, 2012	Grazioli, 2019)	Havers, 201
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						

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

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

1																		
2	<b>Develop educational materials; distribute educational materials</b>	<b>Education</b>	1	1			1	1					1	1		1	1	
3																		
4																		
5																		
6																		
7																		
8																		
9	<b>Develop resource sharing agreements</b>	<b>Resources shared</b>																
10																		
11																		
12																		
13	<b>Distribute educational materials</b>	<b>Clinical practice guidelines</b>				1	1											
14																		
15																		
16																		
17	<b>Facilitation</b>	<b>Problem solving</b>																
18																		
19	<b>Identify and prepare champions</b>	<b>Champions</b>																
20																		
21																		
22																		
23	<b>Inform local opinion leaders</b>	<b>Opinion leaders; fostering positive safety culture</b>	1		1	1												
24																		
25																		
26																		
27	<b>Involve executive boards; Obtain formal commitments</b>	<b>Executive sponsorship/engagement with the state-wide collective</b>	1			1		1	1	1	1		1					
28																		
29																		
30																		
31																		
32	<b>Organize clinician implementation team meetings</b>	<b>Quarantined time for skill acquisition</b>																
33																		
34																		
35																		
36	<b>Promote adaptability; purposely re-examine the implementation</b>	<b>Evidence of local adaptation</b>	1	1	1	1	1	1		1		1	1	1	1	1		
37																		
38																		
39																		
40																		
41																		
42																		
43																		
44																		
45																		
46																		

1																		
2																		
3	<b>Provide clinical supervision</b>	<b>Mentoring/ Supervision/ coaching</b>	1	1	1	1	1	1	1									
4																		
5	<b>Recruit, designate, and train for leadership</b>	<b>Clinical leadership</b>		1	1							1						
6																		
7																		
8																		
9	<b>Use data experts</b>	<b>IT and communication support for new processes</b>						1				1					1	
10																		
11																		
12																		
13																		
14																		
15	<b>(No ERIC strategy)</b>	<b>Align with organisational/ District and Departmental priorities</b>	1															
16																		
17																		
18																		
19																		
20																		
21																		
22																		
23																		
24	<b>Footnotes</b>																	
25																		
26																		
27																		
28																		
29																		
30																		
31																		
32																		
33																		
34																		
35																		
36																		
37																		
38																		
39																		
40																		
41																		
42																		
43																		
44																		
45																		
46																		

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

	Wynes, 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	Total	
													1												
	1			1			1		1	1			1	1	1		1	1	1	1	1	1			
			1		1	1		1		1			1	1							1				
	1	1				1			1	1			1								1	1			
		1					1						1							1				1	
						1						1				1									
	1										1														





1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

		1								1			1								1
			1																		
		1				1			1			1								1	
																	1				
																				1	
	1	1			1			1		1	1	1	1		1	1	1				1
			1													1					
	1		1	1	1			1	1		1	1	1	1		1	1	1		1	1

For peer review only



	Atzis, 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
	1						1				6
	1	1	1	1	1						24
							1		1		11
	1		1	1							16
	1										11
							1				6
											4

For peer review only

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

1										5
1		1		1			1			10
				1		1		1	1	12
		1		1		1		1		7
				1		1			1	14
1							1		1	10
										14
										6

For peer review only

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

	1			1	1		1	1	18
									1
							1		8
1									2
			1	1	1				4
1							1		7
				1	1		1	1	24
	1								4
1	1	1	1					1	
									34

For peer review only



## 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*